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# Beyond the Legalization of Marijuana: Economics of Marijuana as a Drug and Herbal Supplement

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Beyond the Legalization of Marijuana: Economics of Marijuana as a Drug and Herbal

Supplement

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A Thesis

Presented to

the Faculty of Social Sciences

University of Denver

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In Partial Fulfillment

of the Requirements for the Degree

Master of Arts

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by

Ryan T. Freer

June 2017

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### **Abstract**

Normative studies misunderstand a crucial aspect of cannabis legalization: they have not critically analyzed how the pharmaceutical industry might react when synthetic cannabinoid compounds could be incorporated into new products. I argue that when marijuana is federally legal, there will be two independent market developments in: i) the cannabis market, which includes botanic cannabis and herbal supplements sold in retail nutrition stores; and ii) the FDA-approved ethical drug market. How does the drug industry's monopolistic pricing structure lend itself to strategic pricing for these new synthetic cannabinoids? How much competition can we expect between dispensaries and nutrition shops selling herbal supplements? This work seeks to answer these questions by reviewing the literature on pricing and marketing strategies. I find that supplements' pricing strategies are based on production costs and retail shops' degree of market power. Prices for over-the-counter herbal supplements will follow a medium-low price to low price skimming trajectory. From a policy perspective, health insurers may cover these drugs in future drug plans. Synthetic cannabinoids may also be a breakthrough in the battling the opioid epidemic.

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## Chapter I: A Tale of Two Markets

Marijuana has been called many things: weed, pot, reefer, grass, and for some, medicine. It has been used as an herbal remedy dating back to ancient China. In the 20<sup>th</sup> century United States, was seen as a dangerous psychoactive drug deserving of strict prohibition. Some argue that the costs of carcinogenic smoke and toxic gases outweigh its therapeutic benefits. Studies support the medical effects, but they are not unanimous.

In recent decades, federal cannabis legalization has slowly gained momentum. Marijuana has been on a strange trip from toleration, to abandonment, marginalization, acceptance, and soon, capitalization. The timeline below shows the progression in the liberalization of marijuana. In recent years, public interest in marijuana has hit an all-time-high. In the most recent Pew Research poll, 57% of Americans believe marijuana should be legal; 71% of Millennials, 57% of Generation X and 56% of the Baby Boomer Generation support of legalization (Pew Research Center 2016). Public interest is putting pressure on the U.S. Government to make efforts to legalize or decriminalize cannabis. The following timeline marks the milestones in federal marijuana liberalization policy:

**1970:** The Controlled Substances Act of 1970 makes marijuana a Schedule I drug, declaring it as dangerous as peyote (mescaline), Ecstasy (MDMA), or heroin. Legally, it holds no medical purpose and is more addictive and less therapeutically useful than cocaine and other opioids.

**2001:** The Supreme Court of the United States (SCOTUS) rules that there is no distinction between recreational and medical marijuana under California's Compassionate Use Act. The Controlled Substances Act of 1970 precludes the use of cannabis as a medical defense. However, the SCOTUS also determines that states are entitled to medical marijuana programs insofar as it pertains to their 10th Constitutional Amendment Right. SCOTUS determines that California may serve as a "social laboratory" for future marijuana laws. (*United States v. Oakland Cannabis Buyers' Cooperative*).

**2003:** The U.S. Patent Office grants a patent on marijuana to the U.S. Department of Health and Human Services to suggest it may be useful in treating Alzheimer's. (U.S. 6,630,507: 2003) It was the U.S. government's first recognition since 1937 that cannabis may have a medical use.

**2009:** The Department of Justice (DOJ) sends a memo to Attorney Generals across the country, recommending that they not prosecute medical marijuana patients who were in 'clear and unambiguous' compliance with state law (Campbell 2012: 34).

**2013:** The DOJ releases another memorandum. This one is similar to the 2009 memo, but its focus is on preventing the growth of illegitimate commercial enterprises and the exacerbation of public health issues associated with states' cannabis laws. (Cole 2013).

**2014:** A New Mexico court rules that workmen's compensation must pay for a person's medical cannabis if that person is a valid participant in the state's

medical cannabis program. Citing the 2013 DOJ memo, the presiding appellate judge ruled that the reimbursement of medical cannabis does not violate federal public policy (*Vialpando v. Ben's Automotive Services and Redwood Fire & Casualty*).

**2015:** Two separate bills are introduced into the U.S. House of Representatives, which would federally legalize marijuana, remove it as a Schedule I drug, tax and regulate it. It would not, however, require states to legalize it if they chose not to (Ferner 2015). As the time of this writing, the bill is stalled.

**2016:** The Supreme Court denies hearing a lawsuit case against Colorado. The plaintiffs in *Nebraska and Oklahoma v. Colorado* argued that Colorado's legalized marijuana market put a strain on their states' criminal justice resources. Legal experts postulate that the Court denied hearing the case since they had previously ruled on Congress' authority to regulate cannabis in interstate commerce.

**2016:** The DEA decides that it will not reschedule cannabis from its current Schedule I status, but it will increase access to the plant for scientific research purposes—not for commercial development (Department of Justice 2016).

It is quite possible that we could see marijuana legalized within our lifetime. A majority of Americans believe that marijuana should be outright legalized to allow for federal taxation and regulation. Many economic studies argue for this level of legalization, but it is not clear what happens after the fact. These milestones reflect that the marijuana liberalization debate is focused pushing botanic cannabis into the formal



health care system. However, most insurance companies are strongly opposed to covering patients' dispensary purchases, regardless of whether marijuana is federally legal or not. There is precedent for it, but it is rare (Hermes in Vande Panne 2013).

When legalized, how might drug companies react? So far the conversation about legalizing cannabis has largely ignored their incentives to lobby against marijuana—and the incentives they have in developing their own synthetic cannabinoid drugs. From my perspective, we have been talking about why marijuana should be legalized, but neglect to see why it will not (yet): U.S. drug companies must have a clinical alternative to offer patients in the market for pharmaceuticals in order to ensure that they remain loyal customers. Otherwise, patients may leave the drug market when cannabis is more accessible, and drug companies would lose profits.

Furthermore, what kinds of new drug products might they create, and what will pricing structures look like? In this work, I address this perspective. Specifically, how might Big Pharma react if forthcoming marijuana research results in synthetic cannabinoid compounds that are available to create new products? Beyond that, how does the pharmaceutical industry's pricing structure lend itself to strategic pricing for new synthetic cannabinoids? Marijuana legalization would not resolve advocates' fight to make the *Cannabis Sativa L.* plant and all of its derivatives (oil, hemp, etc.) FDA-approved medicine. The Food and Drug Administration (FDA) does not approve plant material as methods of dispensing in prescription drugs (Sabet 2012).

Advocates argue that Big Pharma lobbies against legalization because if cannabis could treat a range of ailments like seizures, PTSD, cancer, etc., then the drug industry

would lose large sums of profits. This is true insofar as the industry is not yet *ready* to enter into the cannabis industry. We assume here that the research that would result from the Drug Enforcement Agency's (DEA) decision to reschedule marijuana might eventually result in new, better cannabinoid drugs. Big Pharma is lobbying against pot's legalization until it has enough research to get better, more effective drugs in the pipeline—ones that could be a safer alternative to highly scrutinized opioid medications.

It is highly unlikely that the federal U.S. government will move toward a full-scale legalization of the cash crop. I suspect that legalization might unfold incrementally in order to allow drug companies time to develop successfully new drug offerings. Specifically, legalization should first include legislation to make an exception to cannabis's possession for scientific research. If profitable, drug companies would no longer have an incentive to lobby against marijuana. This would allow drug development without making supplements and cannabis legal. After that, legalization for medical use would be possible, followed by taxation and regulation of adult recreational cannabis.

If marijuana were to become legal in this context, drug companies would have created synthetic marijuana products to market in the FDA-approved ethical drug market. This is the market in which behind the counter or "legend" drugs and their generic equivalents are sold. These would include synthesized therapeutic versions of those found in the cannabis plant; of these, the most sought-after will be cannabidiol (CBD, the healing component). Tetrahydrocannabinol (THC, the psychoactive component) may also be of interest, but the point is that companies will want to isolate these compounds,

producing lab-manufactured synthetics to make them unique and distinct from any generic oil supplement or botanic strain.

Scientists might uncover as-of-now unknown compounds. They could create a more complete profile of marijuana's chemical structure and understand more fully the interaction(s) of those chemicals.

It is postulated that the beneficial therapeutic effects of cannabis result from the interaction of different cannabinoids and other compounds present in the plant *Cannabis sativa L.* This may explain why cannabis-based medicines made from whole plant extracts may be more effective than single cannabinoid products [like *Marinol* or *Syndros*] (Stott 2004: 85).

This work begins with this hypothesis: if marijuana were legalized for scientific research purposes, drug companies would be able to develop these new and improved cannabinoid drugs. The question is, Assuming that these products are scientifically possible, what might pricing strategies look like?

The purpose of this work is an attempt to analyze qualitatively market developments in the cross-section of the pharmaceutical and legal marijuana industries. By defining the market boundaries, we can determine launch prices for new synthetic cannabinoid pharmaceuticals and OTC herbal supplements. Other important factors are the demand determinants for the products in these markets (income, preferences, etc.). Therefore, this paper focuses on the supply side of bringing drugs to market.

In the real world, how drug companies might organize themselves in terms of pricing decisions and market power depends on working relationships with insurers and other drug companies. Prices are not created in a vacuum; they depend on the industrial environment, including: competing firms and their products, cross-elasticity of demand

and supply, development and promotional costs, patent positioning (and laws regarding such), market power, technical capacity and abilities, and many more (Weston in Chien 1979: 75) These factors create the environment and determine how these companies will operate. This is known as the structure-conduct-performance model that encompasses modern industrial economic theory. Please note that the drug company-drug insurer dynamic presents some out-of-scope considerations. However, I will comment on it in my concluding remarks.

### **The Market Segmentation Model**

Companies act as competing monopolists, as described in Chapter III. They attempt to segment the market into brand loyal customers to gain market share. Advertising attempts to ensure that a customer will not buy the competitor's product. This keeps the different customers that firms sell to independent, limiting the opportunity for "arbitrage" in different markets. It determines monopolists' level of second-degree price discrimination. Drug companies do not launch a single price for the industry, but many: high prices for patients with higher levels of willingness-to-pay, and low prices or free to low-income patients receiving public health care, i.e. Medicaid. "Payers that use economic considerations may receive low prices if this is required in order to demonstrate economic attractiveness. Thus, pharmaceutical manufacturers may be required to set several different prices" (Zaric 2008: 1278). Normally in this second-degree price discrimination, producers will offer different sets of customers a lower price for greater quantities purchased. Firms initially have no method to discern which customers have a low willingness to pay, and which have a higher one. They resolve this,

Varian (1996) says, by changing the quality of the product. Those with a lower willingness to pay, or “low demand”, will self-select themselves to choose the product with a lower quality at a lower price. The same is true for the high demand customer. “If the producer cannot precisely identify the users, it may want to adjust the characteristics of the good being sold so that users *self-select* the product targeted for them (Varian 5: 1996, italics in original).” Likewise, in the market for brand-name and generic drugs,

Many studies trace price rigidity of patent-expired drugs to consumers’ price insensitivity toward brand-name drugs. When a market is segmented between the price-sensitive consumers who adopt the generic and the price-insensitive consumers who continue to use the brand-name drug, the brand-name drug firm can raise its price optimally to its captive or price-insensitive clients and simply ignore the price-sensitive business siphoned off by its generic competitors (Hong et al 2005: 747).

There could be at least three versions of cannabis-based products in the product space. Drug companies are then able to isolate the customers willing to pay for convenience and better quality of care. Customers self-select themselves into either the ethical drug market or into the market for cannabis, depending on the price that they are willing to pay for an improved quality of cannabis that they wish to consume. As the quality of these products decreases, so too does the price. These potential products are:

1. FDA-approved prescription cannabinoid drugs
2. Botanic cannabis (phytocannabinoids)
3. Generic over-the-counter (OTC) cannabis health supplements

Following from this, we could expect to see two distinct market developments within the cannabis industry. In one market, patients purchase FDA-approved drugs. In the other,

patients with a ‘preference’ for natural medicine purchase health care through home remedies, dietary supplements and naturopathic medicines, including botanic cannabis.

To be clear, I argue that people will choose one of three products to consume, and products are differentiated with respect to quality. In fact, it is actually a determinant of product choice. A preference for higher quality, matched with a willingness to pay for it, would place the customer into one of three markets for these products.

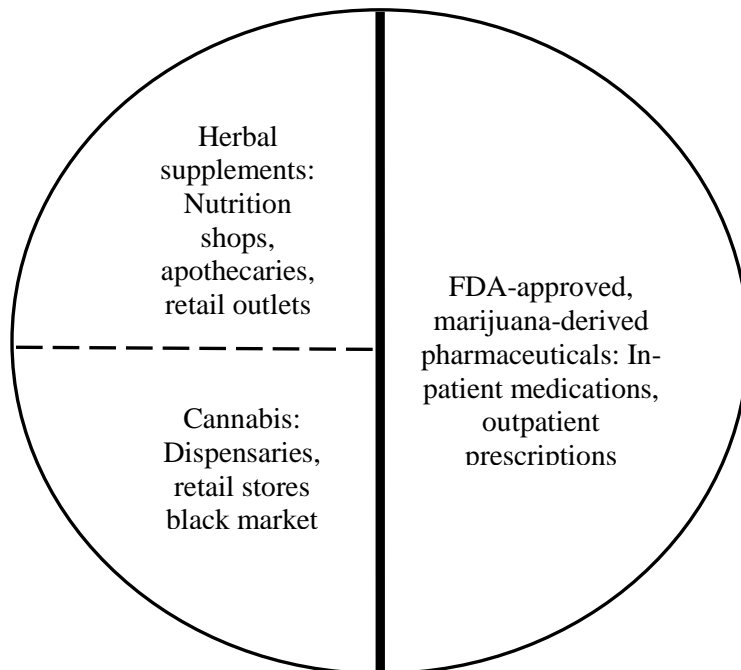
Although product with respect to quality is itself a form of product differentiation, the two can be discussed separately. A quality differentiation is a product decision based on a preference for a higher grade or standard of excellence among products. This is typically reflected in each product’s price. Between ethical drugs and OTC health supplements, the former has a stricter regulatory process to ensure more quality control than a health supplement. In Chapter IV, I compare and contrast the two in further detail.

On the other hand, product differentiation is a product decision based on the characteristics among competing goods. One prescription drug may come in a liquid form while another is encapsulated. One drug may be more effective in alleviating head trauma while the other is intended to treat nerve pain, or each may come with different side effects. Varying product characteristics, and patients’ preferences for them, are factors that create brand-loyalty in competing drug products; price competition plays a minor role in this product decision (Frank & Salkever 1992). In our model, when discussing pharmaceuticals in Chapter III, we are really talking about product differentiation. When discussing supplements in Chapter IV, quality differentiation should be kept in mind.

Below, I define the border between these two markets. This will allow us to review the pricing decisions of pharmaceuticals separately from that of herbal supplements. Herbal supplements and cannabis offer an alternative to ethical drugs; cannabinoids themselves compete with opioids, for example. The two markets do not compete directly, but instead customers self-select themselves into either market, depending on their preferences and ability to pay for higher quality medicine. We further assume that patients are aware of the level of quality they are receiving based on how much they are willing and able to pay for it.

Figure 1 below depicts this product space. There are two large sectors in the marijuana industry. On one side is the ethical drug industry. In particular, it would include marijuana pharmaceuticals: both cannabis-based and -derived drugs, marketed as an alternative competing drug products. The other industry is divided between nutrition shops and apothecaries selling ‘generic’ herbal supplements on the one side, and dispensaries ‘specializing’ in botanic cannabis in the other submarket. Patients may see cannabis and generic supplements with some degree of substitution. Therefore, while the division between the market for ethical drugs and that of the cannabis is ‘sealed off’, the same may not be true for the division between the cannabis and dietary supplements submarkets. This explains why the border between these two is open. As Stigler explains:

An industry should embrace the maximum geographical area and the maximum variety of productive activities in which there is a strong long-run substitution. If buyers can shift on a large scale from product or area B to A, then the two should be combined. If producers can shift on a large scale from B to A, again they should be combined...into a single industry (Stigler 1955: 152).



*Figure 1*

For example, consider the story of *Marinol* (dronabinol). The drug is used primarily in chemotherapy patients to treat nausea and vomiting. It is composed of approximately 99% tetrahydrocannabinol (THC), one of the core healing compounds in traditional marijuana, and sesame seed oil. *Marinol* is made using a process to isolate and chemically rebuild the THC compound. It received its patent in 1986, but not before the DEA had to reschedule synthetic THC—not marijuana proper—to a Schedule III, making it legal for medical purposes and further research.

The drug, however, was not widely accepted, even after its indications (the on-label intended uses for a drug) were expanded to include appetite stimulation in AIDS patients (Stott 2004: 87), resulting in a new drug, *Syndros*. One reason for this is that patients found it to be far less effective than smoked cannabis. Patients preferred cannabis since *Marinol* inadequately addressed their medical needs. Its quality standards were



inferior to cannabis. Customers then moved through the product space, and settled in cannabis submarket, where they remained. At the time, had drug companies patented a substitute cannabinoid similar enough to cannabis and better than *Marinol*'s recipe, patients would have remained in the ethical drug market. Patients will leave this market if there continues to be a lack of alternatives available in it.

A preference for a certain quality and the ability to pay for it also tells us why a patient would choose to take a prescription cannabinoid when botanic cannabis is available. As Varian (1996) concludes, customers may pay a higher price to avoid an inconvenience, or to reduce the restrictions on the use of their product. Examples include: paying extra to use the express lane on the highway, paying a penalty for the freedom to break an apartment lease before it expires, or paying for priority seating on an airline (as in Varian (1996)). We can see that in these new drug developments, where patients face a cash purchase of either cannabis or cannabinoids, the latter is targeted at patients who appreciate the quality, accessibility, and convenience of using cannabis where it is otherwise prohibited in its botanic form. Most states that have legalized or decriminalized marijuana have also banned smoking in public. The convenience of a controlled medicinal substance would be a benefit—as is avoiding the inconvenience of a penalty for smoking in a prohibited area. The same is true in states that choose not to legalize or decriminalize cannabis entirely.

Naturally, one target market for these synthetics could be hospitals and inpatient care—where smoking/inhalation is prohibited, and an injection or an intravenous solution is more effective. For example, *Marinol* and *Syndros* is used for nausea and vomiting

resulting from chemotherapy. Specialized cannabinoids might even provide a safer alternative to chemotherapy! Similarly, for out-patient care, consider patients who are against cannabis for ethical reasons and cannot or will not smoke it. A pharmaceutical pill, spray, or other mode would be regarded as more legitimate if a physician prescribes it to them. It also would allow a person to take their medication in public.

This highlights a second reason: there may be people who need to take a pharmaceutical cannabinoid for employment reasons. Consider an employee who must take cannabis in their health regimen, even at the risk of losing their job. If this employee instead had an FDA-approved drug, they would pass a drug screening with a doctor's prescription and keep their job. This is no different from any other prescription.

Third, cannabinoids' ability to isolate the healing compounds in cannabis, CBD and THC, means that other minor chemicals are not present. A person can avoid the carcinogens from smoking. An ethical drug is more sterile, thereby providing a more valuable health product. Drug makers could potentially provide a more efficient product, without side effects associated with other treatments, like a low risk of addiction. This proved to be an effective selling point for *OxyContin* even if it was blatantly false.

### **Cannabinoids vs. Opioids**

It is a sufficient assumption that *if* marijuana were rescheduled to a Schedule II, drug companies would work to bring these synthetic marijuana products to market. If this policy change were a necessary condition, then opioids would not be on the market.

Opioids are derived from the opium plant, the origin of another Schedule I drug: heroin.

So the question is, if heroin was a limited impediment for opioid drug development, why should we expect that it is a strict impediment for cannabinoids?

The divergence in outcomes between the two depends in part on its history and stigmas associated with each. In short, opioids already had a legitimate accepted medical use long before heroin was outlawed. Morphine (1804), codeine (1832), heroin (1874), and hydrocodone (1920) had all been synthesized before the Controlled Substances Act of 1970 (*Narconon.org* 2017). Morphine especially had already proven useful in wartime as an effective painkiller. The 1924 Opium Prohibition Act made the importation, manufacture, and/or possession of heroin and opium illegal, but the Act made an exception for medical use (Narcotic Drugs Import and Export Act, 1922; Opium Prohibition Importation Act, 1924). The availability of these compounds would facilitate R&D to make stronger painkillers like *Percocet* (oxycodone) and *Vicodin* (hydrocodone and acetaminophen). Consequently, the opium plant from which these drugs are derived is available as Schedule II drug.

Conversely, the Marihuana Tax Act (1937) placed a tax on the commercial sale of cannabis, *including* medical use. THC was not synthesized until 1964. Unlike heroin, it would be another 20 years before it was offered in a pharmaceutical product—and an impossible 6 year time window to get it to market before marijuana became federally illegal; The 1970 Controlled Substances Act effectively made the 1937 Act null and void. Only synthetic THC is available for developing cannabinoids, and its botanical origin is restricted in the United States. In the United Kingdom, it is available for scientific research. This left American pot at a significant disadvantage to produce research and

future pharmaceutical products. Permission to research cannabis in the U.K. would eventually give British drug companies to develop better synthetic cannabinoids (discussed below). Therefore, increasing access to cannabis, through legalization that makes an exception for medical research or other means, is long overdue.

## **Outline**

The thesis is summarized as follows. Chapter II describes the motivations for pharmaceutical companies to develop a synthetic cannabinoid. What are the market incentives, and how do the medical facts on marijuana translate into a marketable product? Chapter II also provides supporting evidence for the economic rationale of segmentation of consumer preferences illustrated in Figure 1. The information about marijuana in general provided in this chapter will be useful for understanding conclusions reached in the following ones. Chapter III serves a critical and dual purpose: it provides a thorough review of the literature on pricing strategies within the competitive monopoly framework. By drawing on some core features of these strategies, and combining this information with marijuana drug development, we can speculate on launch prices and trends for new cannabinoids. Chapter IV follows a similar procedure to describe the marketing strategies for marijuana herbal supplements and resulting prices. Finally, Chapter V summarizes and concludes. It offers insights into policy implications, namely, the potential for health insurance companies to cover these drugs in their health plans; pressures on drug companies to support marijuana legalization; and the opportunity for synthetic cannabinoids to be a response to the opioid epidemic.

## Chapter II: Marijuana in the Marketplace

Until now, we have looked at the theoretical foundations for the present study. The last chapter provided some justifications for dividing the cannabis market. This chapter offers some concrete examples of types of products that might be offered, and how they might be marketed. It will also describe Big Pharma's incentives to create these drugs. If scientists and pharmacists could find a way to harness the healing powers of cannabis in a way that conforms to modern medical practices, they could effectively create an entire new product line to treat a myriad of health problems.

A drug's potential a 'blockbuster' relies on claims about its efficacy, advantage over other drugs, the diseases it can treat, and any unique properties about the new chemical under development. In an economic sense, firms essentially have the opportunity to claim a competitive advantage:

[f]or a pharmaceutical to be a commercial success, it must be well protected in terms of Intellectual Property Rights...there must be a clinical need for the product. It has been demonstrated that [for] certain diseases/conditions...cannabinoids provide additional relief to patients *where all existing products currently available have failed* (Stott 2004: 85, italics added).

The goal for drug companies is to reproduce the effects of cannabis in a synthetic form, package it, patent it, and market it. If a company claims that its product's therapeutic benefits surpass any other on the market, this marketing strategy may lead to a higher price it higher above its competitors, yielding a significant return on its investment (Lu & Commanor 1998). There is much more to be said on pricing strategies; the next chapter

serves as an in depth review of these practices. Next, I will outline the possibilities for synthetic cannabis, in the event that it is offered as a pharmaceutical product. This includes current offerings and R&D for products in the ‘drug pipeline’, and room for improvement in future drugs. I will also put this into context by contrasting it with heroin-based opioids.

### **Synthetic Cannabinoids**

Before we can look at how drug companies might react, we must answer *why* they would want to invest in synthetic marijuana-derived drugs. To name a few incentives: (the exclusion of) competition and capturing market share, gaining new patents and extending old ones, innovation to keep a competitive advantage, and rising shareholder value, which funds financial capital for continuing R&D.

These motivations would eventually lead them to produce a drug that includes minor chemicals in addition to THC and CBD, not just those isolated chemicals. Drug companies could patent a product or process that improves upon *Marinol* or *Syndros* (whose developments also led to the invention of another antiemetic, *Cesamet* (nabilone)). “It is possible that the development of novel synthetic agents with more specific actions and fewer side-effects will extend [synthetic cannabis’s] therapeutic range” (Ashton 1999: 122). Drug companies could develop more products to treat more people, capitalizing upon a huge market opportunity.

In some clinical trials, patients preferred *Cesamet* (nabilone) to other drugs to treat cancerous pain. It did not depend simply on consumer preference of pharmaceutical vs. natural cannabis, but their response to their conditions were relatively greater

compared to traditional drugs—even in children (di Marzo & de Petrocellis 2006: 557). This evidence, though not unanimous, suggests that a maker of an effective cannabinoid could be more competitive than *Marinol*, *Syndros*, *Cesamet*, or other opioids like *Vicodin*. Additionally, the FDA has officially recognized that THC can be used to treat eating disorders like wasting syndrome, and quelling vomiting and nausea during chemotherapy. Future drugs could treat glaucoma, reverse cancer, treat Multiple Sclerosis, and dramatically expand the range of symptoms that these drugs treat.

Making these cannabinoids is not a new venture for drug companies. A few drugs utilize them; *Sativex* and *Marinol* are the most well-known. The former is ‘liquefied marijuana’, and the latter is an FDA-approved, lab-manufactured synthetic. *Sativex* is in Phase III clinical trials, the final stage before a market launch. Barring federal prohibition on marijuana, *Sativex* is set to be the first cannabis-derived medication in the U.S. GW pharmaceuticals, a London-based company, patented *Sativex*. They also make *Epidiolex*, a pure liquid CBD, used in the treatment of epilepsy. GW is the leader in marijuana-based medicine, but they have not yet broken into U.S. markets; larger companies like *Pfizer* show no signs of taking similar initiatives just yet. However, nearly a decade ago, five of the world’s top ten drug companies were developing 18 cannabinoid-related compounds. Plans have since been aborted (*ProCon.org* 2013).

*Sativex* treats Multiple Sclerosis. It is not a synthetic, but an oral spray and derived directly from cannabis. It has been found to be extremely effective, with minimal adverse effects, even in patients without the disease. Patients in the study even responded to it better than other, stronger pain medications (di Marzo & de Petrocellis 2006: 559).

In another study, *Sativex* was assigned a Quality Adjusted Life Year (QALY) of 0.15 over 5 years (Lu et al 2012). This serves as an example to show how companies are improving on the original *Marinol* product, giving way to new innovations, new investment opportunities, and competition. One of the reasons that U.S. drug companies are hesitant to invest in these drugs is because of the international competition from GW. Currently, Big Pharma is essentially protectionist: it sees marijuana (and cannabis supplements) as a threat to their profits on opioids. There is a significant risk in supporting full-scale marijuana legalization and then ‘racing’ to get a cannabinoid to market. They are cautiously optimistic about cannabinoid drug development, but there is less risk in seeing how GW’s products fare before divesting from opioids.

Table 1 lists companies who have developed a cannabinoid, successful or not.

**Companies Developing Synthetic Cannabinoids**

<b>Pharmaceutical Company</b>	<b>Product</b>	<b>Indication(s)</b>	<b>Development Stage</b>
AbbVie	Marinol (dronabinol)	Quell nausea/vomiting during chemotherapy; Reduces neuropathic pain in Multiple Sclerosis; HIV/AIDS appetite stimulant	Approved 1985 as an anti-emetic, expanded indication to HIV/AIDS appetite stimulant 1992, approved for MS pain in Denmark 2003
Valeant Pharmaceuticals Int'l, Inc.	Cesamet (nabilone)	Anti-emetic	Approved in Canada (1982), sold rights to U.S. & U.K. Pharma Companies



GW Pharmaceuticals	Sativex (nabiximols)	Neuropathic and cancer-related pain, Alleviates spasticity in MS	Approved in 27 countries outside U.S., Phase III clinical trials for cancer and MS pain; granted FDA fast-track development
GW Pharmaceuticals	Epidiolex	Alleviate seizures in pediatric epilepsy and other rare syndromes	Early clinical development, granted FDA orphan drug status
Society for Clinical Research (Germany)	Cannador	Muscle stiffness, MS spasticity/pain, post-operative pain management	Phase I clinical trials
Solvay Pharmaceuticals	Dexanabinol	Neuroprotective for use after cardiac surgery, memory gain after traumatic brain injury, possible use as anti-cancer drug	Completed Phase III trials 2004, no significant marketing improvements; began Phase I trial for brain cancer indication (2012)
Pharmos	Cannabior	Anti-inflammatory, treats chronic pain and neuropathic pain; bladder control	Failed IIa clinical trials in 2007; Not approved outside of laboratory research (2012)
Sanofi-Aventis	Acomplia (rimonabant)	Anti-obesity	Approved in Europe 2006, removed from market; Failed pre-clinical trials 2007 in U.S., not approved since 2013

Merck	MK-0364 (taranabant)	Anti-obesity	Failed in Phase III trials; Not approved since 2013
Cannabis Sciences	CS-S/BCC-1	Oncology	Preclinical trials

**Table 1: Adapted from Mintz et al. (2015: 21-22) & ProCon.org (2013)**

Suppose researchers discovered an exotic new plant with naturopathic benefits greater than or equal to marijuana. Drug companies would be highly interested in developing this in a new drug product, and because it does not have the same (legal or ethical) history that marijuana does, there would be no restrictions on its import to the United States, or possession of it in general. Companies could conduct R&D on this new plant’s biologic properties in Phase I clinical trials. This Phase test the drug on small groups of human subjects. If there are no serious side effects or if the drug is reasonably toxic, it would move to Phase II. This Phase still monitors for safety, but the drug is tested for its effectiveness: is it effective in treating the on-label disease or condition? If it showed that the drug is *not* safe and effective or had side effects like severe hallucination on par with a drug like peyote (mescaline), the drug would not proceed to Phase III, which ends in marketing.

There are ten drugs listed in Table 1, and more than half of them have failed. Only 40% were approved for marketing: *Marinol*, *Cesamet*, *Sativex*, *Epidiolex*. At higher doses, the other 60% showed increased risks of complications, the CBD or THC was not pure enough, or did not show significant improvement in quality standards to advance to the next stage of testing. This small sample statistic is not far from the average. Gladin (2005) notes that 70% of products that are developed are *not* marketed. “This means that

the industry has to rely on 30% of products to fully recover out-of-pocket expenses, the cost of all failures, and the cost of capital (DiMasi, 2001)” (12). The problem that plagues failed cannabinoid developments seems to be part of a general trend found in the ethical drug industry as a whole.

The FDA is not opposed to marijuana drug development, expanding research, or approving botanic-derived drugs in general. The U.S. government even holds a patent on marijuana. Patent No. 6,630,507 is the U.S. government’s recognition that certain compounds in cannabis may be useful in treating complications in degenerative brain diseases like Alzheimer’s or cirrhosis; it is not a claim on the plant itself. Though contradictory to the DEA’s claim that marijuana has no medical use, the government allows organizations to use the license as the basis for future research into cannabinoid-related drugs. The patent does not prove that marijuana has a medical purpose for its stated use, it provides a base for future research that prove this claim (Wallace 2016; U.S. 6,630,507: 2003).

This highlights the current paradox: marijuana should be legalized, at least exclusively for research, but the DEA & FDA are not yet convinced that it is safe and effective to warrant its legalization. Because there has been a ban for so long, the research that would legitimize it does not exist, so its prohibition remains. In early 2016, the DEA denied marijuana a rescheduling (again). But it did announce that it would increase access to the plant for research purposes. Prior to that announcement, it was only available through the University of Mississippi. I believe that the U.S. is slowly moving towards legalization, but it will not happen before drug companies can develop and

market a viable cannabinoid alternative. If this happens (as an economist, I can't say much on the scientific possibility, only the economic consequences), Big Pharma will have an alternative for those who wish to try medical marijuana but do not want to leave the ethical drug market. Further, these products will be able to compete with international products like GW's *Sativex* and *Epidiolex*. And yes, cannabinoids would (assumably) provide a safer substitute to opioids. The prescription cannabinoid would allow drug companies to keep the market segmented domestically. The protections on drug companies until these products are launched segments the market internationally—all while maintaining customer loyalty.

Drug companies are simply not yet prepared with a competitive, safe, and effective cannabinoid product. More importantly, the industry is lobbying against marijuana's legalization to protect the 'investment' that they have made on opioids. It is no secret that these drugs have created multi-billion dollar profits for Big Pharma; they see cannabis as a real threat to those profits. It may be that Big Pharma, right now, is only willing to commit their time, efforts, and investments to one set of products. Would they prefer to sell opioids, a cash cow; or cannabinoids, a question mark? Legalizing marijuana right now actually provides a *disincentive* to make new opioids since it increases competition and reduces profits. I tacitly argue, however, that increasing the availability to opioids acts as an incentive to promote innovation and even improve Big Pharma's public image. By developing these products, they position themselves ready to respond to the nationwide opioid epidemic; cannabinoids provide a much safer and effective alternative.

However, I think there is a limit to Big Pharma's intentions. The research on marijuana has not yet caught up to what drug companies want to do with the product. They have not yet developed a 'blockbuster' product. For example, they have not yet created a cannabinoid that is at least as effective as opioids in treating chronic pain. As Big Pharma lobbies against marijuana's legalization, under the DEA's guidance to ease access to the plant, they could presumably—and this is just speculation—simultaneously do R&D to create a viable cannabinoid. Marijuana would not become fully legalized until drug companies are able to successfully launch a product that can compete internationally with GW. So in relation to international market segments, the cannabinoid market is an infant industry in need of protection from international competition. I do not think that they will lobby against marijuana forever. There is definitely a profit incentive in capitalizing in opioids *and* cannabinoids.

### **Foundational Studies**

We have seen it is not very likely that the FDA would approve phytocannabinoids (cannabis *au naturale*) as a prescription drug. There is no legal precedent—much less any economic incentive—for a company to earn a patent on a specific strain of cannabis.

Nonetheless, while discussing this, Grinspoon (2001) makes an important observation:

[w]ith the present prohibition in place, the economic viability of pharmaceutical-industry-generated cannabinoid products and the motivation to develop them will be directly proportional to the vigor with which the marijuana prohibition is enforced...[M]ost patients who find cannabis useful medicinally choose illegal marijuana over prescription dronabinol (Marinol) for reasons of efficacy and cost. One has to ask whether there is any level of enforcement which would compel enough compliance to embolden drug companies to commit the many millions of dollars it will take to develop new cannabinoid products (Grinspoon 2001: 382).

He suggests that there will be two separate market developments when mentioning the (illegal) cannabis market and the prescription drug market. This is similar to my realization shown in Figure 1. He, too, questions whether this separation will be conducive to pushing drug makers into producing marijuana-based drugs if consumers would strictly prefer the cannabis plant. He mentions elsewhere that while the latter is usually more efficacious, there are times when it is not desirable and a synthetic drug is not only more effective, but the circumstances demand it, for example if a patient is unconscious and s/he requires an intravenous administration (381). This could suggest that drug makers may find that selling drugs to hospitals may be especially profitable, or that a prescription should take a form that allows for a rapid onset of the drug's effects, like an injection or oral spray.

Drug companies probably will not steal market share from the cannabis market; those who prefer cannabis are antagonistic towards drug companies. Drug companies sees a much larger revenue potential in marketing towards those who do not or cannot smoke: the elderly, those who oppose marijuana, the employed, and ultimately, those who would only purchase it if paid for by their health insurer. Drug companies will not operate their own dispensaries selling retail cannabis because that is not their area of comparative advantage (although it would be advantageous for them to set up marijuana testing labs and sell equipment). "It is doubtful that pharmaceutical companies would seem interested in developing cannabinoid products if they have to compete with natural marijuana on a level playing field" (Grinspoon 2010: 81). Drug companies can raise

capital and meet quality control standards on a scale that surpasses small-time dispensaries.

Schneider (2014) picks up where Grinspoon leaves: Schneider discusses the corporatization of marijuana and the anticipated (positive) effects on states' tax revenues. Will 'big pot' outpace dispensaries with larger grow operations? He refers to the emergence of these so-called "pot capitalists." Schneider posits that in a legal marijuana market, the cash crop will be distributed, sold, taxed, regulated, and controlled much like alcohol or tobacco is today. "A profit-focused operation run according to the Big Marijuana ethos may only be interested in meeting its quarterly sales projections," rather than focusing on the health needs of the patient (15). Marijuana is likely to become commercialized and mass-produced at the expense of cheaper, more inferior quality pot that does not prioritize the needs of the patient. These businesses, Schneider says, could outpace dispensaries that grow high-quality plants that cater to patients. He believes that once marijuana is legal federally, it will be sold only in convenient stores, dispensaries, or even large box stores much like a Whole Foods or Wal-Mart. He has no intimation that Big Pharma would use it to produce a synthetic version to market new drugs.

We continue to see that quality seems to be most important determinant in product choice. Further, in order to appeal to consumers in the botanic cannabis market, preferences for natural remedies—or a disutility that results from generating revenue for Big Pharma—may dictate that they will not purchase a cannabinoid, regardless of its price. When a cannabinoid becomes marketable, patients in the ethical drug market would be the target market for these products. These patients have been using

prescriptions for years; in a sense, they are beholden to that market. Patients consuming cannabis are loyal to their product as well, as are supplement users. Drug companies' marketing strategy is to target their current customer base, and advertise the higher-grade cannabis alternative as more appealing than supplements or phytocannabinoids. This will help establish brand loyalty in future patients.

Royne et al (2014) find that consumers in each market generally tend to be strongly biased towards either ethical drugs or supplements. More importantly, they discuss how this applies to each patient's attitudes toward health awareness:

Given the differences between the product categories, it can be argued that consumers mindfully and proactively research and adopt supplement products with the intent of preventing a disease or alleviating symptoms of a condition. Conversely, prescription drugs are prescribed to consumers after a disease or condition has been diagnosed by their physician. (Royne et al. 2014: 519).

This supports our assumption that there might exist two separate markets shown in Figure 1, with two distinct types of patients with unique sets of preferences.

Additionally, consumers' preferences for supplements is positively associated with perceived health benefits, so there is a *negative* association with perceived risks; consumers tend (erroneously) to perceive supplements as having fewer risks than prescription drugs (526). Ironically, the majority of consumers of supplements use the product to treat a condition, finding it to be cheaper—but not necessarily more effective—than traditional medicines. A large portion of consumers of these products is uninformed about their actual contents, and is indifferent when told their medical benefits are dubious (Starr 2015: 478). Royne et al. (2014) found that consumers tend to discredit these claims altogether. Consumers may see a product advertised as 'natural', believing it



to be safe. Nevertheless, this claim may be false, the product may contain ingredients not listed, or it may contain ones that are pharmaceutical-like (Sax 2015: 377). This creates a moral hazard problem. Companies make billions in profit because the ingredients in their products (or lack thereof), and the advertising for those, are monitored but not enforced (Starr 2015: 480-1).

In conclusion, if drug companies cannot create loyal customers from the natural cannabis market, demand is not likely to shift by much, and prices and revenues would not increase much further. Therefore, the firm's objective is not to earn customers from a new market (cannabis), but to steal market share from other competitors within the ethical drug market. Cannabinoids may even out-compete opioids; patients will shift demand from the latter to the former. While patients are still ingesting cannabis, they are doing it while still purchasing products in the ethical drug market; patients hold to preferences, increase utility, and Big Pharma might retain—maybe even increase—profits.

The current state of the policy literature focuses on states that have already legalized or decriminalized the plant. These papers often review the 'aftermath' of legalization. These case studies determine how well states are regulating the drug (Hoban & Patterson 2016; Washington Institute for Public Policy 2013), and offers evidence for a nationwide marijuana initiative. One of the more recent seminal papers is from Professor Miron. Miron calculated that a regime that legalizes, controls, and taxes marijuana would create \$10-\$14 billion in tax revenue nationwide: \$7.7 billion in cost avoidance from drug enforcement efforts, and \$2-\$6 billion in tax revenues (2010). Others look at the costs and benefits of federal legalization (Hellman 1976; Shanahan & Ritter 2014).

Proponents argue from a legal or ethical standpoint (Martin & Rashidian 2014; Room 2010), or from a public health perspective (Fischer et al. 2015; Barry & Glantz 2016; Anderson & Rees 2014). Like Schneider (2014), they correctly identify that marijuana will be sold commercially and dispensaries will face increased competition, perhaps even from Big Tobacco (Barry et al. 2014). Some authors in the scientific literature recognize cannabinoids' value in treating drug and opioid related addictions (Cheer et al. 2015), but have not looked at the market developments in the ethical drug industry. They suggest that they hold pharmacoeconomic value, but do not mention that Big Pharma has economic incentives to develop these drugs, just not yet.

### Chapter III: Cannabinoid Drug Pricing Strategies

Until now, we have discussed how pharmaceuticals are marketed and sold. There is much to be said on the topic, especially with regard to pharmaceutical pricing. The pricing for drugs is based in large part on patent pricing and market exclusivity granted by the chemical for the new drug. The following literature review allows us to extract some key pricing structures of the drug industry that will be helpful in the final analysis. Thus, this it serves as the methodology for the thesis. In the course of reviewing the pricing strategies that Big Pharma uses, we can make educated predictions about what we can expect if a drug company were to research, develop, and market a synthetic cannabinoid drug. Pricing strategies are evaluated in the broader, dynamic context of innovation and discovery. In this chapter, we will see how marijuana pharmaceuticals will be priced relative to competitors—both existing and non-existent (i.e. future products that have yet to be made).

This process depends on patents and market exclusivity, so some of these main findings are not so surprising. A company making a unique product targeted at a niche market can charge a higher price relative to other competitors, if they exist. As a general rule for launch price decisions, we can utilize the following rule:

$$price \Rightarrow \frac{u(q)}{c(l)}$$

where  $u(q)$  is the utility of a drug, based on the QALY it delivers,  $c(l)$  is the degree of competition, based on a firm's market power (Lerner's Formula) and  $l > 0$ . Basically, a drug's specialization, relative to the size of its therapeutic market, determines its price. Monopolists gain an advantage if they can distance themselves as far apart as possible from their competition. This creates 'submarkets' in which they exert market power (d'Aspermont et al. 1979). As a reminder, we should think of product differentiation in the ethical drug market as it relates to the comparability of attributes of various drugs.

Consumer goods must add value to the customer's life; they must fill a need. Dean (1969) concluded that monopolies that introduce new "pioneering" products have two main strategies: skimming and penetration pricing. In the first, the price is set high because the new product has no close substitutes in the market. As knowledge of the product dissipates among consumers, the price should tend to fall (Bagwell & Riordan 1991). Over time, the price falls as the firm reaches those with lower reservation prices. Competing products may take on some attributes of the original pioneering product.

In penetration pricing, drug companies will price new drugs higher in order to signal that it performs better than any other option currently available on the market. This is supported by a 'latitudinal region of price acceptance' around reference prices. Patients may be willing to pay slightly more for a product if its higher price is within their frame of reference, but not exorbitantly above it (Kalyanaram and Little 1994). This 'reference' price is formed by comparing similar products and their prices. Over time, patients become accustomed to paying these slightly higher prices, leading to marginally rising drug prices. If this is true, this microeconomic reasoning could explain why marginal

improvements over substitutes induces a slightly higher price that patients will pay. In penetration pricing, companies may price very low to ‘penetrate’ the market, establish reputation for itself and its products, and raise the price over time. This theory of qualitative differentiation between products (and its thrust behind innovation) is a solid foundation for thinking about modern pricing practices.

In the present analysis, we will deduce a pricing strategy for new synthetic marijuana pharmaceutical drugs. There are three pricing trajectories for products: i) prices are set high and fall over time, ii) prices are relatively constant over time, priced at the market price of current market options (i.e. reference pricing), or iii) prices are set low and rise over time.

Dean’s discrete high—medium (“parity”)—low scale is helpful, and it can be more continuous. I will add two more levels: high—*medium-high*—parity—*medium-low*—low. Since we are not dealing with quantitative data, this scale should help us clarify what we mean when a price is high, but not too high, relative its competitor.

If we uphold the assumption of therapeutic markets, option i) seems the most likely. New cannabinoids will have a general application, but they are improvements of older drugs. Over time, as drug patents approach their expiration date or other competitors are introduced, prices will start to fall to a medium-low or parity reference price. The same is true for advertising expenses. Physicians will prescribe drugs to their patients across therapeutic lines regardless of the drug’s indication; the drug’s indication allows for its patent, not its ability to be prescribed in its intended market. Advertising and competitive forces will push prices will keep prices steady for a while before being

pushed down. Thus, prices will initially be set at a medium-high price, falling to a medium-low or parity price.

In this chapter, I will first describe how the ethical drug market is defined. This will help establish the market structure in which Big Pharma operates and tell us how its companies conduct themselves as competing monopolists. Using this setup, I then review the economic literature regarding pricing strategies as they relate to the ethical drug industry. I begin with the general and theoretical evidence, and then move to specifics and empirics. Throughout, my conclusions as they relate to marijuana-based cannabinoid drugs specifically, are grounded in the literature review. As we will see, most theoretical conclusions on Big Pharma pricing structures support empirical ones.

### **Structure-Conduct-Performance**

It is widely agreed that drugs are placed into ‘markets’, defined by the therapeutic benefits that the product delivers. New drugs are produced, marketed, and patented according to the class of diseases that they are intended to treat. This is called the drug’s “indication.” There are, at least, 60 different therapeutic markets. Some examples:

Anesthetics	Oncologics
Antibiotics	Opioids
Antihistamines	Psychostimulants
Barbiturates	Sex hormones
Diabetic Therapy	Statins
Diuretics	Thyroid Preparation

Early studies typically measured a given firm's market power to answer questions about the concentration of firms in these markets (Egan et al. 1982: 30-3). What makes delineating these classes difficult is the fact that one firm can produce various drugs in various markets and can monopolize on more than one of them. Physicians can—and often do—prescribe a drug for 'off-label' ailments, meaning there will likely be some overlap among therapeutic markets.

Assuming that patients with a specific illness create a demand for a particular drug (class), we can say that their demand for a class of illness also defines the therapeutic market. In other words, when a certain population suffers from a disease, patients implicitly demand that pharmaceutical companies create a drug to alleviate the symptoms of that disease (or cure it entirely). On the supply side, drug makers produce drugs to fill this demand. Physicians have the option to prescribe drugs across therapeutic markets, regardless of the drug's final intended use (Tesler et al. 1975: 475). For our purposes, this provokes discussions on cross-elasticity of demand and market power, with a focus on firms' pricing behaviors. Finally, it allows us to see the competition that takes place within the industry, and its effect on a firm's pricing decision of a particular drug.

In the analysis in this chapter, we hold to these therapeutic classes. We will see that defining a therapeutic market as narrowly as possible contributes directly to a drug's specialization. This is integral to deciding a drug's launch price. So we can imagine that when drug companies produce new cannabinoid drugs, they will be marketed within the boundaries of these therapeutic markets. However, due to cannabis's applicability in treating many symptoms across a range of diseases, we can conclude that in the case of

oncologics, drug companies will create a drug that targets cancer generally, as opposed to colon cancer specifically. High prices, therefore, are relegated to specialty and orphan drugs. These prices (and the markets in which they are found) provide an extreme case.

### **Market Structure & Competitive Forces**

Suppose there is an individual drug company. They have researched and developed a new drug and are about to bring it to market. Either there are no companies in this therapeutic market, or no companies have yet successfully developed and marketed their product for sale—they are a pure monopolist. The monopolist innovates new products (new output) only as competition necessitates it (i.e. as patents expire). After earning their patent, they have ‘cornered the market’. They hold the legal right to exclude all competitors from producing the same drug, raising the barriers to entry in the market enough to exclude other sellers.

In this initial scenario, there is one customer, one patient, and no insurance through which the patient can purchase the drug; all expenses are out-of-pocket. As discussed in previous chapters, insurance companies remove (some of) the burden of the patient’s willingness to pay. Relationships between insurance companies and drug makers take advantage of this reduced price sensitivity, and can therefore inflate drug launch prices. Without them, the monopolist calculates a price according to the methods described below. Setting aside insurance plans isolates economic forces that result in drug pricing strategies. In fact, Scherer (2004) says, insurance policies make patients’ price-demand elasticity less sensitive and enhances the drug makers’ ability to price well above production costs (928).



Given a novel drug and a pure monopolist position, the monopolist will charge a high price for the drug, above normal competitive market conditions, where price would otherwise equal the marginal cost. Levy and Rizansky (2014) show that when the monopolist drug maker maximizes profit, the optimal price is higher because drug companies are making a product that delivers substantial health benefits compared to other drugs (2004: 1-5). The monopolist is a single seller in the market, allowing them to differentiate prices among different types of customers with varying income levels.

The monopolist's problem becomes:  $\max_{p,x} \pi = p(x) \cdot x - c(x)$ , where marginal revenue  $R'(x)$  equals marginal cost  $C'(x)$ . Maximizing  $\frac{d\pi}{dx}$  and solving for  $p$ , we derive Lerner's Formula for monopoly power:

$$p = \left( \frac{1}{1 + \varepsilon p_x} \right) \cdot C'(x)$$

Immediately we see that when a monopolist equates  $R'(x)$  to  $C'(x)$ , the degree of the price markup Lerner's formula depends crucially on the degree of own-price demand (in)elasticity,  $\varepsilon p_x$  and marginal cost. It is inversely proportional to the degree of price markup itself. This implies that for specialty drugs, drugs that have a low demand elasticity, -0.1 and -0.21 (Goldman et al 2006), prices are likely to be much higher. Monopolists can exert more market power when the patient has a low price demand elasticity for drugs that treat a serious disease and are therefore necessary to survival. As the saying goes, when it comes to patients' drug treatments, it's "your money or your life!" The more effective the drug is in treating serious diseases, the higher the QALYs it adds to the patient's life, the lower the price demand elasticity, leading to a higher markup price. It is not difficult to see what it implies for marijuana-based synthetic drugs.

Cannabinoid drugs that treat more serious diseases will likely have a lower  $\varepsilon p_x$ , so  $p$  will be higher, and vice versa. Studies have measured  $\varepsilon p_x$  for cannabis, with a range between -0.3 and -0.6 (Nichols & Nichols 2013; Pacula & Lundberg 2014). Using this as an approximate reference, a low price demand elasticity reveals that even for general use cannabinoid drugs, a monopolist drug maker could afford to charge a high markup price.

How does monopolist theory measure up to the empirical evidence? The performance of monopolists in the drug industry was validated in what has become known as the Clemens-Cocks Model. Its main findings were that:

- 1) A firm in a technological environment can adapt its R&D and manufacturing processes to develop and produce products in several areas of drug therapy. This context emphasizes that the behavior of these firms is determined by profit-maximizing decisions that consider several different kinds of drug products.
- 2) As firms attempt to develop singular new products, they develop, as a by-product of R&D, products that compete with existing ones. From an empirical standpoint this can be expected to result in a substantial amount of entry into drug markets, market shares should be affected, and price pressures should be evident.
- 3) When an individual firm is successful in developing innovative new products whose demand curves presumably are favorable relative to costs, resources should flow to that firm as the profit incentive dictates. This implies that the firm that is relatively more successful in the stochastic process of finding new drugs should receive an increased market share and an increased ex post rate of return (Cocks 1975 in Chien 1979: 43).

Pure monopolists in the ethical drug industry is an oversimplification, but it tells us something about how individual companies price their products in the absence of substitutes. The Clemens-Cocks model shows us how companies behave in the face of monopolistic competition. What it doesn't tell us is that when other companies make similar ("me-too") drugs, companies can compete while their products are still on-patent

(each firm goes through the FDA approval process with a slightly different product).

Even if drugs are differentiable, monopolists may engage in price competition.

In this Bertrand-style competition, “competition between the substitute products reduces price somewhat below the monopoly price, depending in part on how substitutable are the two drugs” (Brendt et al. 2011: 9-12). In the latter scenario, individual firms still make rational profit-maximizing decisions, but the presence of other monopolists doing the same thing will inevitably lower the launch price. In a variant of the Bertrand model, the Edgeworth duopoly model shows that for two or more firms with production constraints, the Nash equilibrium may not exist. Competing monopolists’ profit-maximizing prices oscillate between a minimum where  $p = C'(x)$ , and a maximum where  $C'(x) = R'(x)$ —the two extremes of Lerner’s Formula. As the degree of substitution between products decreases, monopolists’ prices become more rigid. “Uncorrelated” goods do not price-compete with each other (Edgeworth 1925: 119-21).

When authors use a Bertrand duopoly to analyze competition, some assume, as in the Bertrand and Edgeworth-Bertrand model, that products between firms are perfectly substitutable homogenous products.

But this framework supposes counterfactually (as Scherer points out), that the manufacturer is a monopolist. The reality is that nearly all brand name prescription drugs compete with a therapeutically equivalent brand name drugs or even chemically indistinguishable generic drugs. A more complete examination of prescription drug pricing would consider the non-cooperative oligopolistic interactions among pharmaceutical manufacturers whose drugs are close substitutes. This can be done using a differentiated-products Bertrand oligopoly model (Elzinga and Mills 1997: 293-4).

A “differentiated-products Bertrand oligopoly model”, which derives from Edgeworth’s “uncorrelated” goods case, is essentially a Hotelling model. In this model, studied more

carefully in the next chapter, the more effective monopolies are in differentiating their products, the greater the profits that they are able to capture. It essentially relies on a company's ability to advertise its 'uniqueness' over its competitors.

Firms are able to obtain these profits because rather than cornering the entire therapeutic market, they advertise to create brand-loyal patients. "[T]he manufacturer can...concentrate on operation as a monopoly firm in the market of loyal consumers" (Ismo 2008: 2 citing Frank & Salkever 1992). In this way, firms retain their customers, effectually making their demand more inelastic. The result is the market power that, *a priori*, we should expect a monopolist pharmaceutical firm to wield. Assuming patients are willing to pay a higher price for a product with fewer side-effects, for example, and strongly believe that their product of choice stands alone in this regard, this would also explain why prices for brand-name drugs may *increase* following patent expiration (Frank & Salkever 1992 citing Wagner and Duffy 1988; Ramsey 2016). Although an insurance company's payment policies are a contributing factor, companies may simply be targeting a higher-income consumer market.

The price for new drugs must cover the costs of R&D from intense competitive pressures by the company to patent a marijuana drug for a certain therapeutic market. The fact that the drug contains synthetic cannabinoids will not be proprietary information. Drugs like *Cesamet*, *Syndros*, and *Marinol* disclose this information on their packaging, and *Sativex* and *Epidiolex* openly claim their use of cannabis extracts—not synthetics—to attract patients to their product; companies forego the secrecy in ingredients typically found in other drugs. This means that companies might lose some of the advantages of

persuasive marketing that convince customers that their product is more unique than their competitor's. As a result, there is a degree of substitution (however slight) of cannabinoid products across a variety of applications. Companies compete on a price point rather than on qualitative differences, as an Edgeworth-Bertrand competition model suggests.

Cannabinoid prices will be set relative to the (non)cannabinoid product with which it competes. Assuming a drug is an improvement over the other, but not so specific as to warrant a high price, a cannabinoid will generally be given a medium-high launch price.

Rather than a company chemically creating a secret new chemical and thus claiming intellectual property over it, the use of synthetic cannabis would not be proprietary information. Marijuana's medicinal benefits have been known for centuries. Unlike any other drug, whose 'recipe' is confidential, cannabis is public knowledge. Any drug company could use it. So, the name of a new drug might convey that it contains a marijuana analog compound. For example, names like *Sativex*, *Cannador*, and *Marinol* are references to Sativa, Cannabis, and "Mari"juana, respectively. Companies would find it futile to try to hide this information from the customer.

The response to this is quite simple. It can be imagined that out the outset of marijuana's legalization (for scientific research purposes), individual drug companies begins a 'race' to be the first to research and develop a new product, one that improves over its predecessors—the 'recipe' contained in *Marinol* and *Cesamet*—and targets a specific indication or therapeutic market. Only those drugs which make it through the FDA's approval process will be granted market approval—the rest will be unsuccessful.

This is not a “winner take all” race, but a “first past the post” one: the first company to successfully market an improved marijuana pharmaceutical will not reveal the new ‘recipe’. The only thing that their competitors will know is that the other has made *some* kind of improvement over the existing cannabinoid recipe, without explicitly stating what that improvement is; they will only learn of the new indication. Drug companies will patent the synthesis processes of the various compounds, and the new compounds themselves. So when a future drug maker develops a cannabinoid drug, it will be patented according to its indication and the process used. Generally, the larger the number of indications, the lower the market price. Competitive forces, as predicted by the Clemens-Cocks model and Bertrand oligopolistic competition, should put pressure on cannabinoid drug prices in the marketplace.

### **Value- and Performance-Based Pricing Strategies**

The price of a new drug depends on a firm’s success in differentiating it from a competing product. With the substitute acting as a ‘reference price’, it determines how much a price may deviate from any other possible substitute, with respect to its therapeutic benefits. For the patient, the reference price establishes a base line for perceived value or the utility of the next best alternative. Drug makers are able to price above this if the net benefits of their product is positive—and below if the additional perceived value is negative (Gregson et al 2005). Firms remain price makers, but they account for improvements over their competitor’s product. For example, prices for current cannabinoid market options like *Marinol* and *Cesamet* will serve as reference prices for new cannabinoid products. To the patient’s knowledge, these are the closest

substitutes in the ethical drug market without consuming botanic cannabis. Product characteristics can be reflected in fewer side effects, higher potency, longer-lasting therapeutic effects, and different modes of administration (e.g. a pill vs. an oral spray). This gives them a competitive advantage over possible substitutes. *Marinol* and *Cesamet* are more potent than cannabis since they offer high THC (psychoactive component) and low CBD (physical healing component) content.

Modern-day drug pricing strategy relies heavily on value-based pricing. In a recent study, the authors used trial data, conditional on its expected benefit added to the patient, the patient's willingness to pay (set at some threshold, which is the only constraint on the optimal price in each stage of development trials). They assigned value-based price was zero if the trial result was not statistically significant, and otherwise adjusted based on added cost-effectiveness. From there, the authors forecasted profit rates using a Bayesian probability analysis and determined a market price (Breeze & Brennan 2015). A statistically insignificant price is zero for the same reason that a drug company will drop a product from the development pipeline if it fails to show effectiveness. As trials progress, if the product does not show promising signs, or if it is not a significant improvement over the company's competitors, development will be aborted. A price of zero (in this study) translates into a product is not adding value to the customer. This approach is a distant relative to the classic study of 'theory of the firm'. At each stage of development, a new product should be priced such that the marginal benefit equals the marginal cost of adding the input.

The most profitable way to attract customers from rivals is not necessarily only to lower price; product improvement and innovation will also contribute to

profitability, and at the margin, the ratio of the benefit added to profit by lower price to the benefit from further innovation should be equated to the ratio of their respective marginal costs (Egan et al 1982: 47-8 citing Brozen 1975).

In other words, the input price should equal its marginal benefit to the final product.

Breeze and Brennan's value-based pricing and the classical theory of the firm come together to inspire Dimitiri's (2014) work. Her paper essentially says that in each stage of the development period, the market price for the drug will equal the expected profits at that stage; as the drug moves closer to marketing, the probability that it will be successful increases, as does the market price. Dimitri considers the development in a network of research firms. Either a drug company could develop the product itself "in-house", or it can buy the rights from another firm. This takes on an important distinction if the drug fails in a phase of testing. The company does not drop the product from its line, but instead:

[these price and profit] considerations provide a benchmark for the market price. If the selling company cannot afford development up to registration [of the new drug] (e.g. it is a small firm), a larger buying firm could exploit its 'buyer power' by negotiating a lower transaction price (217).

Dimitri concludes with something obvious: the price of the drug equals its expected payoff to the firm. Big Pharma will purchase future cannabinoid recipes—failed or not—from smaller, less capital-intensive drug companies, as the Clemens-Cocks model suggests. Larger companies like *Merck & Co.* will have better probabilities at successful development simply due to their larger capacity to conduct R&D successfully. The price at which the rights are purchased from small firms, based on their proven effectiveness, sets a benchmark for the launch price. The QALYs added to the patient sets a premium on this benchmark, an upper limit.



The practice of putting a drug into a price range, rather than a unique discrete price as in Dimitri, is known as performance-based pricing. When a drug meets certain “milestones” or “endpoints” in terms of efficacy (value-based), rather than progressing into the next development stage regardless of efficacy (performance-based), a price could be negotiated (Dranitsaris et al 2015). The proposed policy in Dranitsaris is based on some well-known practices that are widely used in the U.K. Specifically, a drug’s price is based on the Quality of Life Adjusted Years (QALY)—the longevity a medical procedure can add to a person’s life.

Evidence shows that drugs that treat acute conditions have a higher price than those that treat chronic conditions (Taubman & Mason 1989 in Kolassa 1997: 55-56); Brendt et al. (2011) confirm that this is found in the case of specialty drugs: drugs that treat a very specific—maybe even rare—condition. For this class of drugs there are often no close substitutes, so both buyers and sellers know the high price is justified. This is emphasized as a point of exaggeration: this is not the case for cannabinoids. Rather, this contrast helps us understand how new cannabinoid products that treat a broad range of *symptoms* will opt for a lower price than a drug that treats a *specific illness* like a specific type of cancer, Multiple Sclerosis, or seizures. It is unlikely that cannabinoids will be specialty, orphan drugs (*Epidiolex* is the exception, since it is the first of its kind on the market). A drug that treats general symptoms instead of a specific disease has many more competitors. The more intense the competition, the lower the price.

Zaric (2008) formally modeled this. He uses a Markov probability distribution of a disease progression, in which death is the final stage. This distribution models how a

manufacturer will set its drug price based on: a patient's willingness-to-pay, cost effectiveness of the drug, and the aggressiveness of the disease's progression.

There is a relationship between population heterogeneity and the optimal proportion of the population that is targeted. For a relatively homogenous population (not much variation in [the progression of the disease between patients in the population]) it is optimal to set a high price and target a relatively restrictive subset of the population, whereas for a relatively heterogeneous population it is optimal to set a lower price and get a greater proportion of the population. Thus, it is important for manufacturers to understand the entire distribution...when setting prices... (1287).

(It should be noted that in Zaric's study that cost effectiveness has a greater influence on insurer's reimbursement decision of a patient's drug.) When the drug is a one-of-a-kind, and the disease is equally as threatening, the drug company is able to exert a significant amount of market power to get the patient to pay the asking price.

A higher cross-price elasticity of demand will naturally lend itself to lower drug prices. Chen and Rizzo (2010) develop a conceptual framework to find that in the market for antidepressant drugs, which, they say, is known to be a market with many close substitutes. "[I]n markets where products are relatively well-differentiated, higher quality entrants will tend to adopt a market skimming pricing strategy. In more homogenous markets, we expect...a market penetration pricing strategy" (297). This may also occur if consumers are uncertain of the new drug. Companies may trade short-term profit losses "to familiarize consumers with the product, reaping the benefits of higher market shares and prices over time" (Chen 2008: 9-10; Schmalensee 1982). In rare cases, companies will maintain a low price to deter other companies from competing. Once they've cornered the market, they will raise it (Chien 1979: 85).

As the market for which a given cannabinoid drug can be prescribed is enlarged, a skimming pricing strategy becomes more likely. Essentially, U.S. drug makers will launch the drug at a medium-high price to compete for market share sought after by outside drug companies like GW Pharmaceutical's *Sativex* or *Epidiolex*. Eventually, these prices will fall to parity with close (non)cannabinoid substitute drugs with similar treatments and side effects. Even though enlarging the market should reduce prices, drug companies will be able to offer a higher price. Cannabinoids will deliver, assumingly, a better quality of life compared to the product with which it is competing. If this were not the case, they would be offered one 'level' below at a parity reference price. Also recall from Chapter II that the quality, accessibility, and convenience of this product affords it an additional premium above the reference price.

Given the availability to information about synthetic cannabinoids and their utility, companies will not likely try to persuade customers in their advertising that one drug treats only one condition. *Sativex* and *Epidiolex* are formally indicated to treat Multiple Sclerosis and epilepsy, respectively, but their oral spray delivery method makes it quite likely that patients will soon have it prescribed to them for a whole range of therapeutic reasons. *Sativex and Epidiolex* will likely be prescribed across therapeutic markets, increasing the cross-price elasticity of demand. The same may be true of to-be other synthetic cannabinoid drugs.

Regarding general use drugs, how will companies price their rebranded products that are now off-patent and competing with cheaper generics? Consider, for example, *OxyContin* (oxycodone HCL). An improved version would be *OxyContin* + CBD. This

would be repackaged and sold as an ‘improved’ brand-name *OxyContin*. It would be priced higher than traditional *OxyContin* and other competitors like *Vicodin* (hydrocodone and acetaminophen). When synthetic cannabinoid products are rebranded, we should expect that their prices will start a medium-high after rebranding. They will follow a similar trajectory as described above.

In any case, the decline in prices will be the result of a couple things. First, since cannabinoid drugs can be prescribed across therapeutic markets, there is more room for competition. Competition will necessitate more intense advertising—promotional costs which will keep prices pegged to drug prices. According to Chen & Rizzo’s (2010) conclusions, it is likely that prices will remain low. Both the increase in advertising and the increase in value added to the patient’s life will offset any pressures on prices. In the special case where a synthetic marijuana drug treats a specialty market or serious disease where all other products have failed, the drug could actually warrant a further increase in price. This should be considered the exception, though, not the rule.

### **Pricing in Practice: Empirical Work**

Most of the conclusions about how the industry prices its products were found in the early years of the pharmacoeconomic discipline. The most relevant papers often cited from the literature are between the 1960s and 1980s. Reekie (1978) was the first to examine price trends for new drugs, extending Dean’s concepts of skimming and penetration pricing to pharmaceuticals. He found that new pharmaceutical drugs that present pioneering advancements are priced higher than any close substitutes on the market, while imitators are priced much lower.

Like Dean, (1969), most authors in the literature use ordinal terms to describe pricing and profits. “High” and “low” have no apparent numeric value. Reekie (1978) addressed this by referring to prices on a discrete range of low-medium-high price by calculating ratios of the average price of the new product relative to the weighted average price of leading competitive drugs. “Low” prices had a ratio of less than 1.0, “medium” prices, 1.0-1.5, “high” prices, above 1.5.

As patents approach expiration, companies begin to lower prices to anticipate the entry of generic drugs. “While monopoly positions are conferred, patent protection does not normally confer the power to monopolize any of the therapeutic markets. This is borne out by the high turnover among leading firms and the vigorous product competition within these markets” (Comanor in Chien 1979: 39). In a follow-up study to the Clemens-Cocks theoretical model, high market concentration ratios were found alongside high market entry rates: “Successful new drugs appear and seize a commanding position only to falter after five or more years and are replaced by, presumably, better rivals” (Tesler et al. 1975: 460). This model predicts that drug companies making synthetic cannabinoids will monopolize in multiple therapeutic markets, these drugs will compete with existing options, and that firms will be profitable.

The oft-cited Lu & Comanor (1998) study supported Reekie’s findings. They found that pioneering products were priced about 3.2 times any close substitute; new drugs offering smaller, modest gains were introduced with prices 2.17 times substitutes, and those offering little-to-no gain were priced relatively equivalent to substitutes. Although this study is relatively newer, it analyzed new drugs developed between 1978

and 1987. They also looked at these drugs' prices over time, at 4, 6, and 8 year intervals. All prices, essentially, are set based on a qualitative ("therapeutic") improvement over competitors. Thus, at each stage of pre-market and pre-clinical trials, drug companies are reviewing the launch price based on the product's marginal benefit. As monopolists, drug companies are at liberty to set any price for their products, insofar as it reflects a (lack of) similarity in available substitutes and an increase medicinal value.

The dynamic among competing, price-making monopolies is unique to the drug industry. But it should be noted that this value-based approach only sets an *upper limit* price for a pricing range. This determines what the market will bear. The company's perspective sets a *lower limit* for a price range, determined by a minimum return on investment needed to satisfy shareholders (Gregson et al 2005). The evidence makes it apparent that future synthetic marijuana drugs will be priced similarly. Ones that are less addictive than opioids or otherwise offer fewer adverse side effects will afford a higher price. Cannabinoids that are marginally better than competing products will use those products as a reference price.

The rise in prices is largely dependent on the types of patients the drugs target rather than the competition among those drugs which, as we have seen in general use drugs, should be pressured downward (if they are new innovations at the time of market introduction). Further, since demand price elasticity for these drugs is very inelastic (Goldman et al 2006), drug makers with great market power can exploit patient's need for the drug, measured by a higher willingness-to-pay. Drug makers factor this low price demand elasticity into their Lerner's markup price. This shows that the conclusions from

theoretical papers support empirical ones. This would also explain why the prices of specialty oncology drugs have been rising despite small therapeutic gains in new drugs (Howard et al 2015). Manufacturers can still produce drugs that are not associated with large QALY gains, yet they may still fetch a much higher prices since they serve a specialty market. Even if new drugs are small improvements above others, high drug prices are a result of marketing in a therapeutic market where patients have a high willingness-to-pay for potentially life-saving treatments. The new advancement in technology will provide a push for more efficient drugs. Investors will set a lower limit on the price range for cannabinoids. Patients' willingness-to-pay will set the upper limit.

Without identifying a clear independent variable, the effect of patent expiry on price change is ambiguous: prices (and quantities) can rise or fall for drug prices; there is evidence to support both trends. This significant variable, Lakdawalla & Philipson (2012) say, is advertising. It is reflective of drug's launch price and the trajectory that it will follow. When there are multiple firms competing for market share and advertising their own products to patients (and physicians), it offers better insight to pricing strategies. The largest costs tend to be in advertising, which can be as much as twice the expenditures on R&D (Gagnon and Lexchin 2008 in O'Connor 2014: 573). Rising drug prices have to recoup rising developmental and promotional costs.

Recall that Lerner's Formula shows how demand elasticity rises with a restriction in quantity. But this inefficiency can be lessened when the elasticity of demand with respect to advertising is higher. By contrast, patent expirations may reduce output if companies reduce advertising efforts by enough to offset the impact of price reductions.

The estimated demand function implies that in the short run (first 5 months), output decreases after patent expiration because the reduction in advertising more than offsets the reduction in price...not until several years has elapsed does the price effect dominate the reduction in advertising (2012: 153-5, 158).

What that means empirically, Lakdwalla & Philipson find, is that when drug patents expire, ones that remain fully advertised see a price increase and quantity decrease. Likewise, for drugs with little-to-no advertising, prices behave as we would expect according to the standard monopoly theory: prices decrease and quantities increase (168). Given the influx of a variety of cannabinoid products, the direct-to-consumer advertising for these drugs will largely increase in the patent's earlier years. Generally, prices will be set at a relatively high price before falling after patents expire and generics become available. If the product has a more narrow specialization, some companies may increase prices to capitalize on patients' brand loyalty.

At this point, we can see how firms' pricing strategies, when tied to advertising, can explain the problem of rising drug prices across the industry. Though a pressing issue, rising price trends is not the focus here. Our investigation of individual firm's pricing strategies is complete. A drug's launch price is a function of: patients' willingness-to-pay as income dictates, advertising and promotional costs, patient's cross-price demand elasticities for substitutes, and value-based competition among competitors. We have also not considered generic entry into the market. Suffice to say, generic cannabinoid medicines will contribute to falling cannabinoid prices.

Throughout this literature, we have arrived at some important conclusions:

1. Specialization vs. General Use: New drugs are priced relative to competitors. New drugs offering significant benefits over competitors



will be priced higher, but this price is likely to decline over time. The opposite is true of a drug offers marginal or no benefits over other market options. A drug with a very specific indication is priced much higher than a drug that can be prescribed across a range of therapeutic markets.

2. **Skimming vs. Penetration Pricing:** If the patient is uncertain of the drug's effects, drug makers will 'penetrate' the market with an initial low price offering. If the drug is widely anticipated, the opposite is true, and drug makers will 'skim' patients with higher levels of willingness-to-pay for better health, lowering the price over time.
3. **High Market Concentration Ratios:** This leads us to believe that products are priced according to traditional monopolist theory, where marginal cost equals marginal revenue, and the resulting mark-up over marginal cost depends on the elasticity of demand (Lerner's Formula). Firms may also price discriminate among patients' levels of willingness-to-pay.
4. **Promotional Costs:** Price is not the only consideration for a patient's decision to try a new drug. Drug makers gain monopoly and pricing power by creating brand-loyal patients. After patent expiration on name-brands, generics enter the market. Drug makers raise their prices and some patients will continue to purchase the former because of higher income levels or marketers persuade patients that name-brand drugs are of superior quality. In this way, the market is segmented through intense advertising and promotion. Therefore, we should expect some competition

in the drug market to result in a Bertrand-style non-price competition. A large contributing factor to price trends includes promotional intensity.

The output decision in a cannabinoid's pricing requires many inputs, including:

- Cross-market & off-label prescriptions
- Introduction of generic cannabinoid products & international competition
- Improved quality, access, and convenience of cannabinoids over cannabis
- Expected profits determined by the price at which large drug companies purchase intellectual property rights to develop their failed products
- Improved quality of cannabinoids over opioids and other ethical drugs usually associated with addiction and negative side effects
- Drug companies' (in)ability to drive brand loyalty

Many other factors are lost in this discussion. We have not considered: regional price differences, income between patients affecting rebates, reimbursements, and discounts; and we have neglected insurance companies and reference prices as they relate to rate setting. This discussion also neglects direct wholesale prices and other measures of pharmaceutical pricing. Perhaps a future quantitative study could measure the effect of these variables on price. Nevertheless, this study serves as a base model for synthetic marijuana pricing strategies. The literature suggests that these prices will be somewhat high but fall over time. Nothing below a reference price would justify the time, costs, and effort required to bring a new drug to market. If a cannabinoid price were below parity, a drug company would abort its product launch.

## Chapter IV: Marketing & Pricing for Cannabis Supplements

As drug companies deepen their knowledge about cannabinoids and marijuana in general, researchers may uncover new compounds. Unlike single molecule compounds in drugs, these herbal supplements would contain a *profile* of synthetic THC, CBD, and minor compounds that more closely resemble the cannabis plant.

It is postulated that the beneficial therapeutic effects of cannabis result from the interaction of different cannabinoids and other compounds present in *Cannabis sativa L.* This may explain why cannabis-based medicines made from whole plant extracts may be more effective than single cannabinoid products [like *Marinol* or *Syndros*] (Stott 2004: 85).

In this chapter, we review the other half of the market, OTC herbal supplements sold in retail stores vs. cannabis sold in marijuana dispensaries, shown in Figure 1. We explore the marketing options for each, with special attention given to herbal supplements. We then apply these conclusions to rationalize pricing decisions.

These product prices are based on the production costs it takes to bring them to market. Contrast this with pharmaceuticals, whose prices are largely based on market exclusivity. Pricing of herbal supplements depends on consumer demand and a traditional cost-plus pricing method: they are priced at marginal cost plus a rate of profit premium, derived from rents on advertising and some degree of substitution (which would be zero if the goods were perceived as homogenous). Prices will probably be lower for supplements than cannabis, and even lower than pharmaceuticals to reflect a lower grade of quality. Herbal supplements will adopt a medium-low to low price skimming strategy.

As we will see, a lack of quality control and patent pricing, targeting lower-income consumers, increased advertising, and a broader range of therapeutic applications are all factors that will determine this outcome. Note that supplements do not add value to the launch price in the same way that a prescription drug does. This applies to *non-price* competing products. In the marijuana market, presumably the *price* competition determines the final price. In other words, since price is indicative of product quality, product differentiation with respect to quality is the lens through which we examine consumers' product choices.

### **Cannabis as an Herbal Supplement**

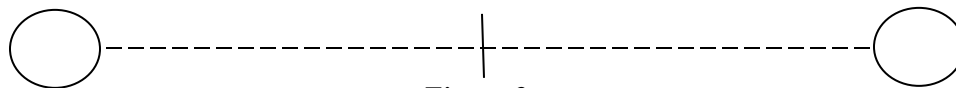
The interaction between dispensaries and nutrition stores provides a unique opportunity to use Hotelling's linear model. It provides rich insight into marketing and pricing structures. Companies compete for customers within their own strata, whether it be physical distance, product quality, or customers' income levels (de Frutos et al. 2013).

Regarding the latter, companies typically market OTC supplements to those with a lower level of willingness-to-pay for health (McCann in Sax 2015: 378). In support of this, evidence shows that the demand for supplements increased during the Great Recession (Gross 2009), when income levels were greatly reduced. Any potential customer using cheaper herbal supplements will be a price-sensitive, moderate-to-light user who does not feel a sense of loyalty to purchase from dispensaries. These customers may find that OTC herbal supplements are more cost-effective for them; they value marijuana's benefits but cannot afford botanic cannabis. Supplements therefore capitalize on a consumer segment with a lower willingness-to-pay and consequently has limited

access to health information on these products. This neatly summarizes monopolists' ability to discriminate prices among consumer markets.

### **Market Structure & Competitive Forces**

Let us first review the basic Hotelling model depicted below in Figure 2. Suppose that there are two stores selling the same good. Consumers are equally spaced between two companies, and the midway point is exactly halfway between both stores. Customers seek to maximize their utility, and minimize transportation costs of travelling to the store. It stands to reason that customers will patron the store nearest to them. If either store decides to relocate closer to the midway point, they will be closer to a greater number of customers and thus gain a larger market share. Each store has an incentive to do this, so in this game's Nash equilibrium, both stores settle at the midway point; each store earns 50% of the market share (Hotelling 1929; Roy 2000). In the Edgeworth-Bertrand version of the Hotelling model, the firm that lowers its price will capture a greater market share, but prices will oscillate between a monopolist's price  $p$ , determined by Lerner's Formula, and  $p'$  (Edgeworth 1925: 119-21) as in the competitive case where  $p =$  marginal cost.



*Figure 2*

We can readily apply this to the marijuana market. Consider two stores: a marijuana dispensary selling cannabis, and a retail shop selling dietary and herbal supplements. On the west side of town, the dispensary serves the cannabis-preferring clientele. On the east side of town, the nutrition store caters to those who prefer health supplements. Customers living on the west side of town receive no utility from cannabis.

They enjoy a positive level of utility from the health supplements purchased on the other side of town—despite the transportation cost that it imposes. In other words, it is still worthwhile to buy the good since the benefit outweighs its cost. The same is true for the cannabis-preferring clientele on the east side of town. In a one time period model, it is assumed that each company has not yet built a new store on the opposite side of town. If they did, Hotelling’s Law tells us that they will be in close proximity to each other. Realistically, if the two stores relocated closer to each other, each would earn a greater market share, but sell their products at lower prices.

Think of the ‘distance’ between stores as a metaphor for product choice within a product space. Customers choose the product that most closely fits their exogenously given preferences. In the market explored in this chapter, there are customers who prefer supplements and those who prefer botanic cannabis. Both products advertise similar therapeutic benefits; however, loyal cannabis customers may find that herbal supplements are therapeutically inferior. Likewise, herbal supplement users may find that cannabis is therapeutically superior, but nonetheless unaffordable. Heavy cannabis smokers are likely to remain loyal to their local dispensary. If they need oils or supplements, they obtain them at the dispensary or at home—not the nutrition store. These users prefer the experience, culture, and effectiveness of smoked cannabis and are willing to pay more for it. They will not get the same utility from simply ingesting a pill! Cannabis supplements therefore serve as a lower-grade option for customers with reduced income levels. In the general sense, these products are *not* acquired tastes; ‘learning’ an appreciation for the

other product creates a ‘transportation cost’ of moving toward that good within the product space.

Hotelling’s Law tells us that firms who can ‘move towards each other’ in terms of product differentiation, will do so. Firms who cannot differentiate themselves will see a loss in market share to their competitor. Given some degree of cross-price demand elasticity, cannabis and herbal supplement users are likely to see the quality between the two with some degree of substitution. (At this point, this degree is indeterminate, but it may be small and positive).

Supplement makers must effectively advertise to cannabis users in order to increase this degree of substitution, though it seems unlikely that they will be successful. We may conclude that supplements will diverge from cannabis in the product space in terms of quality. It does this by advertising that supplements have all the same characteristics of cannabis, but at a cheaper price. This way, they make supplements out to be as similar to botanic cannabis as possible. However, there is actually large difference in quality: supplements are less effective, have lower standards of quality control, and are less potent. Strangely, the two products will diverge in terms of quality, but slightly converge in terms of product differentiation. Since the former effect largely overpowers the latter, cannabis will face less competition from supplements—but this will probably be counteracted by the increase in competition against other dispensaries; it will continue to cater to heavy smokers who are loyal to the cannabis submarket.

This kind of product competition results from market structures for dietary supplements that are far less regulated than that of pharmaceuticals. It would be no

different than comparing competing food products—because supplements *are* considered foods. There is less rigor in terms of development, regulation, and marketing. In fact, the claims made on the bottles are often not scientifically proven, and the FDA does not strictly regulate them. Unlike pharmaceuticals, dietary supplements are not required to prove that they are safe and effective for human consumption before they are sold. Only when a supplement claims to treat, diagnose, or cure a disease does the FDA require that a supplement be approved as a drug. This *laissez-faire* policy on supplements is a construct of the current legislation, the Dietary Supplement Health and Education Act (DSHEA) of 1994. “The regulation created an incentive for marketers to make relatively nonspecific structure-function claims rather than more explicit health claims because structure-function claims did not require documentation of safety or proof of efficacy” (Mason & Scammon 2011: 202).

As noted earlier, a large portion of consumers of these products is uninformed about their actual contents, and is indifferent when told their medical benefits are dubious (Starr 2015: 478). Royne et al. (2014) found that consumers tend to discredit these claims altogether. Consumers may see a product advertised as ‘natural’, believing it to be safe. Nevertheless, this claim may be false, the product may contain ingredients not listed, or it may contain ones that are pharmaceutical-like (Sax 2015: 377). This creates a moral hazard problem. Companies make billions in profit because the ingredients in their products (or lack thereof), and the advertising for those products, are monitored (by the FCC, not the FDA) but not enforced (Starr 2015: 480-1). Moreover, they will come in different strengths to mimic the effects of different cannabis strains.



## **Marijuana Supplement Marketing**

What does all of this imply for marketing cannabis oil supplements? Foremost, the makers of these products would not need to show that they are safe and effective. Even though the information on the medical benefits of marijuana are vast and easily accessible, consumers may be disinclined to research them. If they are likely to buy these products *en masse*, producers need not invest the multi-millions of dollars required of the drug industry to prove product safety. *Sans* patent pricing, this allows supplement makers to price much lower than pharmaceuticals. Implicitly, consumers could use supplements for ‘off-label’ health problems. Supplement makers could advertise this superficial low-cost treatment option for wide-ranging ailments.

There is no assurance that one brand’s version of cannabis oil will be comparable to the next. Different brands could claim that their product comes from a unique strain of cannabis known to treat a certain ailment, but there may not be an accurate listing of ingredients or dosage amounts. This results in products that may have dubious and biological effects in treating a specific condition—and supplement makers need not advertise otherwise. In fact, the risk falls on the consumer for using the product, who is generally uninformed on the ingredients in supplements or erroneously believes that the FDA regulates them. Producers will likely use pharmaceutical-like cannabinoid analogs. The description on the bottle will describe how their product can help alleviate certain conditions, but they will not claim that it can treat, diagnose, or cure them.

Again, since price is indicative of quality, and quality is sub-par, prices for generic herbal supplements could be below parity with cannabis, slightly inflated by

advertising costs. Customers who want a higher quality product must be willing to pay the higher price. This medium-low price falls over time as advertising costs decrease; recall that Lakdawalla & Pilipson (2012) found that declining market prices are pegged to advertising costs. Prices decline as the originality of the product dissipates, and patients ‘learn’ that its quality is inferior to botanic cannabis. It is not likely that prices for cannabis will increase much further. If marijuana were legalized and more “ganjapreneurs” entered the market, profits and prices would be competed away.

## **Chapter V: Are Cannabinoids the New Opioids?**

In the late 20<sup>th</sup> century, the introduction of birth control caused a great shift in the drug industry. In the early 21<sup>st</sup> century, it was opioids. Cannabinoids could prove to be the third great shift. Eventually, marijuana will be federally legalized, taxed, and regulated. Drug companies will have full access to the plant to develop products that will replicate its effects. Although its stigma continues for many who still use marijuana, it is slowly fading; marijuana will emerge into the state-of-the-art medical practice. With the expansion of a revolutionary new class of drugs, could their novelty—and substitution effect on other drugs—reduce prices and demand for competing pharmaceuticals, including opioids? This is an intriguing speculation worthy of further research.

This paper has been a useful exposé of the core of the drug industry's pricing strategies. It helps us understand the strategic process that goes into determining a drug's price, which many deem as overtly exploitative. Most drugs rely heavily on a price that correlates to the advances in medical treatment it has begotten. Often times, the increase in price justifies cost savings elsewhere in the health system, e.g. hospital visits. Our results tell us nothing new in terms of how the pricing strategies will change after cannabis's legalization.

### **Summary of Findings**

This work has been an attempt to bridge the gap in the literatures between the pharmacoeconomic field and the mainstreaming of marijuana. There is evidence that

companies are currently creating these drugs, yet their economic effects in the drug industry, especially cannabinoids' pricing and marketing strategies, has been largely unaddressed. Overall, I concluded that if new cannabinoid drugs are brought to market, prices would be somewhat high. Some drugs will offer a great contribution to the medical practice. If successful, they could treat conditions associated with: cancer, Multiple Sclerosis, rheumatoid arthritis, chronic depression, heart disease, seizures, and more. It is likely, however, that cannabinoids would have a more general application. They would be new and improved rebrands of older drugs, treating less serious conditions like minor headaches. The cannabinoid agent would likely allow these drugs to be used across a range of therapeutic markets because they are designed to treat *symptoms* of an illness, rather than a specific disease itself. Therefore, "high" priced drugs would be specialty drugs, so cannabinoids should be at least one tier below. The lag time between a drug's launch into a therapeutic market and patients 'learning' of its off-label applications would correlate with greater competition and a decline in price.

Similarly, the introduction of generic health supplements could be added to diet and exercise regimens, pre-natal care, and more. However, I concluded that cannabis health supplements would likely be made cheaply, advertised effectively (albeit still dubiously), and may actually compete prices down in the botanic cannabis submarket. This result is a function of a Hotelling product space model. Although cannabis and supplements are not perfect substitutes, the (assumably small and positive) *degree* of substitutability provides price competition nonetheless.

## **A New Way Forward**

This work began with a hypothetical: what would happen if marijuana were legalized? It also began with a series of assumptions, most of which are realistic. Of these assumptions, we assumed that the ethical drug markets and the marijuana markets were separate, that there was very little product competition between these markets' respective products. Admittedly, this assumption may not be sustainable. However, in this work it allowed us to analyze the pricing decisions of each product individually. For example, we can look at the pricing decisions in a segmented market for prescription drugs without the influence of competing products like supplements or naturopathic medicine.

Although removing this assumption will very likely change our results, I would like to reiterate that this work provides a foundation for future studies. Moving forward, future research should examine how these products interact and perhaps complement each other. What could be the resulting price in that case? This would increase competition, more importantly, what marketing strategies might firms devise to reduce any arbitrage?

Furthermore, we also assumed that the market price 'signals' to the customer the quality of the marijuana product that they are buying. This might be a reasonable assumption, but it ignores the fact that prescription drugs (and health care in general) is an experience good. The patient cannot ascertain the quality of care they are about to receive until they have already consumed the product. Patients may self-select themselves into a market, but may not 'get it right' the first time. They might experiment with various cannabinoid products before settling on the most effective one for their needs.

The reality is that patients are increasingly disillusioned with the drug industry. They are substituting pharmaceuticals with marijuana, and drug companies cannot continue to resist legalization, or they will continue to leak profits. Further, opiates are coming under more intense scrutiny. They have proven to be highly addictive, and are a leading cause of accidental deaths across the country. As the epidemic grows more dire, drug companies have an incentive to look into developing cannabinoids. By doing so, they should take on more corporate social responsibility—lest they come under more scrutiny for not taking action, despite being well positioned to do so. Over time, increased sales from cannabinoids may even replace opioids. If marijuana were legalized before drug companies have a viable product, they could lose domestic and international sales. This scenario becomes increasingly probable when considering that nearly 30 states have some form of a medical marijuana program. A shifting power balance to state legalization could act as a catalyst for Big Pharma’s increased cannabis research efforts. Drug companies lobby heavily against marijuana legalization despite definite economic benefits in their favor. Once the prohibition is removed and patients can self-select themselves either into the cannabis market or the insurer-approved ethical drug market, drug companies do not need to worry about losing additional revenue. Therefore, this study supports policy efforts to move towards marijuana legalization for scientific research and possible prescription drug development.

If drug companies could successfully market new synthetic cannabinoids, insurers may be interested in covering them in future drug plans. Insurance companies have significantly more market power to bargain with drug companies. The former can

negotiate at which price they will pay for the drug, and this price will likely be lower than the initial market launch price determined in this study. The entry of generic cannabinoids, especially, will result in much lower cannabinoid drug prices. Cannabis must take this route if it is to find its way into the formal health care system.

It is my hope that this study, in one way or another, has added new knowledge and understanding to the conversation on marijuana legalization. Understanding how Big Pharma operates, and including drug companies in the anti-prohibition debate, may bring a hypothetical legalization to a reality. They are an important stakeholder in the conversation so they must be brought to the table. Moreover, I hope that this study is a step forward in putting the “ethical” back into the ethical drug industry.

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