

A COMPUTATIONAL DESIGN FRAMEWORK FOR
REGULATION VOLATILITY IN THE CANNABIS INDUSTRY

by

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CHAPTER I. INTRODUCTION

The rapid innovation in technology is pushing companies into changing their attitudes towards specific work tasks that generally involve human input. Some people may find that their jobs are irrelevant due to technological change, while some situations compliment the workforce changes. “Experimentation with different techniques and business models requires flexibility, which is one critical advantage of a human worker. Over time, as best practices are worked out and then codified, it becomes easier to break production down into routine components, and then automate those components as technology allows (Economist Intelligence Unit, 2014, para. 21).” This thesis does not dispute positive or negative perspectives surrounding the automation of workers, but rather takes into consideration the reality of technology allowing the amateur to design and create.

Graphic designers are familiar with working in a structured manner such as: working within guidelines, grids, paper sizes, and screen resolutions. Through the advancement of digital technology, designers are able to utilize the web to download typefaces and styles, and work with indexed colors and color palettes. “These parts are modular and mechanical, perfect for automation (Peart, 2016, para.4).” Overall, this adaption to change is essential to design as a discipline since designers seem to slowly be moving away from the form-giving process into more abstract-problem and data-ridden solving processes (Peart, 2016).

This thesis demonstrates the shift in a designer’s role into abstract-problem solving by highlighting issues within the cannabis industry in regard to labeling and packaging regulations. The research conducted around this problem is then used to propose a digital application interface with artificial intelligence (AI) to be used by anyone regardless of their design education. Forward on, this AI application will be called Regulabel. This thesis is essentially automating out the graphic designer in an effort for efficiency, quality, and

accuracy in an industry that lack proper regulation: the cannabis industry. There are similar volatile industries to the cannabis industry (such as gambling) that use AI software (such as Pega & GamblingCompliance) for multi-jurisdictional and multi-product regulation data while also gathering customer data to assist in the marketing and proper use of its products (GamblingCompliance, 2019, Pega, 2019). There is also ProductVision, a software for the food and beverage industry, which uses automated services such as the nutritional labeling module that automatically provides calculations and nutrition values in various template formats (ProductVision, 2019). Through qualitative and quantitative research, this thesis exposes abstract problem of volatility of regulations in the cannabis industry, prohibition's impact on the design history and artifacts of cannabis, and a cross-industrial analysis of government regulation. This thesis then uses that same research to move forward with a framework proposal for Regulabel which can then best adapt to cannabis' volatile industry and packaging and labeling concerns.

In spring of 2019, John Maeda gave a design in tech report in which he covers the latest trends in the technology sphere in relation to communication design (Maeda, 2019). In his talk Maeda distinguishes fluctuating definitions of design since design seems to puzzle both designers and non-designers. Maeda splits design into the following practices: Classical design, design thinking, and computational design (2019). Classical design focuses on aesthetic perfection in a crafted and complete form, a role that designers have been taking on for years. It also focuses on design in practice to create the perfect product (ex. making a beautiful and comfortable chair) (Doucette, 2018). Design thinking focuses on design applied to organizations or strategy (using collaboration and perspectives) (Kleiner Perkins Caufield & Byers, 2016). Due to the industry innovating quicker than product development,

designers have focused on innovating based on user-centric business strategy – requiring empathy (ex. do we even need a chair?) (Doucette, 2018).

Computational design is the result of rapid innovation in technology and designs for billions of individual people in real-time and at scale (Kleiner Perkins Caufield & Byers, 2016). This type of design is: usually applied to computation hardware or software, can sense or augment, connects millions of people, involves data, and is the kind of design practiced in Silicon Valley (High Resolution, 2017 & Doucette, 2018). Computational design is relatively new process in the design space and has a fluid meaning, but many of these definitions have the following aspects in common:

- Parameter settings – tests artificial intelligence (AI) driven designs with set restraints by a human
- Visualization tools – allows designers to create prototypes to test new ideas
- Data – uses data points to facilitate new designs
- Processing power – uses cloud-based and automation power to make designs
- Generative design – creates, tests and analyzes various design iterations

(Doucette, 2018).

Again, this thesis focuses on highlighting an abstract-problem with design research and allowing designers to train AI that shapes software that impacts the world. The future of designers will be less on visual designs and instead will supervise, mentor, set and test the parameters for computational designs (Doucette, 2018). Chapters four and five in this thesis provide details of what is required to set and train distinctive parameters for Regulabel's proposed AI software. Unlike classical design, computational design is also usually never

finished. It relies more on adaptation and perfection along the way (bug fixes and application updates) than a perfect finished product as seen with classical design (High Resolution, 2017).

After highlighting the industry's volatile regulation and historical problems, this thesis uses design research methods to clarify these problems that affect cannabis companies. The research uses design thinking methods along with a computational design proposition to focus on the ability of cannabis companies to efficiently and accurately inform consumers on packaging and labeling about the products they are producing. All while following jurisdictional regulations to avoid violations. Resolving the struggle of cannabis companies in staying compliant with well-researched regulations can push forward the legitimacy of selling cannabis in a federally unregulated market.

The cannabis industry is very unique since it is the first time a federally taboo industry has emerged to some legal status in a time of integrated digital technology. This gives the cannabis industry to tackle problems in a way no other adult-use industry has had the chance to –using the proposed research and design methods can streamline the cannabis industry's lobby towards federal lawfulness. The following section examines the problem of labeling and packaging in the cannabis industry and its volatility through the lens of a communication designer using design research methods.

What is an X-problem?

First off, there are varying levels of problems that designers try to solve (ex. simple, complex, wicked and x-problems). “A wicked problem is a problem whose social complexity means that it has no indeterminable stopping point (Tonkinwise, 2015, pg.11). An X-problem is similar to a wicked problem except it is distinguishable in the following ways:

1. The presence of competition

“Disruptive competition and blurring of industry boundaries as companies leap into each other’s spaces, diversifying beyond their core categories into realms previously reserved for partners or adjacent companies (Richardson, 2010, pg.2)” For example, the blurring of the cannabis industry’s boundaries due to the overlap of regulated (legal) and unregulated (illegal) purchasing behavior in states, varying public perception, and the lack of available consolatory services (since it is a federally illegal industry).

2. Growing customer base that demands superior experiences

“More demanding customers who place a higher premium on the experiential qualities of using a product — ease of use, how it makes them feel, how it fits into their lives, what it communicates to others — that go above and beyond familiar objective criteria like performance and price (Richardson, 2010, pg.2)” This demand for experiences is not only applied for the consumer of cannabis but also the business side of the industry. This is where cannabis companies and manufacturers need software and that is user-friendly for efficient workflows and production especially when ever-changing state regulations make staying in compliance a struggle.

3. Integration of various products into comprehensive systems

The need to create integrated systems of physical products, software, online experiences, and services that work as a single whole. Often these integrated systems are the keys to expansion beyond core areas, as well as to meeting

customer needs in ways impossible from a more isolated offering (Richardson, 2010, pg.2).” Due to federal illegality, there are issues that companies working in the cannabis industry must face such as: varying retail laws between states, varying packaging and labeling regulations between states, and the federal ban on scientific research on cannabis which has led to some unfamiliarity with all of the effects from cannabis on the human body. Companies should integrate with other data systems to share information regarding regulation, packaging materials and suggesting nutrition label information so that efficiency and innovation is not stifled.

4. The practice of design iteration to test methods and ensure validity

(Richardson, 2010). Any prototype for Regulabel that might be produced (with a team of developers after this research) will have to undergo multiple design iterations after creating specific user tests to ensure a successful digital application.

It is these X-problem attributes that align perfectly with the problems that cannabis companies face while trying to label and package their products. Solving this particular problem around cannabis labeling and packaging from the business side was exposed through the communication designer’s initial observation that the cannabis industry needs to elevate its product standards, quality, to match the elevation of the public’s perception of cannabis (which will be detailed later on in this research). This initial observation then led to the question: what might be the most efficient way for cannabis users to be informed about the cannabis they are consuming when traditional product checks and balances aren’t applied

due to the industry's federal illegality, especially when it comes to food safety and nutrition (Caswell, J. & Mojdzuska, E., 1996)? The answer is cannabis product labeling and packaging. This led to the analysis of the information on cannabis product packages and the process the cannabis company completes to reach that particular package.

These designed and packaged forms of information may give cannabis consumers a perception of legitimacy even with the lack of federal oversight. Product labeling should also be seen to go beyond its influence as a direct shopping aid for consumers since it also influences: "product design, advertising, consumer confidence in food quality and consumer education on diet and health (Caswell & Mojdzuska, 1996, pg.52)." It must be noted that consumers don't always necessarily look at product labels and packaging, but studies show that when a product is viewed as hazardous or less familiar, the more likely consumers are to carefully read and adhere to labels (Laughery & Wogalter, 2014, Caswell & Mojdzuska, 1996). This is an advantage for the cannabis industry since its products are newly emerging.

Any proposition that assists cannabis companies in all aspects of labeling and packaging could change any illegitimate perceptions of cannabis into one that is more professional and trust-worthy. This is the type of problem that a communication designer should be solving.

The X-problem Design Research Methodology

Secondly, this thesis research uses the design firm Frog's X-problem methodology to create a clear understanding cannabis labeling and packaging regulations from the business and production side before implanting plans for Regulabel to assist with such problems. Frog has been at the forefront of human experience through design since 1969. Frog was first a design agency that had grown into industrial and mechanical design and now functions

in software territory as well. Corporations such as Apple, Disney, Microsoft and Siemens all have been clients of Frog (Richardson, 2010).

Some may believe that innovation failures come from within an organization, but external factors should also to be considered since these can increase complexity in problems (Richardson, 2010). Especially since the cannabis industry has a social complexity that most industries do not have. This is where Frog's X-problem methodology can "clarify the problem and help focus innovation efforts more productively (Richardson, 2010, pg.3)." The X-problem methodology uses the following methods during research:

- **immersion**
- **divergence**
- **convergence**
- **adaptation**

This methodology creates value in a cannabis' shifting political landscape. Adapting Adam Richardson's quote from his book *Innovation X: Why a Company's Toughest Problems Are Its Biggest Advantage*, the methodology is summarized in the following manner:

- **immersion** develops an understanding of how the cannabis industry is
- **convergence** and **divergence** conceptualize how the cannabis industry could be
- **adaption** looks at what the cannabis industry is becoming (2010).

By using the **immersion** method, a historical review was conducted of cannabis label and package design, cannabis propaganda, and cannabis legislation. The outlawing of cannabis in the early 20th century has resulted in limited artifacts and historical records concerning cannabis labeling and packaging. The Antique Cannabis Book (a free online library for cannabis history and antiques) has gathered pictures of cannabis packaging and labels from small American museums and antique collectors. The historical cultural and legislative aspects of the cannabis industry were derived from a combination of federal documents, publications regarding cannabis history in human culture and politics, and academic reports on the various effects of cannabis on health and culture.

Immersion was also used for the visual analysis of current design trends in cannabis packaging found from various cannabis brand websites and design blogs. This analysis then paved the way for the examination of current packaging and labeling regulations provided by the FDA and legal cannabis states, while comparing the legislative history of similar taboo products (alcohol and tobacco) to predict future cannabis regulation changes better. The primary sources of this information were obtained from articles from The National Center of Biotechnology and Information, Journal of Cannabis Therapeutics, International Journal of Drug Policy, Harm Reduction Journal, government websites and other online news sources.

This thesis research also uses **divergence** for the following theoretical and historical frameworks to influence its development: alcohol prohibition, federal vs. state governing policies, and U.S. tobacco and alcohol product labeling and packaging regulations.

Convergence was used to explore current FDA labeling and packaging policies and current cannabis labeling and packaging trends. Based on this research, the **adaption** method can then combine what the labeling and packaging are currently for the cannabis industry, and

what it potentially could be. Synthesizing all this research then lead to the developmental framework of Regulabel. There is currently no other published study that analyzes cannabis labeling and packaging in a historical and cultural comparative with other adult-use products, nor is there an adaptive design solution for cannabis labeling and packaging that proposes adaptive and user-friendly results for cannabis companies while catering to public health and safety.

This thesis proposes a computational design answer to this X-problem by enabling cannabis companies to design their product packaging and labels with the AI program Regulabel. Regulabel can provide checks and balances in a fluid market, while also providing design services that can assist in elevating the consumer's perception around the brand. Regulabel can help cannabis companies design products while also being considerate of user experience (UX) needs during their label creation process to ensure efficiency and accuracy in every way possible.

As state governments and private companies work together to form seed-to-sale tracking and point-of-sale systems for cannabis (due to the absence of federal support and funding) the X-problem attribute of integration comes into play. This highlights the need of software being able to integrate with different sectors of the cannabis industry for a more effective and efficient employee and product development work flow. The following section specifies the unstable historical and regulatory aspects of the cannabis industry and how it has led to design issues for cannabis companies and their products.

Political Environment Around Cannabis

The social acceptance of cannabis use in the United States has grown in the last few decades. With nearly thirty states approving medical or adult-use of cannabis (Fig. 1) (Procon

Org, 2017), the necessity for states to create regulatory systems and enforcement programs is fundamental for safe cannabis cultivation, manufacturing, distribution and use. The reason that states are responsible for the implementation of such regulatory measures is due to the banishment of cannabis at the federal level.

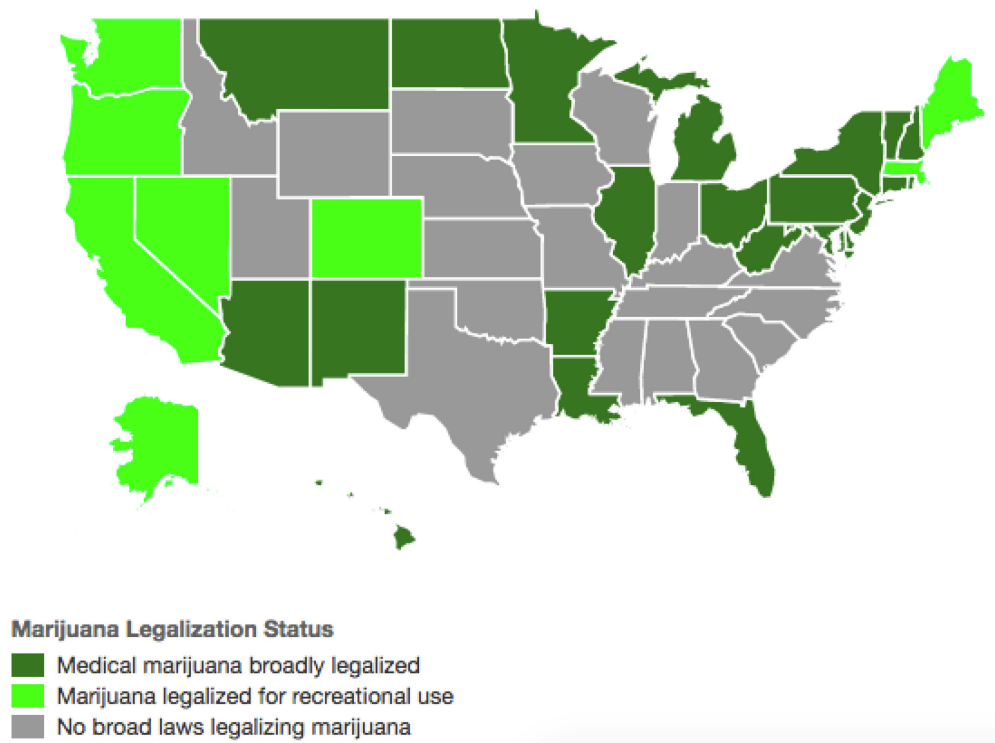


Figure 1. Map of marijuana legalization in U.S. (The Governing of States and Localities, 2018)

The Drug Enforcement Administration (DEA), a federal entity, considers cannabis to be a schedule 1 (out of 5 schedules), which is “anything that has a high potential for abuse, no accepted medical treatment use in the United States, and a lack of accepted safety use under medical supervision” (DEA, 2017, pg. 9). The Food and Drug Administration (FDA), which protects “public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation’s food supply, cosmetics, and products that emit radiation” (FDA, 2017, para. 1), has no authority over

cannabis medicinal or adult-use products due to its DEA drug scheduling. Now, due to absence of federal oversight, individual states that have legalized cannabis for medical or adult-use are now liable for ensuring that cannabis companies (and products) will achieve operating with quality assurance, standards and safe practices.

Compliance in Cannabis Labeling & Packaging

Cannabis companies must adhere to state regulations regarding the packaging and labeling of their products, which have only recently been drafted for recreational use as well as for medical use. Compliance is difficult, however, because states are continuously changing these regulations as policies develop and ongoing scientific research about cannabis is updated. Some of these changes include changes to cannabis warning symbols and product information requirements (Grossman et al., 2016, BAS Research, 2017).

The details between various state's packaging and labeling regulations also differ; as some states only permit medical cannabis, while others also support adult-use. The type of approved cannabis use will dictate how that cannabis product will be marketed within that state. Each state has a different perspective when legalizing cannabis, in which they implement various guidelines to obtain those objectives. Thirty-one states began passing laws regarding medical cannabis, while eight states (Washington, Colorado, California, Alaska, Oregon, Maine, Nevada, and Massachusetts) have pushed further for full, adult-use legalization (ProCon, 2017). The difference in state policy perspective has led to states experimenting with multiple strategies that lead to inconsistent regulations, specifically in labeling and packaging (Grossman et al., 2016). To highlight the variables to consider when designing for cannabis packaging, regulations from the U.S.'s most dominant cannabis states were compiled from this research to create the table on the next page. Fig. 2 demonstrates

cannabis labeling regulation variances between California, medical and adult-use in Colorado and Washington from 2018.

Early legalizing states (Colorado, Washington, and California) have started creating frameworks for regulation on packaging and labeling that a newer legalizing state can model off of (Marijuana Enforcement Division, 2018, Washington State Liquor and Cannabis Board, 2016, Manufactured Cannabis Safety Branch, 2018). However, when comparing state cannabis regulations, each state's enforcement-program capability must be considered. Each state allocates different budget and loan amounts for start-up and the hiring of employees for cannabis enforcement. These programs will have various state allocated funds to craft cannabis policies—which is why some states have more detailed and thought out regulations than others at the moment (Eschker et al., 2017). Even though California, Colorado, and Washington have a more mature industry than others, their regulation models are for adult-use and may not fit well with medicinal-use only states and their objectives.

In the absence of the FDA, states are responsible for accurately labeling the amount of Tetrahydrocannabinol (THC), the psychoactive molecule that is found in cannabis; the amount of Cannabidiol (CBD), the non-psychoactive molecule in cannabis information; dosage; and ingredients on cannabis products for its consumers (Ripley, 2017). A recent scientific discovery in cannabis (and in other plants) is the existence of Terpenes, a hydrocarbon compound that gives strains distinct scents (fruity, piney, and spicy). Currently, terpene labeling is optional for all states. “Growers seek to prioritize terpenes in their strains to enhance the flavor and scent, helping with both the taste and marketing of the product (Fiorillo, 2018, para. 7).” Scientific research, marketing strategies, and cannabis consumers seem to find these terpenes important in distinguishing strains. As scientific research on cannabis itself accelerates, modifications to cannabis products will always be made. Cannabis

packaging and labeling information must keep pace with these modifications to appease its consumers.

VARIANCE IN STATE LABEL & PACKAGING REGULATION

Required Label Statements for Flower/Concentrate	Medical Colorado	Adult-use Colorado	Washington	California
Grower License No.	X	X	X	X
Manufacturer License No.	X	X	X	X
Retail Store License No.	X	X	X	
Patient number	X			
Batch No.	X	X	X	X
Net Contents	X	X	X	X
Potency Statement	X	X	X	X
Highlighted & Bold Potency Statement	X	X		
Universal Symbol	X	X		X
Universal Symbol w/ words	X	X		
Sale date	X	X		
Pesticide statement	X	X	X	
Harvest date			X	
Manufacturer info				X
Manufacture date				X
Solvent list	X	X	X	
Child proof package		X	X	
Ingredients list	X	X		X
No regulatory oversight	X	X		
Medical use only				X
Complies w/ testing	X	X		
Long term risks	X	X	X	
Pregnancy / Breastfeeding warning	X	X	X	X
Driving impairment	X	X	X	X
21 & older			X	X
Smoking is dangerous to health			X	
2hr effects delay				X
Habit forming			X	
Not to be used outside of state			X	

Figure 2. Variance in state label and package regulation; table created using information from state published regulations in 2018. The most detailed cannabis regulations come from “The Colorado Code of Regulations”, which is why both medical and adult-use data is available.

Another aspect of labeling and packaging compliance is ensuring that all information on cannabis products is accurate. In 2015, a study from John Hopkins University analyzed over 47 cannabis brands in the United States and found that 60% of products understated their THC content on labels, while 23% overstated the amount (Thomas, 2016, Vandrey et al. 2015). This inaccuracy causes concern for licensees who may get fined or a violation of inaccurate labeling, and also for consumers. Non-compliance does not only affect cannabis companies, who are wasting their resources on packaging and labeling trying to comply with changing regulations, only to have their products recalled and their businesses fined for violations, it also impacts the cannabis user who is misinformed about the product they are consuming.

Proposition for Regulabel

This thesis analyzes survey data (Appendix A) taken from cannabis manufacturers in a climate of swiftly changing regulation, then synthesizes this data along with immersion research (to be detailed later) to propose Regulabel. Using design thinking and user empathy, Regulabel ensures the correct and most effective packaging and labeling of cannabis products, which leads to a compliant cannabis company in an industry with volatile regulations. Regulabel can certify the accuracy of existing cannabis label content with options to update labeling with required state regulations as they swiftly change, thereby preventing state regulatory infractions for cannabis licensees, and ensuring standards for public health and safety. Creating these package design and data-ridden regulatory parameters for Regulabel is an example of the future of designers setting and testing these parameters for computational designs (Doucette, 2018).

Regulabel also assists in the design development of cannabis packaging by using computational design with state-filtered regulation data, consumer-tailored design recommendations, options based on product-specific point of sale (POS), or retail transaction data. An example of this will be if a particular age group or concentrated location shows specific purchasing patterns of a particular strain (Indica or Sativa) of cannabis. Regulabel can then recommend color palette, typefaces and type size accordingly (e.g., larger text type-size for older users, the state-recommended minimum type size, or state-enforced warning label content).

States also have various types of cannabis markets, which range from unregulated to medical and adult-use. Business entities responsible for labeling and packaging cannabis also vary depending on state laws; regarding carrying multiple types of cannabis licenses (cultivating, manufacturing, retailing, distributing and testing) (Cannabis Control Commission, 2018). Although Regulabel could be useful to medical cultivators and manufacturers, that is not the focus here. Instead, the focus is on why and how the tool would be utilized by adult-use cultivators and manufacturers, who have an opportunity to attract users through commercial packaging. Within the context of this thesis, any organization that participates in the commercial packaging or labeling of cannabis will be referred to as a cannabis company. As more states are legalizing adult-use cannabis, and retail sales for such products are projected to surpass the medical cannabis market almost double by 2020, Regulabel will be hugely beneficial to adult-use cannabis companies (Walsh, 2017).

Graphic Designers in Cannabis Companies

Regulabel can assist start-up cannabis companies who lack the staff or design skills, especially since 49% of cannabis businesses were established after 2015. Although there is promised growth potential for jobs in the cannabis industry, many cannabis companies are small, family-owned organizations (Walsh, 2017). Smaller companies mean that employees have to wear different task hats. Also, employers end up hiring individuals that might not have a visual design background and do not have time to keep up with specific regulation changes. To better understand the cannabis market regarding design tasks, a survey was sent out to cannabis companies in various states (Appendix A).

According to the data from this qualitative research, 80% of cannabis companies reported that they employed less than six people in their organization. With a majority of companies employing only a handful of people, 70% of manufacturers claim they do not have a certified graphic designer on staff. When asked if whoever designs the packaging is responsible for other job duties, 50% of the individuals responding claimed they were both the CEO and the graphic designer. The 33% of manufacturers that do hire a designer for their labeling and packaging, most (87.5%) employ them for contract work only.

An AI tool like Regulabel can benefit diverse users with various skill levels. A traditional design agency hired to produce packaging for a company would not need design assistance or templates provided by Regulabel, but they can benefit from assistance regarding regulation about an industry (cannabis) outside of their own. It is essential for start-up cannabis companies to be diligent about branding and products, especially since retail cannabis chain stores are popping up and are starting to dominate in specific cannabis product lines. The cannabis market is “maturing, and longer running cannabis retailers can gain benefits over their smaller competitors through brand recognition. (Walsh, 2017,

pg.150).” Gathering this data regarding the company employee count, employee-type, and skill levels of the employee designing the packaging is essential in determining the needs of the user of Regulabel, and an example of a communication designer using design research to help determine what the best computational parameter settings might be for Regulabel using the results of this gathered data.

Why Does Regulabel Matter?

It is imperative that cannabis companies follow compliance to have a successful, safe and legal organization. Regulabel is an adaptive digital tool that can assist cannabis companies with such goals. To better understand the regulation volatility cannabis companies experience – they were asked about their habits for compliance and experience with state violations (see Appendix A). Data from this survey shows that many companies are spending up to three hours daily analyzing a state’s regulation changes. Regulabel can be exceptionally useful for those cannabis companies that are (11%) or are planning (44.4%) to operate in numerous states, which multiplies the time needed for regulation research. Evidence also shows that a more significant part of the participants did not employ a certified graphic designer, which legitimizes a proposed interactive style template or guide to assist such cannabis companies in solidifying their brand and product.

When asked about state violations, 10% of surveyed cannabis companies had some violation from the state. This percentage of violations may be due to states still collecting revenue and raising budgets to hire, and properly train employees, and enforce regulations on licenses; and as funding increases, so will the efficiency of such state programs. When asked about package recalls, 22% of manufacturers have lost up to \$10,000 each due to such circumstances. This loss makes up about 3.7% to 4% of an average cannabis company

operating expenses, which can range from \$240,000 to \$270,000 annually (Walsh, 2017). According to the report “Product Recall: Managing the Impact of the New Risk Landscape,” the food and beverage industry has an average recall claim of \$1.5 million, while manufacturing/processing/metal processing had an average recall claim of \$820,000 (AGCS, 2017, pg.8). If we look at the pharmaceutical industry (in which some states cannabis falls under) factors such as mislabeling are the reason behind 51% of recalled items (Snyder, 2016).

In terms of communication design, Regulabel also matters because its development supports the notion of the shift of the designer’s role by allowing the automation and ease of modules assisting the amateur in creating visual designs. However, this particular design amateur is settled in an unstable and federally illegal industry that requires multiple layers and parameters around the development of its AI. This thesis gives insight of what is required from a communication designer to set and train distinctive parameters for a proposed AI software.

Competitive Market Analysis

There are many private cannabis compliance consulting companies such as Adherence Compliance, BioTrackTHC, and MJ Freeway, that run in-person compliance audits and on-site inspections, sell basic training for state compliance, and seed-to-sale tracking software (Kind, 2017). These training services help prepare cannabis companies before state official audits to prevent fines and violations. These in-person training seminars can cost over \$1500 per person or over \$2000 per day if the cannabis company is in a different state than where Adherence Compliance is situated (Adherence Compliance, 2017). Enrolling in a new class every time regulations are updated can be costly to cannabis

companies. Many of these compliance and seed-to-sale tracking programs (except for Adherence Compliance, which has an app in beta, but does not specialize in labeling and packaging) currently do not offer online labeling and packaging compliance checks, nor do they have reactive design features and tools that use product data for easy auto-fill or drag and drop information. In addition to individual cannabis companies integrating Regulabel for their labeling and packaging design needs, it would be possible for the previously listed compliance companies to also integrate Regulabel in order to improve their service.

The predominant market aligned with Regulabel are private (adult-use) cannabis companies who are starting to adopt competitive, for-profit regulations, in which visual design is imperative for brand recognition (Carnevale et al., 2017). If future changes in the policy landscape lead to a single government body regulating the cannabis industry instead of individual states, then Regulabel could be funded and distributed by the Federal government to assist cannabis (and potentially other stigmatized and currently illegal but beneficial medicines such as MDMA, psilocybin mushroom, kratom and ayahuasca) industries with compliance in packaging and labeling of its products. There has also been a push for the public sector to adopt user experience (UX) design principles for more efficient systems (Fox, 2015), and Regulabel can potentially assist government entities to disseminate information seamlessly and efficiently.

Research Limitations

Due to the rapidly growing cannabis industry and the timely manner of this thesis, regulation volatility may be a limiting factor. Much of the cannabis industry and compliance analysis occurred early on in the research, and it is possible that conditions may rapidly change in the regulatory landscape from the start of research to the end. Political taboo also hinders effective cannabis research and survey reporting since many are wary to answer due to possible tracking of identity information from the federal government. This factor limits accurate representation of the perspectives that cannabis companies and cannabis consumers have about the current industry.

The federal restrictions placed on conducting scientific research with cannabis is due to its substance scheduling with the DEA. This DEA drug scheduling obstructs the advancement of cannabis research and does not give a complete scope of the long-term effects of cannabis on the human body. Since scientists cannot “better address key public health questions about the therapeutic and adverse effects of cannabis and cannabinoid use” (National Academies of Sciences, 2017, pg. 382), it then affects the accuracy of cannabis information on packaging and labeling. Although state legalization has resulted in economic growth and cultural acceptance in the past few years, to make any negative or overtly positive assumptions about the effects legalization has on public health and safety would be premature.

Another limitation is data results gathered from the survey conducted for the cannabis companies. There is no way of ensuring that the results collected are from state-approved operations. Illegitimate cannabis companies, which can function in a storefront but are not state registered in medical or recreational states, do not have to pay licensing and registration fees. Avoiding fees can reduce the number of functioning costs and can allow

such companies to deter compliance audits by state officials. This limitation does not give an accurate account of how many cannabis manufacturers are violating label and packaging regulations. With these limitations on the data derived from the cannabis industry, it prohibits the communication designer from knowing how reflective these results are to the actual legal industry. Without accurate results reflective of real-life then it is difficult to solve a state-legal cannabis company's need. However, the flexibility and adaptability of Regulabel can allow for required updates to reflect new scientific findings and survey reports, as state cannabis authority branches mature and have more accurate cannabis industry data. This is due to Regulabel's computational properties – meaning that it relies on adaptation than initial perfection.

This chapter wraps up the explanation of the changing roles of designers from beautifying to design thinking. It also reveals the X-problem methodology implemented in Regulabel's research to help determine the best way to assist cannabis companies in labeling and packaging their product, while completing a competitive analysis. The next chapter dives into the details of immersion aspect of the X-problem methodology by understanding the historical and political context of why the cannabis industry is the way that it is, and how that affects the cannabis industry today and also development of Regulabel.

CHAPTER II. IMMERSION RESEARCH OF CANNABIS HISTORY IN THE U.S.

Even though the federal government currently deems cannabis illegal, cannabis was added to the United States Pharmacopeia library in 1850. The United States Pharmacopeia is an entity that continues to create standards for all medicines. After cannabis was approved a medical substance, it was also then prescribed by doctors in the variety of over-the-counter products (ProCon, 2017). Due to the working conditions and consumer product quality of the time (wearing uncomfortable shoes, walking long distances, eating contaminated food causing skin and stomach irritation), most cannabis products came in the form of lotions, patches or oral medicines (Antique Cannabis Book, 2018).

The history of packaging and labeling of cannabis for over-the-counter purchase and consumption in the U.S. —a history to which this thesis contributes—started a long time ago. However, the labeling and packaging history of cannabis is mainly understudied compared to other substances like tobacco and alcohol due to the prohibition of cannabis in later years. This chapter provides historical and cultural context around cannabis and its packaging and how it translates to distorted perspectives surrounding the industry. All of which are important to a communication designer in determining the current state of the cannabis industry and its impact on the companies that function within it.

History of Medical Cannabis Packaging & Labeling Design

In the late 1800s cannabis was stored and kept dry in glass containers called apothecary jars by local druggists and chemists. Since these jars were made of glass and ceramic, which during those times could be more expensive than the product it was holding, they were usually cleaned and reused by both druggists and patients alike (Fig.3). Ceramic containers

traditionally held cannabis flower, while glass containers held tinctures and liquids. Although much of the cannabis bulk was stored in bins and wooden boxes (Fig.4), products placed



Figure 3. Apothecary cannabis jars (Antique Cannabis Book, 2018).



Figure 4. Apothecary bulk cannabis wood drawers (Antique Cannabis Book, 2018).

out front were usually stored in apothecary jars. These containers would also serve as promotion for the product, so the more attractive the receptacle, the more product they sold. Storefronts would utilize anything from mason jars, formerly containing preserved fruit, to custom, handcrafted glass vessels for storing product.

Due to the lack of cannabis research in the 1800s, there was no understanding of cannabis' multiple strains and the different impacts of each strain. As prescriptions for cannabis medicines were regularly used, patients noticed and complained about inconsistencies with product potency and physical effects (Deangelo, 2017). Some patented cannabis medicines also contained other ingredients, such as cocaine or heroin, which caused illness or addiction for some patients. There were no manufacturing standards for any industry in America during this time, which lead to varying levels of potency in different brand names and resulted in cannabis poisoning (or overdose). Many physicians then began recommending only specific brands of tinctures (which had formula consistency) to their patients to prevent cannabis poisoning, and coffee to combat any overdose symptoms (Antique Cannabis Book, 2018).

Until the early 1900s, many businesses sold falsely advertised health-tonics and inconsistent products, which ranged from cures for baldness to inflammation-reducing snake oil (Gandhi, 2013). It was not until the journalist Samuel Hopkins Adams published a series of articles that exposed many widely used cures as dubious and containing random ingredients. Adams's publications caused uproar from the American public and led to Congress passing the Pure Food and Drug Act of 1906 (TruthinAdvertising, 2018), which forced the listing of active ingredients on labels and packages.

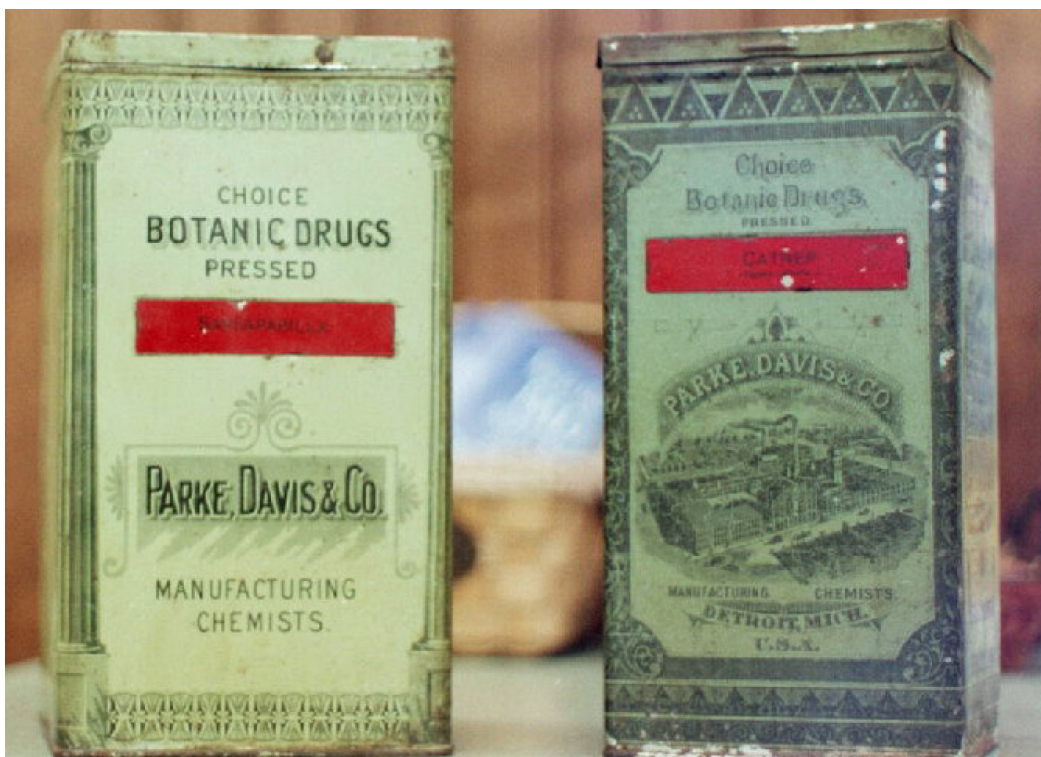


Figure 5. Branded cannabis tin containers (Antique Cannabis Book, 2018).

Specific Medicines.

AMERICAN HEMP.

(CANNABIS SATIVA.)

LLOYD BROTHERS, CINCINNATI, O.

Specific Use: In wakefulness, low mental conditions, and in painful urinary affections.

Dose: R̄. Sp. Med. American Hemp, ʒss to ʒj.
Water, ʒiv.

Misc.

Sig.: A teaspoonful of the dilution every hour. Shake the bottle before giving each dose.

Poisonous in Overdoses.

Indications: Great nervous depression; irritation of the genito-urinary tract; painful micturition, with tenesmus; ardor urinae, scalding, burning, frequent micturition; low mental conditions; wakefulness, with unpleasant dreams during momentary sleep; spasm and painful conditions, with nervous prostration, and in cases of nervous debility, with headache, palpitation of the heart, with sharp stitching pains in the heart; hallucinations; cerebral anaemia from spasm of cerebral vessels.—*Am. Disp.*

POISON.

ANTIDOTE.—Stomach pump or emetic of mustard, zinc sulphate, or apomorphine. Give strong tea and coffee. Keep patient in motion and awake. Liberal doses of sweet spirit of nitre to encourage renal action. Catheterize, and give stimulants, particularly small doses of Specific Medicine Belladonna, or atropine sulphate.

Feller.

Figure 6. Lloyd Brothers specific medicine; was the only documented branded cannabis tincture that was sold in 1938, after the outlawing of cannabis in states (Antique Cannabis Book, 2018).

Brand names were assumed by the public to be greater in quality than local apothecary products (Wilkof, 2016). "The medicine man's key task quickly became not production but sales, the job of persuading ailing citizens to buy his particular brand from among the hundreds offered. Whether unscrupulous or self-deluded, nostrum makers set about this task with cleverness and zeal (Young, 1961, p. 166)." As a result, local druggists at apothecary shops started competing with higher-grossing pharmacies, which could provide these expensive brand name products. This shift of products having a brand identity and marketing materials is one of the reasons there became a decrease of apothecaries over time. These pharmaceutical brands (Fig.5-9) eventually took over apothecary products, which could no longer compete with pharmaceutical branding.

The most recognized of these vintage tinctures is the Parke-Davis cannabis fluid-extract bottle from the mid-1920s (Fig. 8). It embodied the era's advancement in medical product information and consumer safety. The label for the Parke-Davis cannabis extract included product information such as expiration dates (which at the time was unprecedented), the percentage of alcohol, type of cannabis, and a USP symbol (to inform the consumer that it meets U.S. Pharmacopeia standards) (Antique Cannabis Book, 2018). The label also consists of a "poison" warning, which the Federal Government newly requested manufacturers to include due to a fear of child poisonings (Jones & Benrubi, 2013). Studies regarding the stability and strength of cannabis products over time found that cannabis lost its potency when it is exposed to air and light (Thomas & ElSohly, 2016). Due to loss of potency, pharmaceutical manufacturers started using darker colored bottles for light protection and sealed the top with beeswax or corks for an airtight container, which is seen with Parke-Davis bottle.

One must look through the lens of packaging and labeling (as well as advertising), at the design history of cannabis and alcohol before they were prohibited, and find that mostly illustrators, sign painters, and advertising agencies were commissioned to brand, label, and package their products, as well as to create advertisements (Remington & Bodenstein, 2003). A popular over-the-counter cannabis product in the U.S. was the cannabis corn remover (Fig.9 & 10). These pre-packaged corn cures varied considerably in design and packaging; ranging from text-only to colorful illustrations. (Most states have restrictions on cartoon illustrations today). The information on each package and label also varied. Some went into great detail with attached information panel, while some only bared the minimum information required during the Pure Food and Drug Act of 1906 during that time (brand name, list, and percentage of active substances) (Antique Cannabis Book, 2018).

Cannabis plants were used for its hemp and medical benefits in its initial integration to the U.S. consumer culture but were then used as a pawn in government politics and corporate America. Just as the Pure Food and Drug Act was passed and consumer products were being held to a higher standard, cannabis was removed from its legal status and slipped into prohibition. Prohibition led cannabis to be omitted from the regulatory eye of government and private companies. Illegalizing cannabis also halted any further cannabis research, both medically and scientifically. More research is needed on cannabis, especially since the current climate perceives the plant safe for specific medical uses (Burns, 2017).



Figure 7. Branded cannabis tinctures (Antique Cannabis Book, 2018).

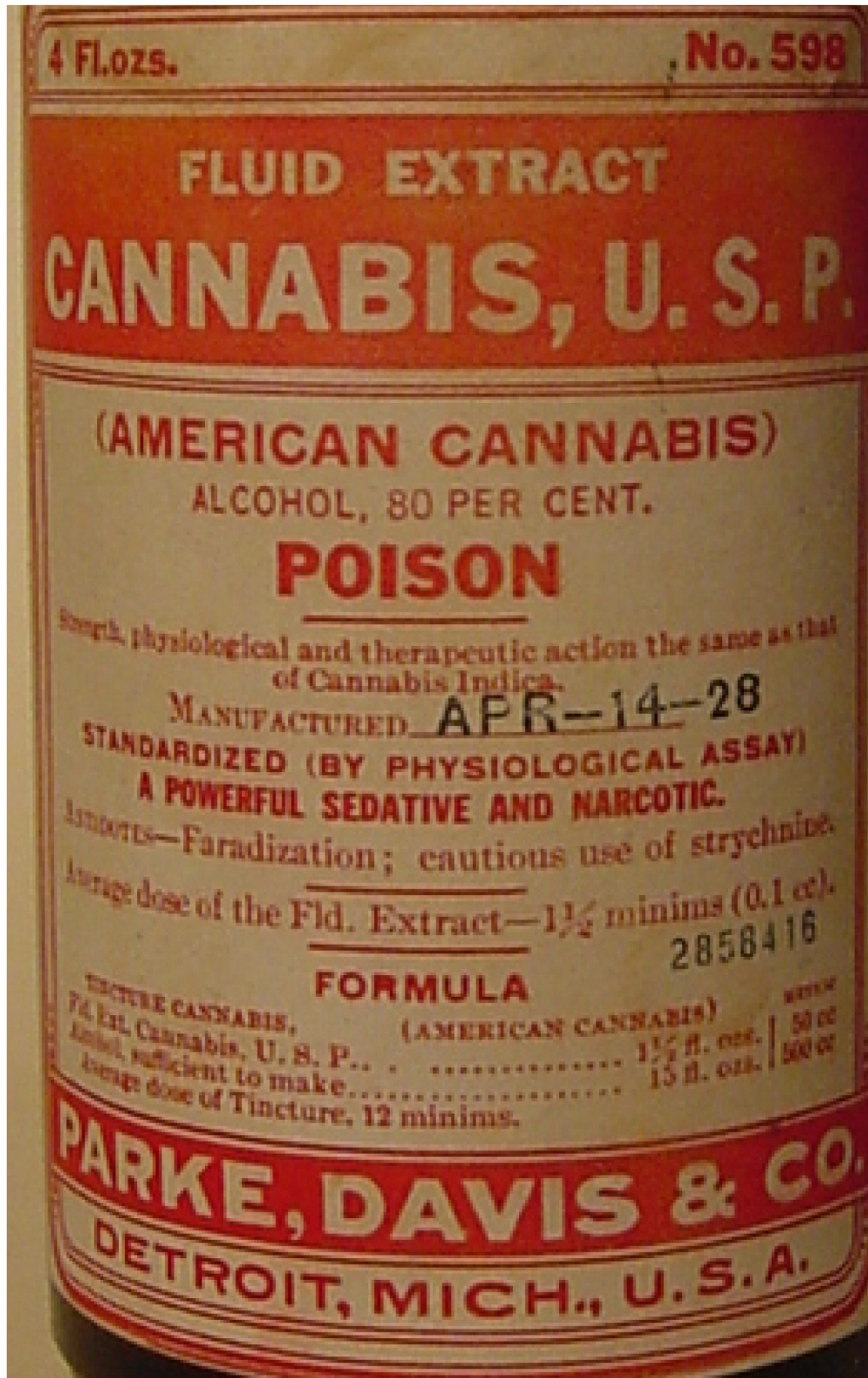


Figure 8. Parke-Davis cannabis fluid-extract bottle (Antique Cannabis Book, 2018).



Figure 9. Examples of cannabis corn relief packaging such as Davies Rose & Co. and Johnson & Johnson (Antique Cannabis Book, 2018).

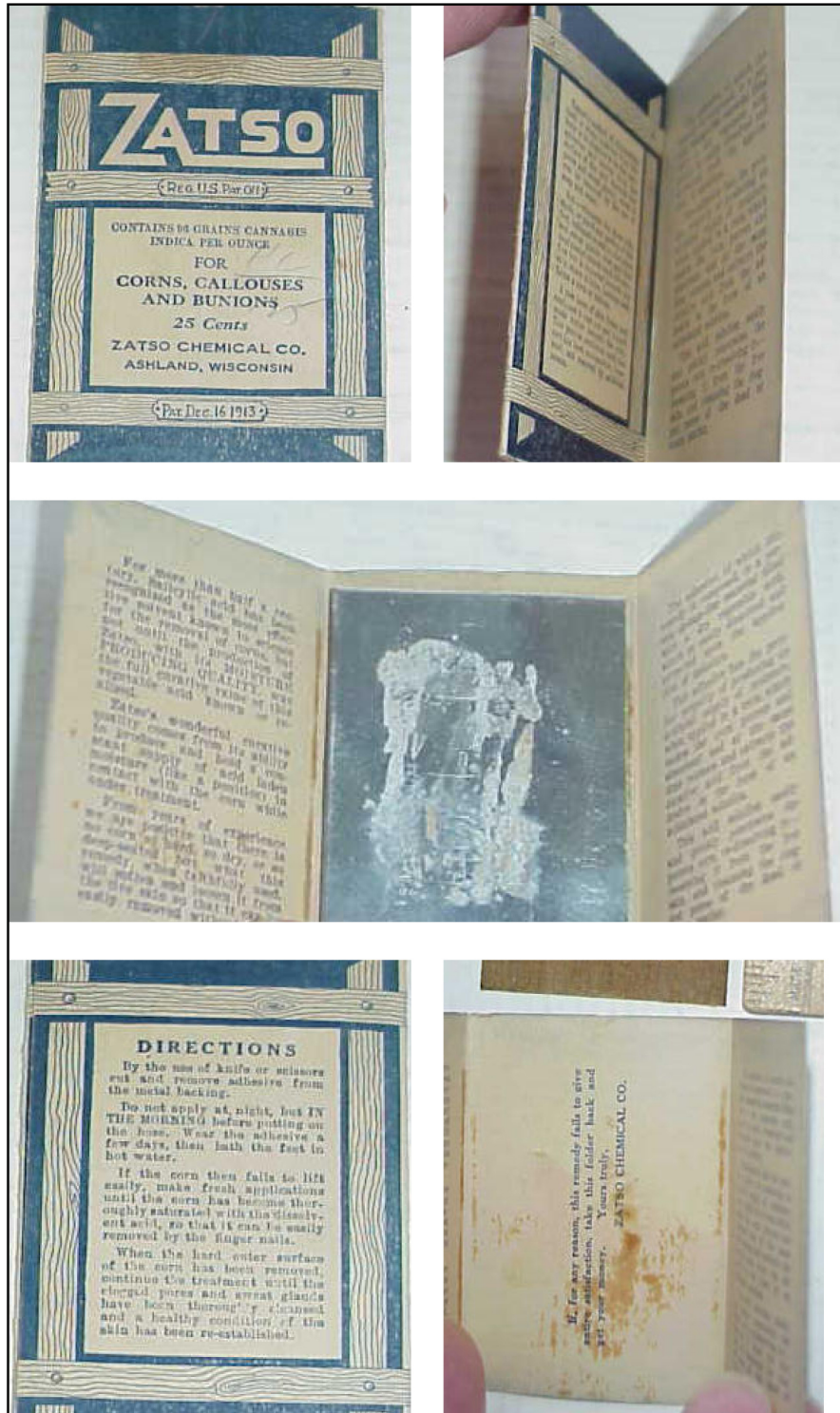


Figure 10. Detailed cannabis corn packaging; from 1913 ZATSO Chemical Ashland Wis Corn Bunion Remover (Antique Cannabis Book, 2018).

The Politics Around Cannabis and Its Impact on Regulation Volatility

It is clear that early use of cannabis was prevalent in American culture and sold in store fronts. Around 1910 was when the American perception around cannabis began to change to a negative one. As refugees escaped the Mexican Revolution to the United States, they brought along cannabis to cure their ailments. Unfortunately, politicians used the term “marijuana” in newspapers to distort American's familiarity with cannabis and to highlight the anti-immigrant sentiments associated with Mexican, Indian, and West Indie refugees (Deangelo, 2017). The prohibition stance has been active in the 100 years since.

The taboo and anti-immigrant narrative associated with cannabis will persist as long as these social issues do, which makes future policy around cannabis a cloudy one. Having unstable policies, guidelines and regulations around cannabis makes compliance a struggle for cannabis companies. It this political volatile characteristic that makes Regulabel a valuable tool. It is important for a communication designer to be aware of the industry's historical and political origin in order to properly empathize with cannabis companies, and to create product value during Regulabel's development.

From 1911 to 1927, eleven states (Massachusetts, Utah, Wyoming, Texas, Iowa, Nevada, Oregon, Washington, Arkansas, Nebraska, and New York) began outlawing cannabis. The slow outlawing of cannabis started happening during the middle of alcohol prohibition. The Department of Prohibition eventually lost the war against alcohol (Procon, 2017), but the War on Cannabis started. The loss of the department led to the creation of a small agency called the Federal Bureau of Narcotics (FBN or now DEA), which in 1930 was run by Harry Anslinger, an old employee of the Department of Prohibition before its shutdown, and who became known as the father of cannabis prohibition (Hari, 2015, Warf, 2016). The primary focal point of the FBN was fighting the opium and heroin trades, but

Anslinger set out to create more revenue for his department by creating propaganda surrounding the drug “marijuana,” or cannabis. Anslinger’s cannabis propaganda targeted low-income people and minorities, which would eventually result in nation-wide social injustice and eventually the federal banning of any research, or use of cannabis (Hari, 2015).

There was research evidence in support of positive uses of cannabis even during Anslinger’s propaganda and claims. Britain’s Indian Hemp Drug Commission Report from 1894 has dismissed any destructive or majorly adverse mental or physical effects on humans. The American Medical Association (AMA) was also bombarding him with evidence of the therapeutic benefits of cannabis. Despite the advice from researchers, Anslinger’s proposal moved forward, and in 1937 Congress enacted the Marijuana Tax Act. This act did not directly outlaw cannabis but put a very high tax on anyone who grew, sold, or bought it, making it virtually impossible to buy or sell. The high price of production led to the elimination of all products containing cannabis from stores and in 1941, and the deletion of cannabis from the United States Pharmacopoeia (U.S. Cong., 2009). Years later in 1967, the United Nations (UN) Single Convention on Narcotics, which aimed to halt cannabis use other than for medical and scientific purposes, hired Harry Anslinger as a U.S. drug policy representative (United Nations, 1961). Anslinger then spread cannabis misinformation to the whole world (Deangelo, 2017), and paved the road for federal prohibitions on cannabis (ProCon, 2017).

In 1970, the passing of the Controlled Substance Act (CSA) listed cannabis as a schedule one substance (Stamberger, 2016), and federally illegal which it remains to this day. In the following year, the National Commission on Marijuana and Drug Abuse, which was an organization appointed by Nixon to research the plant, suggested decriminalizing cannabis possession. Nixon ignored their recommendation (ProCon, 2017). Responding to

the CSA, the non-profit group NORML (National Organization for the Reform of Marijuana Laws) filed a petition in 1972 to the DEA, imploring it to reschedule cannabis as a schedule two substance, so that cannabis could be used for medical purposes. Jack Lawn, the DEA Administrator, then denied the petition and claimed it had no medical use (U.S. Cong., 2009). In the early 1980s, U.S. courts began adopting a zero-tolerance policy in the sentencing of those found guilty of marijuana-related crimes, and political candidates more actively campaigned for harsher laws against cannabis production, distribution, and use (Warf, 2014).

When cannabis non-profits and other advocates, including AIDS patients, relentlessly protested against the DEA scheduling of cannabis; the federal government responded by establishing the National Institute on Drug Abuse (NIDA) in 1974. In 1978, the Investigational New Drug Compassionate Access Program (INDCAP) was established to help patients receive treatment with cannabis through the NIDA. The conditions for considering patients to the INCAP were: chemotherapy-induced nausea, vomiting, glaucoma, spasticity, and weight loss (U.S. Cong., 2009, Werner, 2001).

Despite states green-lighting cannabis plants for medical research in AIDS and cancer populations, the FDA decided to fund the development of a synthetic THC pill (Marinol) to substitute THC from the cannabis plant. State researchers recommended that smoking or vaporization of THC was superior for dosage control compared to gastrointestinal ingestion, which made taking Marinol difficult for cancer and AIDS patients with severe nausea. By 1996, with the lack of adequate THC delivery systems to patients, and the continuing battle over federal drug scheduling, the states had decided to start taking cannabis regulation into their own hands (Werner, 2001, Pacula, Chriqui, Reichmann, & Terry-McElrath, 2002). It is because of this moment that conflict between federal and state

authority over cannabis has impacted the current process of creating compliant labeling and packaging for cannabis a hassle, especially products that are to be sold in multiple states.

It is the inconsistency and lag in political processes that has hindered regulation and scientific research related to cannabis in the 1980s. History has indicated that prohibition does not majorly discourage usage, but instead dictates even higher prices than found in the free market. Prohibition also correlates with increased violence and drug abuse behaviors (Thornton, 1991 & 1998). Prohibition of cannabis led to hidden indoor grow facilities in America, which were light and climate-controlled. To recover these new fixed costs, growers started cultivating plants with higher THC potency to raise prices against competition Mexican and Jamaican cannabis product (Warf, 2016).

The prohibition of cannabis mimics alcohol prohibition since the illegality of alcohol also made high potency use become standard practice. The Iron Law of Prohibition states that “the more intense the law enforcement, the more potent the prohibited substance becomes (Cowan, 1986, pg. 27).” When there is no or inconsistent regulation (as was the case of products in the U.S. before the establishment of the FDA), substances can become more potent, vary in potent consistency, and the mixing of random or hazardous substances is more likely, which does not happen in industries when there is a regulation of standards (Thornton, 1991). Products that follow regulations and are appropriately labeled by trusted and branded companies are likely to be purchased by a customer.

Prohibition of cannabis also led to the federal government trying to control distribution by destroying cannabis crops. In the 1960s, cannabis sold after the spraying of dangerous pesticides by the federal government; often resulted in sickness (Thornton, 1991). Moreover, if underground sellers wanted to test cannabis products for toxicity and potency before distribution, they were unable to do so because laboratories are banned from testing

illegal material (DeAngelo, 2017). Another pitfall of prohibition is that cannabis users cannot publicly review or complain about the quality of cannabis products without implicating themselves partaking in illegal activity (Miron, & Zwiebel, 1995). Cannabis grown in an unregulated market lacks packaging and labeling since there are no proposed regulations by any state authority. Many cannabis consumers do not know what kind or how strong the cannabis is or what strain they have due to lack of proper labeling and packaging.

This interaction (even though it may be illegal) between product and consumer highlights the consumer's uncertainty in the product they are purchasing. If cannabis companies in legal states were packaging their products with the highest standards in regard to proper labeling and quality of packaging, then that could eventually impact buying behavior in the illegal market as well. This is possible by the scenario of cannabis products in legal states being taken across state borders, with some people buying bulk to sell illegally (Wilson, 2019). Cannabis companies whose products consistently have quality product may gain a reputation of being trust-worthy from cannabis users in the U.S. Extracting this information is important to the communication designer in developing product value for Regulabel. This research that highlights potential brand awareness in consumer buying behavior is important to cannabis companies and therefore should be considered in the development of Regulabel.

Cannabis prohibition was intended to improve the health of Americans by removing socially stigmatized substances from the free market; however, the lack of government oversight and regulation has led to questionable growing and manufacturing methods that put user's health at risk. Since studies show that prohibition does not majorly deter illegal consumption of substances (Thornton, 1991), it is time the federal government refocuses its

prohibitionist framework to a regulatory one. Until then, Regulabel can fill in potential gaps and experiences in packaging and labeling regulation volatility for cannabis companies.

Until prohibitionist narratives are gone, the political climate around cannabis will remain murky, creating a regulatory gap within and between states that adversely affects businesses, consumers, state and local economies. An overview of cannabis in U.S. history gives evidence of its tumultuous regulatory territory, and how even over 100 years later prohibition ideologies still hold strong within the federal government. Acknowledging the cloudy future of cannabis policy highlights the need for a digital solution that is adaptable and flexible, especially since individual states are continuing to create and sell their cannabis products regardless of federal prohibition. To revisit the idea of the changing role of the designer (from ornamentation to setting AI parameters), a communication designer will find this history of cannabis regulation to be an essential aspect in the immersion research in the development of Regulabel as stated in chapter one.

Current Public Perception on Cannabis

Public perception and policies regarding products that have a stigma continue to change, even with long-established substance industries such as alcohol (Al-Hamdani, 2014) and tobacco (Goett, 2016). National Surveys indicate that people ages 12 and up consider cannabis use to be less risky to one's health (34% perceived great risk) than that of the tobacco (72% perceived great risk) or alcohol (68% perceived great risk) use (SAMHSA, 2016, pg.3). At this critical moment when public perceptions about cannabis are changing, cannabis companies have an opportunity to impact purchasing behavior and health and public safety positively, while promoting their brand. They can do so through packaging and

labeling that more accurately communicates safe practices, product quality and adapts more efficiently to updates regarding cannabis's risks and benefits.

However, the Trump Administration continues to push prohibitionist ideologies with Attorney General Jeff Sessions ending The Cole Memo. The Cole Memo were federal guidelines that protected cannabis states from federal interference (Waldman, 2018).

Although members of Congress are drafting up a bill to protect a state's rights to grow and sell cannabis (Alden, 2018), political discrepancy and slow judicial processes are the main factors that cloud future progress for the cannabis industry. The swaying governing landscape is one reason why regulation around cannabis labeling and packaging is complicated. Politics around adult-use substances (tobacco and alcohol for example) have historically been slow and tedious, which also end up creating gaps in regulation and efficiency. It is likely that due to such causes, that states will practice various state regulations for decades to come. The future of cannabis regulation is no more apparent to us now than it was a century ago. This makes using a tool like Regulabel valuable to a cannabis company.

The Cole Memo encouraged many investors to partake in the cannabis industry since it claimed that it would not go after individuals that were complying with state cannabis law, which has resulted in an economic boost for the sector (Taylor, 2013). Major corporate companies (e.g. Scott's Miracle Grow) and celebrities (e.g. Willie Nelson, Whoopi Goldberg, Tommy Chong, Snoop Dogg, Wiz Khalifa, Montell Williams, Trailer Park Boys, and Melissa Etheridge) have made investments in cannabis companies and products that have pushed the industry even more towards legitimacy (Kindland, 2017, Walsh, 2017).

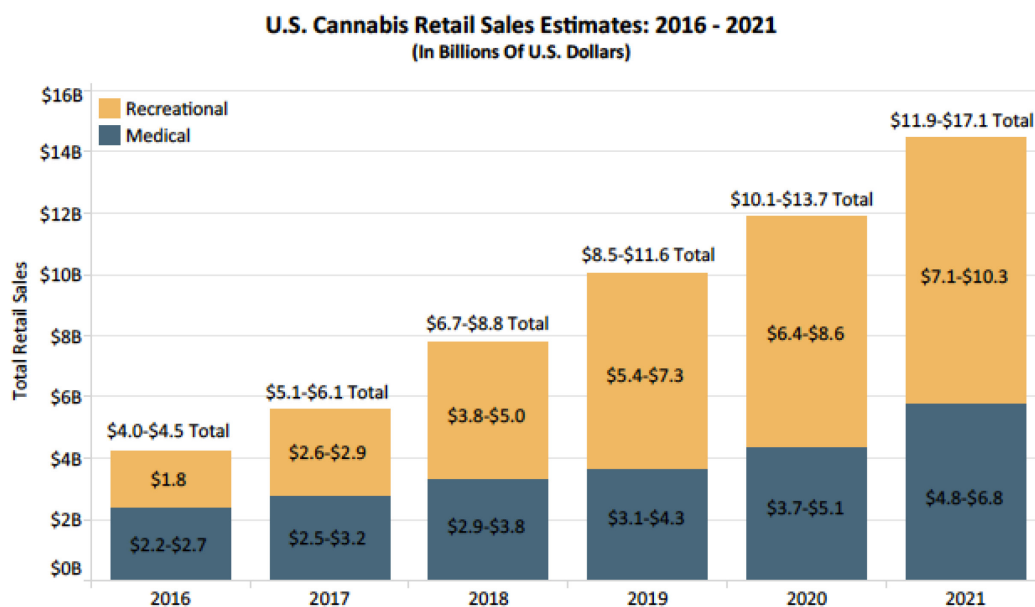


Figure 11: U.S. cannabis industry total economic impact (Walsh, 2017, pg.5).

The cannabis industry is projected to see a growth of up to 8.8 billion in retail sales in 2018 (Fig. 11), since states (California, Florida, Massachusetts, and Nevada) have medical or recreational programs that are now becoming active (Walsh, 2017). Regulabel can guide this booming semi-legal industry to grow faster and into a refined, accurate, and legitimate one. Accurate and design-focused labeling will translate to more informed purchasing behavior on the part of cannabis users. When it comes to informing consumers, there are two informative layers to packaging and labeling. The first is the placement of mandatory labeling information enforced by federal organizations. The second is the placement of material and visuals by the cannabis company. Chapter four provides detailed examples of how labeling and visual design elements influence the intended behavior outcomes of consumers. Information of intended behavior outcomes can be trained into AI by a communication designer. This intelligence can be helpful to the amateur designer who might have knowledge on verbiage or design visual elements that might be best used to portray a

given message about a product or cannabis brand. Having a communication designer set the parameters for Regulabel (with adequate research and user-testing with cannabis companies) would lead to less user error and could ease pains experienced by cannabis companies trying to stay compliant in labeling and packaging. The following chapter investigates the convergence aspect of the X-problem methodology by trying to conceptualize what the cannabis industry could potentially be. This is done by analyzing the regulations and political and cultural atmosphere surround somewhat similar adult-use products: alcohol and tobacco.

CHAPTER III. DIVERGENCE RESEARCH ON REGULATION VOLATILITY IN SIMILAR INDUSTRIES

Like the cannabis industry, the alcohol and tobacco industries have had to adapt to labeling and packaging regulations over time (as scientific research exposed dangers), and at a high cost (lawsuits and product recalls). The cannabis industry has parallels with both the tobacco and alcohol industries. Regulabel can use these parallels in predicting future state regulations for cannabis labeling and packaging; resulting in compliance and the most appropriate method to packaging or labeling cannabis. These predictions can curb lawsuits and product recalls that other industries have endured. An example of product parallels is seen in the administration of THC through smoking cannabis flower, which is similar to smoking tobacco for nicotine. Parallels with the alcohol industry also align with the cannabis industry from a political standpoint. Both alcohol and cannabis have gone through prohibition; both have a history of underground markets, crime, and political disputes over formal regulation. This chapter will converge research from the cannabis industry with studies from tobacco and alcohol industry regulation to predict volatilities and what the trajectory of the cannabis industry could be.

Regulation Volatility in Tobacco Labeling & Packaging

The U.S. cigarette packaging regulations have been under on-going litigation due to FDA releasing laws on graphic images on packaging in reaction to international WHO tobacco guidelines. The tobacco companies fought and won to get U.S. courts to strike down these new FDA guidelines, claiming there was no evidence that graphic images of symptoms deterred smoking (Ingram & Yukhanaov, 2012). The regulations that currently rest on tobacco companies in the U.S. are from the Federal Cigarette Labeling and

Advertising Act of 1966, with larger warning label requirements amended in 2009 (Tobacco labeling Resource Center, 2018). Given that cannabis is similarly stigmatized as tobacco and alcohol, there is the expectation that its industry will face similar demands on packaging and labeling, making the future relevancy of an adaptive visual cannabis labeling and packaging design system a practical one.

The second cannabis-tobacco industry parallel is the use of electronic pen dispensers. The FDA drafted a set of proposed regulations for the tobacco industry on electronic nicotine dispensers. These proposed regulations are not yet final but can be adopted by the cannabis industry. The cannabis industry has products such as vape-pens that mimic the functions of electronic nicotine dispensers (which have an explosion risk, yet there are no regulations for enforced warnings) (Wackowski et al., 2017). The proposed labeling and packaging guidelines for new tobacco products by the FDA include nicotine exposure warning, a statement regarding the addictiveness of nicotine, coil resistance, battery capacity for aerosolizing apparatuses, and child-resistant packaging (U.S. Dept. Human Health and Human Services, 2016).

Regulabel will be able to predict regulation trends and alert cannabis companies to label cannabis vape pens with warning labels regarding an explosion risk, something the FDA has not yet considered for new electric tobacco products. This is an instance where the X-problem methodology can help a communication designer create value for Regulabel by using this information to set AI training parameters. Programming the right parameters is essential to the creation of Regulabel since the goal is to ease workload and keep cannabis companies in compliance.

Regulation Volatility in the Alcohol Labeling & Packaging

The emergence of alcohol prohibition, also referred to as the Temperance Movement, was a reaction to the rise of religious revivalism. The Temperance Movement saw alcohol as a social evil that caused men to be unproductive and violent and led to the passing of the Eighteenth Amendment, which prohibited the consumption and sale of alcohol. After many years of failed enforcement (just like with cannabis), the amendment was repealed in 1933, making it the only amendment ever to be abolished to date.

The absence of a regulatory body over the alcohol industry led to a drawn-out conflict between the FDA and the Bureau of Alcohol, Tobacco, and Firearms (BATF). Under the Food, Drug and Cosmetic Act (FD&C) of 1938, the FDA was allowed to regulate food (and drink) safety and labeling by forbidding the adulteration and misbranding of foods, and also mandated the labeling of ingredients and quantity of food in packaging (Myers, 2002). With its achieved reputation of protecting the health of American citizens, the FDA considered alcohol to be a food item that fell under the FD&C and pushed BATF to include ingredient labeling on alcoholic beverages. The BATF had initially declined to add ingredient labeling to beverages. However, due to the Federal Alcohol Administration Act of 1940, the BATF was forced to work with the FDA in regulatory oversight. The FDA deferred labeling of alcoholic beverages to the BATF as long as they adhered to FDA standards (O'Neal, 2016).

The BATF had initially tried to create an FDA modeled compliance guide for ingredients, but under pressure from the alcohol industry, eventually denied the labeling altogether (Myers, 2002, O'Neal, 2016). The reasons for rejecting the ingredient labels from the BATF were “the cost to the industry and consumer would not be worth the benefit received, the content of alcohol is already heavily regulated, that labeling ingredients have

little value or can be misleading, might hinder trade negotiations, and is only supported by a small percentage of the public (Myers, 2002, para. 37).”

In response to BATF’s denial and the rising studies of Fetal Alcohol Syndrome (FAS), the FDA declared they would enforce ingredient labels and health labels on all alcoholic beverages (Myers, 2002, O’Neal, 2016). The proposal from the FDA caused a backlash from the alcohol industry claiming the FDA had no jurisdiction on enforcing labeling regulations, and in 1976 led to the filing of *Brown-Forman Distillers Corp. v. Mathews*. District Court Judge James F. Gordon, who saw the case, revoked the FDA’s authority on the matter. He “ruled that a conflict existed between the 1935 Federal Alcohol Administration Act and the 1938 Food, Drug, and Cosmetic Act, and although the FDA was responsible for addressing issues of adulteration of alcohol, their jurisdiction stopped short of any form of alcohol beverage labeling (O’Neil, 2016, pg.116).” The BATF administered no ingredient labeling requirements, which led many to believe that the alcohol industry had the BATF in their pockets (O’Neal, 2016).

This instance is an example of an industry that had just become legal and did not have proper labeling and packaging regulations to follow due to politics from within the federal government. Although many cannabis companies do strive to create quality products, there will always be outliers that will try to take advantage of an unregulated market. If states that do not have enough funding or workforce to enforce or train for compliance adequately, then they may recommend new cannabis companies to use Regulabel for labeling and packaging compliance. Without this converging research, it would be difficult for a communication designer to determine what the future of the cannabis industry might look like, and therefore design an adequate AI software.

As the studies supporting FAS grew over time, the National Institute on Alcohol Abuse and Alcoholism (NIAAA) published a warning about the dangers of alcohol consumption among pregnant women. In response, the FDA called for the BATF to consider applying warning labels regarding the NIAAA warning. However, in 1980, in a federal court-forced joint report, the BATF and FDA concluded that there would be no warning labels on alcohol. The report claimed the following: awareness campaigns would work better than warning labels on products, there was no specific scientific evidence claiming what the safe levels of alcohol consumption for pregnant women are and might create a stigma for women around drinking (U.S. Department of the Treasury & HHS, 1980).

Even though both departments previously had decided for no labeling in 1980, the Alcohol Beverage Labeling Act of 1988 was instated and “required five separate warning labels to be rotated regularly on the containers of each brand of alcoholic beverage made by a manufacturer (Myers, 2002, para. 83).” Like tobacco, which also requires label rotation to change consumer behavior, Regulabel can schedule cannabis companies for required label rotation — making the predicting intelligence of Regulabel a valuable one to avoid violations.

The passing of the Alcohol Beverage Labeling Act was due to the alignment of political and social conditions. Cautioning consumers about health risks became normalized as drug and tobacco industries began labeling their products. Cigarette-warning labels were also being studied and compared to the alcohol industry since risks of fetal development was a shared issue (O’Neal, 2016). The alcohol industry also became aware of the legal benefits of labels, since it protected companies from being sued over adverse health effects. So finally, after lengthy regulation battles from 1940 to 1990, the BATF proposed a final rule on

labeling for alcohol; health warning statements must appear on the labels of all containers of alcoholic beverages sold or distributed in the United States (BATF, 2001). In 2017, the Alcohol and Tobacco Tax Bureau (TTB), previously the BATF, became the governing body that regulates alcohol products. The TTB requires that manufacturers provide consumers with the following information on all distilled alcohol: brand name, class and type designation (gin, vodka, or whiskey), alcohol content, name and address of distiller, country of origin, presence of coloring material, treatment with wood, FD&C yellow #5 disclosure, saccharin disclosure, sulfite declaration, commodity statement, statements of age, and health warning statement (TTB, 2018).

The drawn-out and shifting politics around the regulation of alcohol was because of conflicting beliefs on alcohol consumption, and the role of government after alcohol legalization. An examination of how long regulation hearings have previously taken in federal judicial systems, concerning the tobacco and alcohol industry, reveals the possibility of a similar legal landscape if cannabis were ever to become federally legal. If the federal government were to de-schedule cannabis from the DEA's list, then it is possible that the new federal governing body of cannabis may distribute or recommend Regulabel to cannabis companies to help pad labeling and packing regulations through AI predictions until old judicial processes take time to finalize the rules.

States that practice adult-use cannabis laws have also adopted marketing tactics (commercial, competitive and regulated) that are generally used by the alcohol industry (Carnevale et al., 2017). Such a capitalistic industry model creates an opportunity for cannabis companies in the adult-use states to create brands and products that can differentiate themselves from competition and to also attract consumers. This type of

industry model is an example why Regulabel would be most useful to cannabis companies that are involved with adult-use states.

Dissimilarities to be Noted in Divergence Research

Despite its similarity to the alcohol and tobacco industries, the cannabis industry faces unique challenges. Cannabis is not only a substance for adult-use; in many states, there is the legalization of cannabis for medical use (Hwang, & Clarke, 2016; Lukhele, & Motadi, 2016; Cassa et al., 2017), which requires a different approach to packaging and labeling products. This approach is more in keeping with the pharmaceutical or drug industry, which caters to elderly and sensitive populations, where the accuracy of dosage, potency, and research is vital.

The history of pharmaceutical drug regulation is the same as cannabis (at the time cannabis was considered medication) but only until 1910, which is when propaganda against cannabis started to spread and it was removed from shelved products. The establishment of the FDA in 1930 jump-started research, safe practices, and regulations in the drug industry all the way into the late 1960s, and until now. When it came to drug labeling and packaging, the FDA was the first to require “patient package inserts (1970), tamper-resistant packaging (1982), and drugs facts label on over the counter drugs (1999) (FDA, 2006, pg. 3).” It is unfortunate that the cannabis industry is both unwatched by the FDA and missed these advancements in consumable product practices from the 1930s.

Some adult-use cannabis states are modeling labeling and packaging off the alcohol and tobacco industry regulations, but given its similarity to pharmaceuticals, cannabis regulations require considering factors that the other industries do not. In contrast to alcohol and tobacco, cannabis has many forms of consuming other than smoking and drinking

(vaping, dabbing, tinctures, and edibles). Although there are similarities between cannabis and other regulated adult goods, early-legalizing states cannot keep using alcohol or tobacco policies to cover all cannabis regulation because cannabis is a different product in itself (Caulkins et al., 2015).

After converging current cannabis industry research with historical and current regulation research from the tobacco and alcohol industries, a communication designer can make research-based decisions regarding the hierarchy and values of programmable features into Regulabel's AI. The following chapter breaks down the user-centric research methods engaged in this thesis and elaborates what communication designer would need to create value for Regulabel as a product for its intended target market, which is the average cannabis company as stated in chapter one.

CHAPTER IV. USING CONVERGENCE AND ADAPTATION TO CREATE A COMPUTATIONAL FRAMEWORK

This chapter now demonstrates the communication designer's last two phases of problem-solving through design research: convergence and adaptation. Using these methods, the designer can assist design amateurs by creating AI software that automate design functions. These design functions would be trained to the AI by communication designers.

As stated earlier, convergence methods will be used to determine the environment around current FDA regulations. This chapter also illuminates the current labeling and packaging trends that are being used in the cannabis industry. Intriguingly, some of these trends in the industry are considered to be in violation of state cannabis laws. Combing data from the divergence and convergence research, the adaptation method drives the initial steps to create a computational framework known as Regulabel.

Using Volatility to Make Regulabel a Valuable App

This thesis exposes regulations problems within the cannabis labeling and packaging. Those problems are the constant changes in cannabis labeling and packaging regulation (chapter one), which are due to political instability and advancements in cannabis science (which will likely last years to come). Packaging and labeling are essential in terms of communication to the consumer about the product, which is why it is necessary for cannabis companies to be diligent with brand projection. Regulabel can benefit cannabis companies that need assistance with establishing a brand with assistance in creating visually aesthetic materials and providing assets such as typeface suggestions and color combination, grid and layout templates. This can be achieved by using current technological trends to develop a digital program that revolve around AI and integration to various digital platforms.

The reason for developing Regulabel as a software application (app) with AI was because any print medium, such as booklet or guide, would expire very quickly and would not be able to integrate to a company's cannabis seed-to-sale software. This integration is crucial for transfer of specific cannabis information (THC potency, strain name, particular dates). This is largely the reason computational (design) methods are used in the development and training of Regulabel's AI. Regulabel will adopt AI in its system which will have the ability to integrate with other programs for data points that best fit the equation for the labeling or packaging problem, making Regulabel a more effective and efficient way to label and package cannabis for the average (6 people) cannabis company. Creating Regulabel as an app will allow its AI to scan for possible cannabis labeling and packaging infractions while the user is designing and typing in real time. A website that only distributes cannabis information and design suggestions would not be able to analyze keystrokes or visual design elements that could potentially lead to a state violation.

Regulabel as an app alert a user of potential violations while the user is actively designing a cannabis package or label. Regulabel is to cannabis packaging and labeling as Grammarly (AI powered app) is to writing on digital platforms (2019, Grammarly). Regulabel also has integrated features that allow users to select templates to assist with layout and spacing (e.g. columns, gutters, bleeds), while also suggesting color combinations and typefaces for design-forward product branding. This thesis research exposing the regulation problem in the cannabis industry is the initial step to ensuring that Regulabel develops to be a valuable app. By using the X-problem methodology, this thesis immerses into cannabis' past and present, as well as analyzing convergence and divergence research in similar industries to best predict the future of the cannabis industry. This thesis does not solve the

illegality of cannabis but works with cannabis' unstable environment to create the most accurate and well-designed cannabis packaging.

Creating Value for the Regulabel User

The needs of an adult-use cannabis company designer (from now on the user) have been divided into functional needs and experience needs. These needs ensure that Regulabel is a valuable system for its users. Functional needs “are needs around a customer goal and the related capabilities required from the product (Richardson, 2010, pg. 76),” and experience needs, which involve “the ease-of-use and quality of use (Richardson, 2010, pg. 76).” The functional needs users require of Regulabel are compliance verification for state, local and some (cautionary) federal regulations. Regulabel’s AI would process most of these functional needs. To determine the experience needs of Regulabel, elements of computational design would be applied by using generative design to create app design iterations that will be analyzed and tested (Doucette, 2018).

To understand the user’s perspective, a user persona (fig. 12) was developed to portray the behaviors of a Regulabel user. By exercising the user persona and creating a stronger product value in Regulabel’s development, a touch point analysis was conducted. The touch point analysis is divided into two phases: user journey map and touch point matrix (Richardson, 2010). A user journey map illuminates the tasks required of a user (in this case Jon) that designs for cannabis products without Regulabel. Using this journey map (fig. 13), we can observe the user’s required goals, tasks, questions, and barriers. After acknowledging these key opportunities Regulabel can aid those gaps that the user experiences. Opportunities were found by evaluating the user’s cannabis design experience with the following questions:

- Goals-** what are the user’s goals?
- Activities-** what is being done by the user at this phase?
- Questions-** what concerns does the user have during this phase?
- Barriers-** what issues may hold back the user from moving forward?

After the creation of a cannabis company’s journey map, we now focus on the touch-point matrix. The touch-point matrix map illuminates those same user tasks, but with the use of Regulabel and how it aids the user’s initial barriers (e.g. amateur designer and time-consuming tasks) and questions (Fig. 14). Regulabel’s touch-point matrix reevaluates the cannabis company’s journey experience with the use of its AI and involves itself (catching trigger words and missing statements) with the company’s labeling and packaging compliance goals.

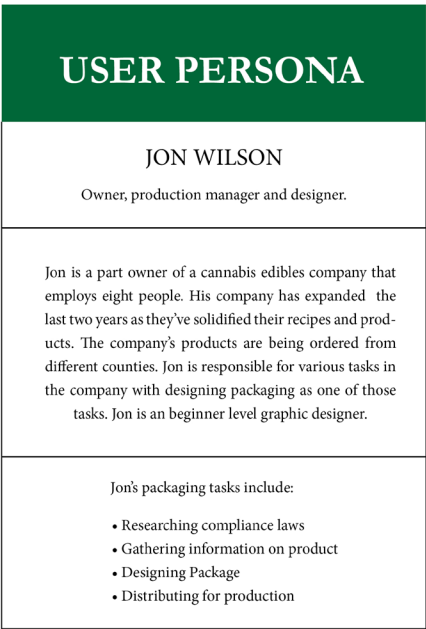


Figure 12. User profile; for Jon, a Regulabel user.

USER JOURNEY MAP		Scenario: Jon is tasked to design a label for a gummy candy. This is his process without Regulabel.		
Below are Steps Jon takes to design a label or package for a cannabis product	JON'S GOALS	JON'S ACTIVITIES	JON'S QUESTIONS	JON'S BARRIERS
RESEARCH	State & county regulation compliance	Navigate through state websites and documents	Is this up to date? When will they release new guidelines?	Using other cannabis brand packaging as reference for regulation
GATHER	Accurate information	Images, copy, product information, and statements	Is this product sold in multiple states? Any new required labeling?	Time consuming, pixelated files and outdated information
DESIGN	Protect & advertise product	Select materials, open design platform, layout content	Content legible? Is design attractive to the right people? Cost effective?	Amateur designer, time consuming tasks
DISTRIBUTE	Send for production	Export & send e-mail	Proper file size & type?	Product violations or recalls

Figure 13. User journey map; for Jon, a user of Regulabel.

TOUCH-POINT MATRIX		Scenario: Jon is tasked to design a label for a gummy candy. This is his process with Regulabel.	
Below are Steps Jon takes to design a label or package for a cannabis product	APPLICATIONS USED	INTERACTIONS WITH REGULABEL	REGULABEL'S MESSAGES
RESEARCH	Regulabel	Provides user with location forms and labeling & packaging related filters for: state, city, product type, and package	What state will this product be sold? What type of cannabis product are you packaging?
GATHER	Regulabel Seed-To-Sale Software	Provides auto-fill seed-to-sale data for potency, strain name, license number, warning statements, and ingredients list	Allow Regulabel access to seed-to-sale software?
DESIGN	Regulabel Adobe Photoshop, Illustrator, CorelDraw	Provides choices for multi-grid layouts, Color palettes based on themes, cloud-based typefaces selected for small information, alerts user of trigger words such as "candy"	Browse typefaces for: title, sub heading, copy and small copy
DISTRIBUTE	Email platform or Cloud	Recommends user with best export options	Export As: PNG or SVG

Figure 14. Regulabel touch-point matrix.

“While touchpoints are about the quality of experience that customers have while engaging with your company, ecosystems are about how a combination of components—hardware, software, services, underlying technologies, even multiple companies—come together to deliver the functionality that a customer actually uses”

(Richardson, 2010, pg.96).

As mentioned in chapter one, X-problems need integrated systems such as software to work efficiently and harmonious as one. What follows is the proposition of an integrated ecosystem which evidences the variety and complexity of Regulabel’s auto-fill data and drag and drop tool.

Regulabel allows the integration of:

- labeling and packaging regulation data
- point-of-sale data into (from seed-to-sale software)
- leading design platforms (ex. Adobe Creative Suite)

The ecosystem for Regulabel (Fig. 15) would include cloud computing, Regulabel’s own AI software, the access to integrate into leading design and seed-to-sale software (BiotrackTHC, MJ Freeway, Adobe Creative Cloud). Regulabel could be considered as a vehicle between cannabis data and a design platform. Since there may be multiple design platforms, Regulabel will have the capacity to interact with more than one design platform or software. Further research would be needed to see which programs would qualify.

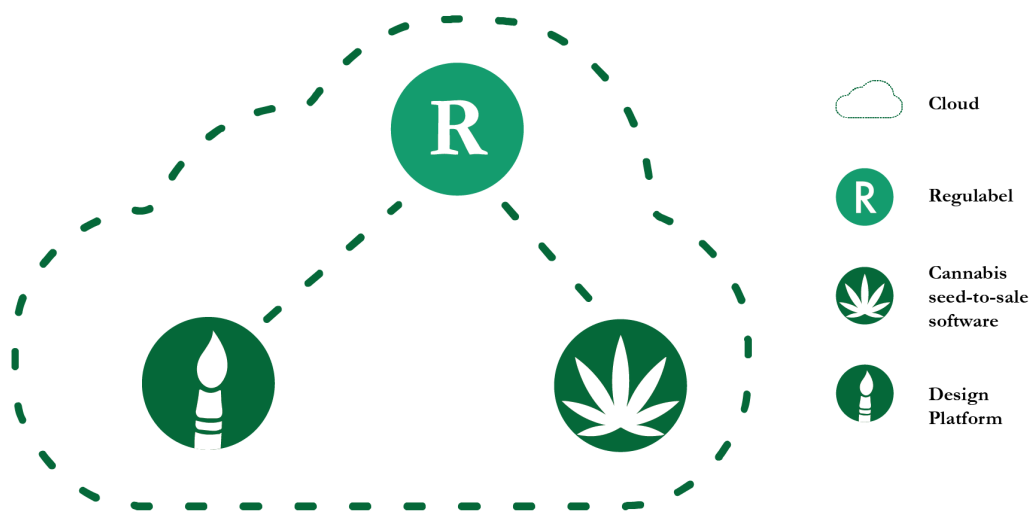


Figure 15. Regulabel integration map.

Regulabel has the capability to be integrated to various software apps, which is a reflection of society’s climb to technological and more efficient ways of completing tasks. Generally, many apps are now available in the smartphones of any amateur, providing assistance or solutions in any niche situation and the outlets (websites and social media) to share those findings. This ability to share information and images instantaneously has created a shift in digital culture from the dissemination of information to content co-creation – dismantling the “hierarchy structure of knowledge creation and dissemination (Addyson-Zhang, 2017, para.11).” Advancement in digital culture has forced the amateur to practice design (choosing of cover photos and page templates) and is pushing this practice to become more widespread. Regulabel is a reflection of the growth of digital tools (and ways of learning) that are currently developed to assist its users by completing tasks more efficiently.

Regulabel creates value for its users with saving time on regulation research and recalls, informing users about regulation and design, allowing companies to focus its energy on creating, and improving and marketing their product. Regulabel will be able to create consistent and accurate information on cannabis products and is essential for safe consumption and awareness. As discussed in chapter one, historical evidence portrays a shift in American consumer culture regarding the branding and proper labeling of medicines to be more trust-worthy than that of apothecaries that had unregulated products.

Ensuring that cannabis companies follow the standards programmed into its AI, Regulabel can potentially assist in consistency, quality and the trust of the cannabis consumer. This in turn elevates the reputation of the cannabis industry (and a cannabis company) to a professional trusted one, rather than one still practicing in the underground market. The following sections inform how data from various outlets have an impact on the parameters that need to be set by communication designers in Regulabel's AI.

Although the following sections go detail aspects of Regulabel's AI, it is important to remember that Regulabel is not the focus of this thesis. This thesis focuses on the changing role of designers, the new tasks that involve discovering problems (volatility in cannabis regulation), and training AI using design research and computational design. Regulabel is a result of that research, but it does in no way mean that it will be the only result.

FDA Regulation Impact on AI Parameters

Regulabel will be designed to keep current with state-specific cannabis regulations, but also with federal regulations that apply to food, beverage, and prescription drugs. Modeling federal labeling regulations (food, prescription drugs, alcohol, tobacco) onto cannabis labeling regulations, as a preventative measure, can protect the cannabis company

from violations. An example of Regulabel adopting regulation frameworks is when medical cannabis is labeled or packaged at an approved state source or dispensary. These medical cannabis products should also model the FDA guidelines for prescription drugs. These labeling requirements include:

- name and place of business of the manufacturer
- directions for use
- no misleading statements
- statement of ingredients
- required warning label statements
- expirations date (FDA, 2015)

Cannabis regulations are not the only ones going through constant changes. Federal provisions around labeling and packaging on legal consumer products (not cannabis) “have become increasingly subject to regulation and litigation because of changing dietary guidelines or health and environmental concerns (Purmehdi et al., 2017, pg. 36).” Cannabis products (specifically edibles and medicine) should adopt these FDA legal medical and consumer labeling guidelines. Regulabel can also keep tabs on changing federal guidelines to ensure users are following the most recent regulations.

There have been efforts by health advocate groups internationally to push for equal public health awareness for all consumer products, and advances in label regulations from the FDA are all efforts to change consumer-buying behavior (California Center for Public Health Advocacy, 2015). The FDA requires companies that produce consumable products to state specific ingredients, which due to advancement in dietary science are always

changing. To ensure that companies are accurate regarding the nutrition facts label, the FDA announced the following changes in 2016 (Fig. 16):

- **Calorie information** is bolder and bigger. In terms of design, this draws the reader's attention to information they might find vital in the hierarchy of information displayed.
- **Serving size/per container:** The serving size font has increased to reflect the actual eating habits of Americans and is larger with bold type and attract the reader's gaze.
- **Calories from fats** has been deleted from previous regulations since science now determines that the "type of fat is more important than the amount of fat consumed (FDA, 2018, para. 2)."
- **Sugar information** must now include a listing of sugars (from syrup, honey, fruit, and vegetables) that are added during the manufacturing of the foods (FDA, 2018).
- **Nutrient information** must now include vitamin D and potassium, due to a drop of these nutrients in American diets, while vitamins A and C have been removed since deficiencies are now rare (FDA, 2018).
- **Footnotes** on the bottom of the nutrition label now include a more accurate definition of percentage of daily value (FDA, 2018).

These various state perspectives on the regulation also reflect the state's intended behavior outcome of its citizens surrounding cannabis. Situations like this can create fluctuating variables (eg. types of warning statements) that can be entered into Regulabel's algorithm.

Information such as warning and product use statements on labels and packages have been developed through research and policy to inform consumers about: potential hazards, safe usages associated with that product, and to also protect businesses from being sued by consumers (Purmehdi et al., 2017). These policies can differ in the way they disperse product information to consumers, especially if we shift the focus from cannabis onto the tobacco and alcohol industry. "U.S. alcohol regulations seek to limit use in specific circumstances (e.g., by youth or by adults at work, in public or while driving) but do not seek to discourage use. In contrast, U.S. tobacco regulations focus on actively reducing the size of the industry (Carnevale et al., 2017, pg. 74)." It is currently unclear whether the future cannabis regulations will seek to limit or discourage use, which is an essential aspect of creating labeling and packaging content and visual design elements.

The textual information on labels and packages are some of the more prominent ways consumers receive product information. State entities can try to affect consumer behavior by forcing companies to state specific statements on their products. The intended behavior outcome splits label content into two different categories: safe use and cessation (Purmehdi et al., 2017, Strathan et al., 2002). Safe use (or positive) warnings are usually associated with recommendations or procedures for consumer protection from immediate harm (e.g., do not drive machinery under the influence), or align with the user's consumption objective. Many alcohol labels follow this format, with messages such as "drink responsibly" or "drink in moderation" (Al-hamdani, 2014, Kersbergen, & Field, 2017). Cessation (negative) warnings, on the other hand, do not have instructions for proper use.

Instead, they discourage consumption by stigmatizing use. The depiction of tobacco is in a cessation manner, (e.g., Smoking can kill you), which promotes dismissive attitudes towards cigarettes (Strahan et al., 2002). States are likely to have various perspectives in the intended behavior outcome of consumers of cannabis product. Regulabel can assist in selecting the best statements by breaking down the message content, and by comparing state cannabis law trends and patterns.

Some states are also now requiring a universal symbol warning on the packages of products that contain THC. However, each of these states has designed their interpretations of a universal symbol, which defeats the purpose of the symbol is "universal" (Fig. 17). Regulabel can also provide the ability to download high-resolution state specific universal symbols while suggesting placement on a layout (based on sizing and suggested spacing between design elements). This feature could be useful since some states also do not specify the placement of a universal symbol. Some states like California opt for the symbol to be placed in the front of the product package (Fig. 18).

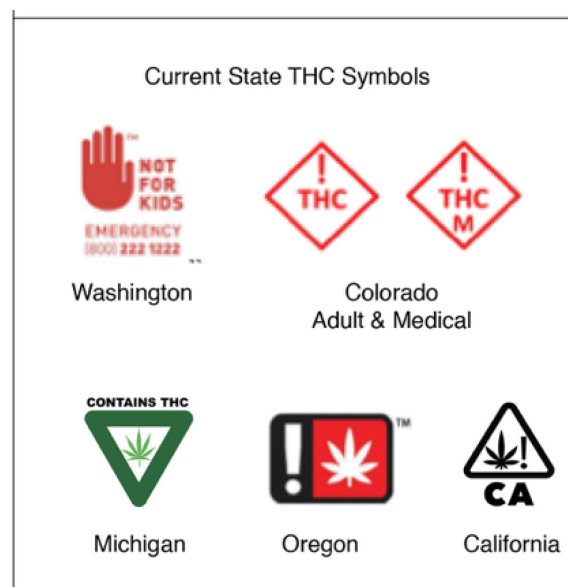


Figure 17. Universal state THC symbols (Grossman et al., 2016, LARA, 2018).



Figure 18. California state universal symbol (Legion of Bloom, 2018).

The difference in policy perspective has led to states trying multiple strategies that lead to inconsistent regulations, specifically in labeling and packaging (Fig.2) (Grossman et al., 2016). Even states that share similar views on the approach to cannabis legalization have regulation discrepancies. For example, Florida (medical state) does not allow the use of “marijuana in a form: of smoking, commercially produced food items other than edibles, or marijuana seeds or flowers, except for flower in a sealed, tamper-proof receptacle for vaping (Norml, 2018, para. 2).”

This regulation is unique since many medical states allow the use of cannabis flower for smoking, and since cannabis flower holds 66% of retail sales for the industry (Walsh, 2017). Regulabel can suggest statements to cannabis companies, with these limitations (Ex. that a statement on flower products claiming – that such flower product cannot be smoked and is for vape use only). This can potentially boost revenue for a cannabis company while following specific state regulations.

Terra Case Study

There are layers of regulations (both federal and cannabis-specific) that cannabis companies must stay current with and adhere to, in order to avoid any possible federal or state involvement or violations. A case study on adult-use Kiva Confections product, Terra, reveals that even though some products have good branding and design, they have overlooked some variables regarding compliance (Fig. 19). First, the provided Terra nutrition label is not compliant with current FDA labeling regulations. Second, the state of California has banned the mixing of cannabis with alcohol or caffeine. Espresso beans have an average of 7g of caffeine per bean, making such product likely to receive a state violation (Caffeine Informer, 2018). Regulabel can use AI to scan for violation trigger words in labels or packages may curb manufacturers from full production, saving them money. Especially in states like California, where “packaging was reported as a top ten cost 25% of the time, and about one in 20% reported that marketing costs were top ten (Eschker, et al., 2017, pg.30).



Figure 19. Terra packaging & nutrition label (Kiva Confections, 2018).

Cannabis Data Impact on AI Parameters

Another critical aspect is the accurate labeling of cannabis information. This information usually includes cannabis potency, solvent list, ingredients list, common product name, cannabis facts, and pesticide statements. As with other labeling and packaging variables, there have been various perspectives on the requisites for cannabis information on packages.

In potency labeling, all cannabis products are advocated by states to have a cannabis facts panel for potency information. "Potency labeling is critical for cannabis consumer safety, just as active ingredient content is for prescriptions and proof is for alcoholic beverages (Grossman et al., 2016, pg. 18)." States regulations vary regarding cannabis facts, with some only requiring THC and others CBD, and states might consider other content optional for potency variance, potency per unit or potency by weight.

There are also disputes regarding whether all cannabis products (flower and concentrates) need an ingredient list or only products with infused cannabis. Regulabel system also keeps track regulations that do not have proper detailing and, therefore, reveals wiggle room in the system should a manufacturer wish to exploit the gap. For example, Regulabel can assist users with Florida's ban on "smoking" cannabis flower by using labeling. Regulabel can suggest labeling such as "flower for vape purposes only." Others might opt to be conservative, complying with regulations in every way to prevent future recalls or violations.

There can also be a variety of marketable strain names such as Girl Scout cookies, fruity pebbles, green crack, animal cookies, and gorilla glue. Restrictions on marketing that are attractive to children and violating trademark infringement are why some state regulators think that strain names should not be mandatory for labeling (Leafly, 2018, Hirsch, 2017).

When it comes to naming cannabis strain, there has been a growing trend of attaching a strain name to cannabis products to help distinguish multiple products for consumers.

However, strain genetics (Indica & Sativa) vary even if they have the same name (e.g., Sour Diesel & Blue Dream) and policing the consistency of such strains is difficult (Chen, 2017). This inconsistency is due to the lack of state, and the FDA monitored cannabis regulation.

Accurate information labeling is especially crucial for medical cannabis, where in the medical industry consistency is essential for safe consumption. Regulabel can verify accurate potency labeling by comparing data inputted in design with data from a company's existing seed-to-sale software by using the production batch number to look up lab tested potency results.

There are some instances in regulation that some cannabis companies find unnecessary such as the required labeling of cannabis products claiming if they have passed or not passed a contaminant test. Although there are many benefits to having contaminant (mold and pesticides) statements for cannabis products, there is some contradiction since regulations do not allow the sale or transition of cannabis product if it has not passed contaminant tests (Marijuana Enforcement Division, 2018). The labeling of a “not passing” contaminant statement on a product is another regulation where there might be disputes in a state perspective, creating another variable that can be used in Regulabel's algorithm.

Cannabis Company & Regulatory I.D. Data Impact on AI Parameters

Other types of information that are usually required on cannabis' packages are: regulatory identification and contact information. Regulabel has the option to be integrated with existing cannabis seed-to-sale programs (BioTrackTHC & MJ Freeway) to gather company contact information (which was difficult to acquire when initially sending out

Regulabel's cannabis company survey). Most states (Washington and Colorado) generally required the following company contact information:

- Cultivator address
- Cultivator phone or email
- Manufacturer address
- Manufacturer phone or email
- Retail store address
- Retail store phone or email

The regulatory identifications are considered to be the various cannabis license numbers for each cannabis product dispensing facility. Depending on the type of cannabis product and state objectives, regulations might require license information contain numbers from all companies that were a participant in the creation of the product (Grossman et al., 2016). With these regulations in mind, it is important to know that cannabis manufacturers can acquire their flower from other cannabis cultivators to make oils and edibles, requiring multiple rows of regulation license numbers. The following lists required cannabis regulatory information on labels or packages:

- Cultivator license number
- Manufacturer license number
- Retail store license number
- Patient number
- Cannabis Batch number

By using integration methods, Regulabel can easily provide users with the required information and numbers from seed-to-sale software. With these adaptable and integrated features that allow the easy copy-paste of detailed information, Regulabel can potentially reduce time in gathering product information for its users.

Package Design Data Impact on AI Parameters

Regulabel will have features that suggest companies with color themes, typeface families, text sizes, image sizing, content spacing, and informative symbols that improve design, readability, and compliance. These design elements are an essential part of visual information on labels and packages. Packaging and labeling are essential for communication to the consumer about a cannabis product, which is why it is necessary for the average cannabis company (where 70% don't have a graphic designer on staff, as stated in chapter one) to be diligent with brand projection.

These design features in Regulabel can assist companies in creating a graphic design that looks professional instead of amateurish – portraying the brand as trust-worthy and communicating product information clearly that is deemed important within a practicing state. The following statements about Regulabel's features are supported by a study surveying 395 people about their general purchasing behavior (Zekiri & Hasani, 2015, pg. 235). Regulabel's design module can be used for warning statement visual recommendations, such as color or typeface size to highlight information or health messages. These highlighted warnings can aid to influence 85% of people that will make visual choices. Safe-use or cessation-use recommendations can influence 73% of people who make language-based choices (Strahan, et al., 2002).

Regulabel's layout and grid module, as well as its color palette module also assist users with the needs of "79% people who agree that packaging color was a purchasing influence and 84% of people who agree that package design was a purchasing influence (Zekiri & Hasani, 2015, pg. 235)." There have also been documented findings regarding the value of innovation and efficiency in package design, and how it increases product value in the eyes of 86% of consumers (Zekiri & Hasani, 2015). These are all factors that cannabis companies need to consider along with government regulations that have an impact on the types of messages companies can promote on their products. Mastering these methods are essential for a start-up to medium-sized cannabis companies, who want assistance with state compliance to avoid violations.

Packaging uses process principles (visual aids) to persuade consumers. The properties of packaging can assist a cannabis company with product protection, an advertising canvas for brands, and identifying or differentiating particular brands. Companies, with financial means, usually consider market research to determine which visual factors attract consumers before designing a package for their product. The market research informs companies about perceptions based on previous knowledge and individual desires. Companies can then use this research to determine "packaging elements, shapes, colors, sizes, and labels might influence consumers to respond positively (Zekiri & Hasani, 2015, pg. 232)."

Regulabel's AI will also allow the exchange of market data information and point-of-sale information from whichever seed-to-sale software it has access to. This feature allows Regulabel's AI to determine if a particular strain is selling in higher units in certain areas or by specific age groups. Most cannabis retail locations require cannabis consumers to provide government identification, and this information is usually saved. Regulabel, using this

informative data, can recommend tailored design elements and packaging templates for its users.

Even though regulation specifics vary by state, there is a general agreement on the necessary information that cannabis products should display. This includes that cannabis product labels must be: in English, in finished form and ready for sale before reaching the distributor, provide inventory tracking information, in readable font, not infringe trademarks, not to be designed in a manner attractive to children, must not contain the word “candy” or “candies”, or be positioned in unobstructed and conspicuous way (Marijuana Enforcement Division, 2018, Washington State Liquor and Cannabis Board, 2016). Below are examples of cannabis packaging and labeling looks like today, and how some are violating state and FDA regulation (Fig. 20 – 25).



Figure 20. DoeBoy logo and labeling; might attract children and violate copyright infringement (Jakhar, 2019).



Figure 21. Lazy Mae's packaging & logo; might attract children (Lazy Mae's, 2018).



Figure 22. Paradise candy packaging; and labeling is a potential violation (Paradise Candy Company, 2018).



Figure 23. Capn' Cosmic's logo; and package is subject to copyright infringement and attractive to children (Analytical 360, 2018).



Figure 24. Eye candy edible co. labeling, and package is subject to copyright infringement and attractive to children (Eye Candy Edibles Co., 2018).



Figure 25. Pre-rolled shine papers, gold cone and hand-woven gold can be considered to be attractive to children (Shinepapers, 2018).

Although all states recommend that labeling and packaging should not appeal to minors, they do not specify the criteria for determining if a given package is appealing to children or what constitutes a cartoon (Grossman et al., 2016). With regard to policies about products that are appealing to children, the alcohol industry has some states (Alabama) that entirely prohibit any sales of alcohol-adulterated candy. While other states (AZ, CO, FL, HI, KY, LA, MD, MN, NE, NH, NJ, NY, TX, & VA) have age restrictions of 21, leaving the rest of the states to have no age restrictions on alcoholic candy (National Confectioners Association, 2007). These age-restriction regulations may be a shared when the same states apply them to cannabis products (THC or CBD) in the future. Regulabel can inform cannabis companies on new regulations on experimental cannabis products such as: candy, chocolate, cereal, and fruit drinks.

Current Packaging Trend Impact on AI Parameters

Cannabis companies in adult-use states are also pushing for innovation when it comes to package design. Some companies have started to use nitrogen sealed processes for their packaging. "This process of oxidation works as an accelerator for toxic growths like mold, yeast, and other harmful bacteria that could prove dangerous if smoked alongside the marijuana they inhabit (London, 2017, para. 3)." This sealing process is usually a part of the food packaging industry but is also beneficial for the cannabis industry. It allows cannabis dispensaries or consumers to store for more extended periods without losing potency and moisture. Although the cost of producing nitrogen sealed cannabis is much too expensive for most cannabis companies, it is a different approach to packaging other than glass and plastic containers. Regulabel can provide estimates using cannabis product units provided by the seed-to-sale software and parameters trained by a designer into its AI.

Another increasing cannabis packaging trend is the metal tin can method of packing (Fig. 26). This method of packaging also allows for extended storage of cannabis, by protecting the product from light and air until opened. Even though this might be a cost-effective way to store product, it might frustrate some consumers who like to smell or see the cannabis they are purchasing (London, 2017). Regulabel can predict product responsibility by analyzing a cost-benefit relative to the market and regulations within their particular state.



Figure 26. Cannabis in a tin can package (London, 2017).

A company called Lowell Smokes has created cannabis packaging that is stylish, functional, and recyclable. Growing cannabis can use up resources like electricity and water; some cannabis companies are lowering their carbon footprint by pushing "green" packaging (reusable, recyclable, or degradable materials). Lowell Smokes also creates cannabis flower bouquets, a product packaging method that is unique to the cannabis industries (London, 2017). However, such packaging might be subject to violations due to no childproof container, no labeling or potency information. Regulabel could have assisted such company in alerting them of such violations. Regardless, it is still innovation and quality that push industries discover methods to better their product or brand to jump-start competition (Fig. 27 & 28).



Figure 27. Lowell Smokes green packaging (Lowell Smokes, 2018).



Figure 28. Lowell Smokes green flower bouquets (Lowell Smokes, 2018).

Programming Regulabel to have information and intelligent suggestions regarding various types of packaging will benefit users. Some users may need assistance in creating packaging to help that to stand out and protect their product. Others may find estimated cost benefits more appealing. These AI training parameters are ways that a communication designer can ensure market relevancy due to the shift from classical design to computational design as mentioned in chapter one.

CHAPTER. V: CONCLUSION

The US Bureau of Labor and Statistics estimates that there will be a “0-1% growth in traditional graphic design positions between 2014 and 2024, well below the anticipated 7% growth in the all sectors of employment (AIGA, 2017, para. 4).” This thesis supports the designers shift from the traditional design tasks to skills that revolve around identifying problems in the world and training AI parameters. This thesis is an example of a communication designer’s skill to recognize, frame and solve problems, and in turn, use that information to create new tools, interfaces, and interactions that can shape the world (or cannabis industry). The problem that this thesis solves is a complex problem (with social and political elements that create fluctuating constraints) that is found within the in the cannabis industry.

The problem in this case was the volatility in cannabis labeling and packaging. The design research conducted around this problem was synthesized to create a computational application framework. The research around the framework for Regulabel contributes to the design discipline as an example that encompasses design thinking (X-problem solving by synthesis) and computational design in its AI framework development. The framework for Regulabel provides one possible computational solution to the cannabis industry’s regulation volatility through an AI app. By using computational design, Regulabel can potentially aid in efficiency and accuracy in the rapidly changing cannabis industry.

As mentioned in chapter one, this thesis is following the shift in a designer’s role by allowing the automation and flexibility of a design interface to be used by anyone regardless of their design education. The multi-layers in regulation from both federal and state has ensured a list of variables to consider when creating a package for a cannabis product. These variables make compliance for cannabis companies difficult regarding packaging and

labeling. Also, the constant updating within these multi-layered regulations is tedious for some companies to practice efficiently. The framework for Regulabel uses AI technology and the integration of multiple platforms to curate information and bridge gaps in digital experiences. Regulabel also takes into account, in terms of digital experiences, that people want to take an active role in content creation. Regulabel allows users to design with suggestions based on changing data, allowing users to make the most educated decisions regarding packing and labeling.

The research to create value for Regulabel distinguishes the labeling and packaging needs of an average cannabis company, while synthesizing historical data to construct an adaptable digital tool. “It seems that AI-in-design research can be aimed either at design supporting (through interactive systems that aid the designer’s creativity) or at emulating design (through developing computational machines that design) (Cross, 2006, pg. 40).” Regulabel allows for design support by providing modules that can provide intelligent design suggestions and accurate content.

Since data (appendix) shows that many cannabis companies are spending up to 3 hours daily analyzing regulation changes, Regulabel can save them time every day, making business more efficient. Evidence also shows that a more substantial part of the participants did not employ a certified graphic designer, which legitimizes a proposed style template or guide to assist such manufacturers in solidifying their brand. Through its AI, Regulabel can create efficiency by the cutting-down of time that is used by companies while conducting regulation research and limiting design iterations when submitting package design to a state authority for approval before market distribution. It can also boost the public perception of legitimacy by ensuring safe products and packaging design options.

Using Adaptation in Future Prototypes

As mentioned earlier, the adaption part of the X-problem methodology focuses on what the cannabis industry is becoming. The prototype for Regulabel would be an example using adaption with computational design to keep up with what the cannabis industry is becoming in terms of labeling and packaging. While creating the prototype, it is important to remember that one of the quintessential aspects of computational design is the act of generative design – creating, testing and analyzing various design iterations. This thesis sets up the framework for Regulabel, but the next step would be to create a functioning computational prototype to better determine the experience needs of the user and test the digital capabilities of Regulabel. These steps will also involve marketing its computational framework to gather funding from outside sources to facilitate a team in furthering the proper development of Regulabel.

The type of AI in Regulabel's system will be “purely reactive and have the ability neither to form memories nor to use past experiences to inform current decisions (Hintze, 2016, para.6).” Regulabel's AI architecture for regulations and design variable analysis would be composed of an artificial neural network (ANN). The information processing of ANN's is modeled after the animal cerebral cortex, which must be taught different patterns. “The processing ability of the network is stored in the inter-unit connection strengths, or weights, obtained by a process of adaptation to, or learning from, a set of training patterns (Gurney, 2004, pg.13).”

After these nodes are organized and layered, learning patterns are inputted into the system through the designated input layer, while all the processing happens in the hidden layers in and among the weighted nodes. After processing the hidden layers can then provide with a range of customizable options for each independent packaging or labeling solution

(University of Wisconsin, N.D.). Each ANN undergoes supervised learning with different types of modules, in which nodes are activated by error and comparison analysis to create various outputs (Fig. 29). In the spirit of computational design, this neural framework would need to go through many iterations with a team of developers, engineers and designers to ensure proper functionality.

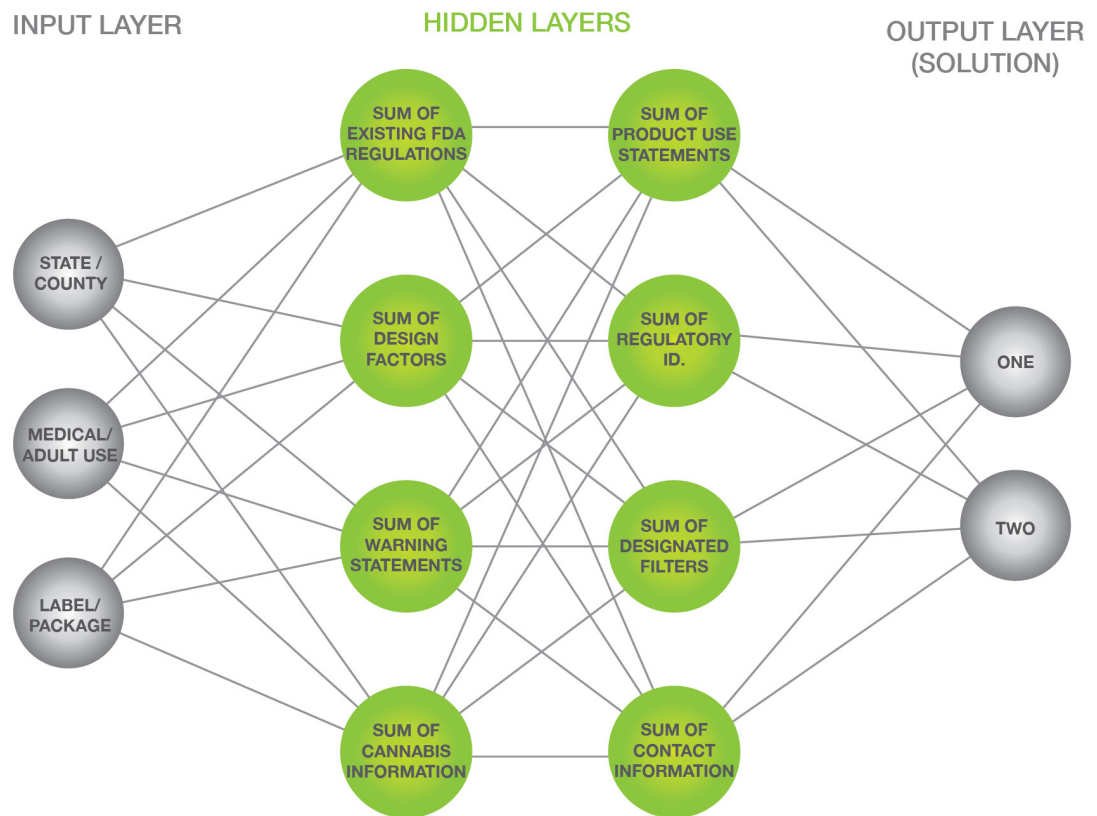


Figure 29. Diagram of Regulabel's proposed ANN

This team will then be able to help in the future development of a working prototype for Regulabel, in which supervised learning can sharpen its product information, wording of proposed warning statements and labeling and packaging regulations. It will take many iterations to have a proper functioning application on Regulabel's back end. This will involve user-testing after each iteration to ensure proper design and user workflow. It will also take time for designers to create a brand guide alongside the look and feel for the front-end of Regulabel. Designers must keep the experience simple and intuitive for optimum user-friendliness. Further research in AI integration with third-party applications would also be one of the steps to define which of the leading seed-to-sale software companies would find value in Regulabel and accept the exchange of information through application integration.

Since the cannabis industry is newly emerging, this is the perfect opportunity for a cannabis company to establish their place in the market. Using Regulabel can lead to the rise of cannabis products with accurate labeling and design-forward brands, creating competition for superior products and eventually leading to an industry seen by the public as regulated and trustworthy. Most importantly in the context to this these, the research around Regulabel also illuminates the tasks that will be required from communication designers in the future.

APPENDIX SECTION

To better understand the landscape of labeling and packaging for cannabis manufacturers, an online survey was distributed cannabis manufacturers in the U.S. The data for the polls was collected March 2017 to April 2017, and all participation was entirely voluntary, anonymous, and there was no monetary incentive to participate in the survey. The majority of cannabis manufacturers were found through online cannabis business directories (medicaljane.com and edibleslist.com), which combined had over 340 related cannabis companies listed. However, while browsing through these directories, over 160 of these registered cannabis manufacturers either did not have proper contact information, a functioning website, or Facebook company page (several companies only have social media pages for contact).

It is not clear whether these cannabis manufacturers were shut down due to federal or state enforcement, or by the business suffering profit-loss. Although other market studies do show that, in the cannabis industry, large portions of manufactures are profitable or break-even (85% of flower cultivators and 79% infused product producers) (Walsh, 2017). 138 cannabis manufacturers had email information or Facebook account available and were eligible to participate in the survey. Out of the 138 only ten submitted responses to the study. It is possible that the result of low survey yields is due to the Federal disapproval of cannabis, and precautionary measures taken by companies by responding to unfamiliar emails or messages. Perhaps in the future, a more direct and in-person approach would retain better survey yields. It is also difficult to establish whether any of the cannabis manufacturers listed on such online directories are operating in an unregulated market. Meaning these businesses operate without state-appointed licenses or their states do not have proper regulations set up yet (ex. in early 2017, California, Michigan and Montana)

(Walsh, 2017, pg.172). These factors may distort the output of answers from survey respondents since it does not reflect the business practices of a legal functioning cannabis manufacturer.

According to data, 80% of cannabis manufacturers employed less than six people in their organization. With a majority of companies employing only a handful of people, 70% of manufacturers claim they do not have a certified graphic designer on staff. When asked if whoever designs the labels and packages is responsible for other job duties, 50% of the respondents claimed they were the CEO as well as the graphic designer. The 33% of manufacturers that did hire a designer for their labeling and packaging, most (87.5%) employed them for contract work only. When asked about what design programs they use manufacturers replied with Adobe suite (44.4%), seed to sale software (11.1%), Microsoft Word (20.4%), and the rest (20%) had no answer. Half of the manufacturers were satisfied with their current design programs, while the other half was pleased. Also, since most states require companies to have a seed-to-sale software program, all were asked about the design capabilities of such an application. Many (60%) said that their software had no label or package design functions.

Cannabis manufacturers were also asked about their habits for compliance, with a numerous (70%) checking daily for all regulation updates, while some (20%) only did so biannually. Manufacturers (60%) also claimed that it took them anywhere from 1 to 3 hours to research any regulation updates, with a majority (90%) retaining this information from state websites. When asked about state violations only 10% had any violation from the state. Lack of violations may be due to states still collecting revenue and raising budgets to hire correctly, train employees, and enforce regulations on licensees. Regarding package or label recalls, 22% of manufacturers have lost under \$10,000 due to such circumstances.

Participants (44.4%) also claim they are planning on selling their brand in other states, while a few (11%) already are. Manufacturers were asked how vital product labeling and packaging was to them, with 70% claiming 10/10 importance for labeling and 80% claiming 10/10 importance for packaging. Manufacturers were also asked if they would be interested in a digital tool that ensures they were compliant in labeling and packaging while using their preferred design platform and many (77.8%) answered yes.

Although data regarding companies receiving violations for not following regulations will change as organizations and governmental systems become established, there are still various benefits for cannabis manufacturers to having a digital tool that assists them in labeling and packaging compliance and design. Since data shows that many manufacturers are spending up to three hours daily analyzing regulation changes, a digital tool can save them time every day, making business more efficient. Evidence also shows that a more substantial part of the participants did not employ a certified graphic designer, which legitimizes a proposed style template or guide to assist such manufacturers in solidifying their brand.

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