Lenient Ingredients: Why America Needs Stricter Legislation for Products

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On my honor as a University student, I have neither given nor received unauthorized aid on this assignment as defined by the Honor Guidelines for Thesis-Related Assignments.

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Introduction

Citizens' Wellbeing

The United States has a pressing need for strict regulation and comprehensive information about products and their health respectively as citizens suffer from companies' exploitation of flaws in food, cosmetics, and drug legislation. American citizens best highlight this problem: 50.9% of American adults have at least one chronic health condition ranging from lower respiratory diseases to high cholesterol (Bauer et al. 2014). Some important health issues, although preventable, are widespread such as obesity which affects approximately one-third of the U.S population, both adults and children, which is regularly followed by other potential chronic diseases (i.e hypertension, heart disease, colon cancer) (Smith et al. 2016). With these overwhelming widespread diseases, these statistics highlight not simply the lack of individual responsibility but the need for American legislators to pay closer attention to consumers' health in order to prevent this major public health crisis.

Flaws in Product Approval Process

Although extensive, many flaws exist within the product approval process. Flaws in the process are required to be taken seriously as products that humans utilize for consumption and skin-contact are present in our daily lives and can permanently affect us. Current legislation contains flawed and biased processes that allow companies to continue to place misinformation on product labels while adding potential hazardous and addictive substances into their products. With this negative activity, it is imperative that the United States deeply scrutinize food, cosmetics, and drug legislation to prevent further harm on citizens. Therefore, we must question, what organizations are responsible for this product oversight, why exactly is the process flawed,

and what efforts are underway to solving this pressing issue? These problems cannot be ignored as the effects of these substances can cause lasting changes. In the long-term, Americans' lives will be at stake as seen from the past where deaths and deformities resulted from oversight.

Background

History of Legislation

The history of food, cosmetic, and product legislation in the United States is the story of the struggle to guarantee consumers access to safe and healthy products. Ever since goods for consumption, cosmetics, and medicinal purposes have been used in commerce, the potential for sellers to cut corners by adulterating, substituting, or diluting expensive ingredients with the potential side-effect of harm was always present (Motarjemi et. al, n.d). Before major legislation, companies could seamlessly lead lobbying efforts, legal challenges, and resistance to inspections and testing of food, drug, and cosmetic products, thereby introducing faulty and potentially dangerous products to the market (Borchers et. al 2007). Therefore, legislation and legislative bodies were created in response to growing concerns over these problems, particularly companies creating products that contained harmful additives or preservatives that lead to harm and even death. Particularly, the publication of the book “The Jungle”, by Upton Sinclair in 1906 revealed to Americans the brutal, unsanitary, and inhumane practices of meat processing (Borchers et. al 2007). This coincided with the first significant piece of food legislation, the Pure Food and Drug Act of 1906 which led to the creation of the Food and Drugs Administration, enforcing manufacturers to accurately label products and discontinue malpractices of the time (Borchers et. al 2007) . The culmination of all the milestone events demonstrated the long tumultuous battle between consumers and companies.

After the Pure Food and Drug Act, another notable incident occurred where the tragic deaths of 107 people, mostly children, occurred from the consumption of a toxic ingredient in a customized version of Sulfanilamide, a medication consumed for the purpose of treating a variety of infectious bacterial agents (Borchers et. al 2007). This led to the creation of the Federal Food, Drug, and Cosmetic Act of 1938 which established more stringent systems for evaluating and testing the safety of new products before being sold to the public (Borchers et. al 2007). Major legislation such as the Pure Food and Drug Act, the Federal Food, Drug, and Cosmetic Act, and many other new laws, amendments, and legislative bodies helped create the foundation for consumer protection in regards to food, drugs, and cosmetic products.

Beyond legislation, other federal agencies were created such as the U.S Department of Health and Human Services (HSS) and the U.S Department of Agriculture (USDA) in order to provide informative resources such as food pyramids and food labels to ensure consumers could educate themselves and make better decisions (Jahns et. al 2018). Certain foods were also fortified with different vitamins and minerals to ensure consumers could have adequate intake to prevent diseases from deficiencies (Black et. al 2003). However, these actions do not make the United States immune to future mistakes as demonstrated by many high profile cases such as the thalidomide crisis which caused the birth of thousands of deformed infants in 1962 (Janssen, 1981). Many biases also still exist surrounding legislation, notably with large multinational corporations and legislative bodies mingling their interests together.

Multinational corporations

Multinational corporations play a role in affecting the legislation in many ways. Although food processing has become a global industry, creating supply chain efficiencies around the

globe, it has given power to only a few companies, thus creating the potential for power abuse. For instance, 30 companies account for a 3rd of the world's processed food, five control 75% of the international grain trade, two control half the sales of bananas, and three trade 85% of the world's tea (Fellows, 2009). Beyond the food industry, these trends also occur in the manufacturing of pharmaceutical drugs and cosmetics, demonstrating the homogeneity and extensiveness of these trends

Because of their large size and power, corporations can fund expensive lobbying campaigns that may hide under the guise of promoting public health but actually serve their own corporate interests. Large multinational corporations can and will change public health measures from dietary guidelines to food safety regulations causing public outcry such as in 1991 where the USDA was criticized for being pressured by meat and dairy lobbying groups to halt a food recommendation guide (Nestle, 1993). These power struggles highlight the alarming level of corruption and influence that the food industry holds over public health policies and regulatory bodies, which can ultimately harm the interests of the general public. The fact that even the USDA, a federal agency responsible for promoting and protecting public health, can be influenced by the lobbying efforts of large corporations, speaks volumes about the need for greater transparency and accountability in the food industry.

Research Methods

Literature Review

Literature review was utilized extensively in order to understand the problems surrounding food, drug, and cosmetic legislation. First, papers that provided general overviews on these problems (i.e the history, actors at play, etc) were read. Next, I read different articles, papers, and analyses that provided different facets of the problem in order to demonstrate the

United States' need to amend and create new legislation. These included papers that aggregated the flaws behind different legislation, case studies demonstrating legislative attempts successfully intervening tobacco and opioid companies, and other results demonstrating the United States' potential to improve these problems.

Legislation Analysis

To demonstrate the scope of the problems surrounding food, drug, and cosmetic legislation, I read many studies analyzing how faulty legislation assists companies to manufacture harmful products. In one study, one hundred ingredients lists were analyzed to uncover the loopholes of legislation surrounding 'natural substances' allowed to be produced and sold in ingredients. This study found that within the lists, there were many problems including unavailable classification of hazardous effects, non-disclosure of the dangerous constituents from the 'natural substances' label, substances that are not disclosed as possible allergenic ingredients, and many other problems (Klaschka, 2016). This concealment, obfuscation, and privatization of important information from consumers demonstrates the loopholes surrounding legislation and how it is not adequate enough to meet their demands. Table 1 summarizes these inadequacies with the left column describing the shortcomings of natural substances legislation and the right column adding additional insight to these comments.

Table 1.

List of Natural Substance Legislation Shortcomings (Source: Klaschka, 2016)

	Comments
(a) Examples where compliance with legal requirements needs to be improved	
Producers do not always use the INCI names	Some substances can be identified if one makes the effort and compares the names with the descriptions of the origin in the INCI list
Many natural substances are classified differently by various notifier groups (self-classification)	Notifiers should find joint classifications. It is difficult for the external user to decide, which classifications are the correct ones. Even for CMR substances there are no harmonized classifications
Many natural substances are not catalogued in the C & L inventory although they are used in products	Data on classification and labelling and data on constituents are publically available only for a minor part of natural substances
Natural substances (being UVCB substances) must only be registered according to REACH, if they meet the criteria for classification as dangerous ([20] Art. 2(7)(b) and Annex V (8))	Many natural substances are not notified in the C & L inventory yet, therefore it is not clear whether they are or should be classified and labelled and hence registered. So far only very few natural substances classified have been registered
Manufacturers should clarify substance identities and specify all known constituents of a UVCB substance which are present above 10 % and all components which are relevant for classification with the IUPAC name, CAS number and percentage in the UVCB substance [47, 48]	Only very few natural substances comply with this requirement so far. Therefore, it is hardly possible to calculate the classification of most natural substances as mixtures according to the ECHA guidance [49]
Information should be publically available if it is 'essential to classification and labelling,' such as 'the degree of purity of the substance and the identity of impurities and/or additives which are known to be dangerous' ([20] Art. 119)	Toxicity of multi-constituent substances is dependent on the constituents. A proper assessment requires these data, but the publically availabe data are very scarce
Risk assessments of single substances should consider various discharge patterns and entry paths	However, the constituents of multi-constituent substances are usually not considered in risk assessments of the single substances (e.g. risk assessment of limonene does not include discharge of *Citrus* preparations)
The general public should be provided with safety data sheets or sufficient information for safe handling about dangerous mixtures ([20] Art. 31)	Consumers are informed only in special cases, e.g. some hair dyes about special safety arrangements. Most consumers do not expect that personal care products can be dangerous mixtures. It must be questioned whether the ingredient lists are sufficient information for safe handling
(b) Examples where natural substances and cosmetic products are granted special waivers	
Cosmetic products are not classified and labelled, even if they contain dangerous substances above the thresholds ([8] (A) Art. 1 (5))	Consumers have the right to know. This exception for cosmetic products impedes a suitable risk communication
'26 fragrance allergens' are only listed on the containers if they are added as single substances	Many natural substances are mixtures that contain some of the 26 fragrance allergens as constituents, which arrive 'incognito' in the products
Other mixtures—but not cosmetic products.—which are not classified as sensitizing but contain at least one sensitizing substance must be labelled with EUH208 'Contains (name of sensitizing substance). May produce an allergic reaction.' ([8] Annex II Part 2 2.8)	Most cosmetic products, also natural products, contain sensitizing fragrances or preservatives. Only informed persons recognize them in the ingredient lists. The label EUH208 with the two short sentences would particularly be important for personal care products. Therefore this exception should be abolished
CMR substances may be used if their "use has been found safe by the SCCS" [22]	This does not correspond to the precautionary principle in the chemical legislation and to the 'right to know' for the consumer. There should be no exceptions for CMR substances. They should not be allowed in personal care products, even if they are natural substances
The chemical safety report does not need to consider the risks to human health from the use of cosmetic products ([20] Art. 14 5(b))	Realistic risk assessments should consider the complete sum of exposure routes. Exposure via personal care products is not negligible
Data on cosmetic ingredients need not be transmitted in the supply chain ([20] Art. 2(6b))	Manufacturers and downstream users of cosmetic products should be informed like manufacturers and downstream users of any other products. This exception should be deleted to improve transparency and risk communication
Chemical safety reports are not publicly accessible	The public availablity of chemical safety reports could improve transparency [50]
SVHCs must be authorized before they are placed on the market or used, unless they are used in cosmetic products ([20] Art. 56 (5))	With this exception for cosmetic products, authorization will affect other uses and will not enforce substitution of SVHCs in personal care products. This exception should be deleted to improve consumer and environmental protection

Included in the faulty legislation is the biased product approval process for foods, drugs, and cosmetics. Generally Regarded as Safe (GRAS) status constitutes that a chemical or substance added to food is considered safe by experts under its intended use. However, food businesses can have in-house employees or hired consultants to evaluate GRAS status of a substance in a product, creating a bias to not evaluate their own products under independent scrutiny and incentive for food businesses to reduce costs(Knezevic et., 2021). Unsurprisingly, of the 3941 food additives with GRAS status in 2018, only 263 (6.1%) had data on reproductive toxicology data, a demonstration of the substantial gap about potential health effects of food additives, particularly in this case for consumers' who require this data for possible pregnancies

(Trasande et al., 2018). To entice companies to inform the FDA about the safety of their GRAS ingredients, the FDA created a voluntary program where manufacturers could send safety information of an ingredient regarded with GRAS status and ask for a FDA review (Maffini et. al, 2017). This voluntary process however is inherently problematic because it once again incentivizes companies to cut corners as the process is entirely optional. As of 2017, more than 1,000 chemicals have completely avoided FDA scrutiny through the GRAS exception (Maffini et. al, 2017). Completely biased processes such as these are the foundation for citizens believing that products containing long-named ingredients that can potentially harm one's health are the conventional norm.

More scrutiny also needs to take place for the entire product approval process. On top of harmful ingredients in products, the packaging of the product also can affect the product. When the packaging of a product comes in contact with the product, it can create a negative synergistic effect. Indirect additives (adhesives, dyes, coatings, paper, plastic, etc), material coming in contact with food, cosmetics, and drugs have been shown to potentially negatively affect human development from metabolic changes to reduced fertility and thyroid alterations as seen in Table 2 (Trasande et al., 2018).

Table 2.

List of Indirect Food Additives with Corresponding Health Concerns (Source: Trasande et al., 2018)

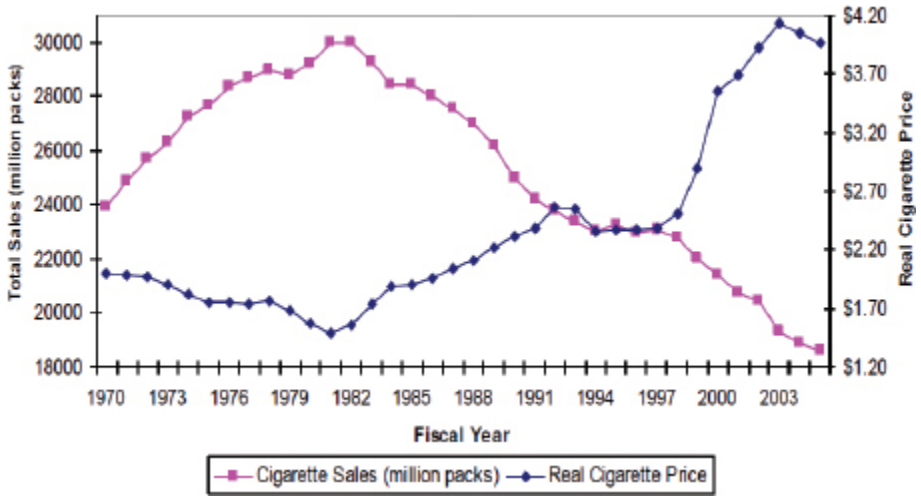
Category	Chemical	Food-Related Use	Selected Health Concerns
Indirect food additives	Bisphenols	Polycarbonate plastic containers	Endocrine disruption[11,–18]
		Polymeric, epoxy resins in food and beverage cans	Obesogenic activity,[19,–22] neurodevelopmental disruption[23,–26]
	Phthalates	Clear plastic food wrap	Endocrine disruption[6,27,–29]
		Plastic tubing, storage containers used in industrial food production	Obesogenic activity[30,–32]
		Multiple uses in food manufacturing equipment	Oxidative stress,[33,34] cardiotoxicity[35,36]
	Perfluoroalkyl chemicals (PFCs)	Grease-proof paper and paperboard	Immunosupression,[37,38] endocrine disruption,[39,–41] obesogenic activity,[42] decreased birth wt[43]
	Perchlorate	Food packaging	Thyroid hormone disruption[44,–46]

Case Studies

From the analysis of ingredient lists and the legislation around it, it is evident that there are many shortcomings that need to be addressed. The problem can seem large and insurmountable but by looking into the past, it is worth noting that historical precedent exists for enacting changes to implement more stringent legislation to safeguard consumer welfare, as evidenced by the case of the major tobacco industry and food labels reformation in the United States. Before warnings, cigarettes were marketed in an effort to make tobacco use appealing, even espoused as having health benefits. When warnings were first introduced by the U.S in 1966, they were vague on the sides of the pack (i.e "cigarette smoking may be hazardous to your health") (Noar et. al, 2016). Over time, legislation required that cigarette companies move warnings from the side of the pack to the to the front of the pack with included full-color warning imagery (Noar et. al, 2016). As a meta-study showed, the following concurrent results occurred after these front-of-package implementation occurred: 1) increased knowledge about smoking risks; 2) increased quitline knowledge; 3) increased calls to quitlines; 4) reductions in cigarette consumption; 5) increased quit attempts; 6) increased short-term smoking cessation, and 7) reduced smoking prevalence (Noar et. al, 2016). In some countries including the United States, a tobacco tax was enforced, thus increasing cigarette prices, which also correlated to a reduction in consumption as seen in the graph in figure 1 demonstrating the relationship (National Cancer Policy Forum et. al, 2013). Therefore as a result of public health policy intervention, strengthening warnings on cigarette labels and incorporating taxes were associated with reductions in smoking behavior globally.

Figure 1.

Graph Showing Inverse Relationship Between Trend Lines of Cigarette Sales and Real Cigarette Prices in the United States (National Cancer Policy Forum et. al, 2013).



Front of package (FOP) labels are another example of how proper public health intervention helps enhance a consumer's ability to stay healthy. As increased amounts of processed foods came into the marketplace, consumers requested information to help understand the products they purchased, resulting in the FDA proposing regulations that specified a format to provide nutrition information on packaged food labels in 1972 (Symbols et. al, 2010). Although information such as the number of calories, grams of different macronutrients and micronutrients were included on food labels, several food manufacturers added unproven health benefits onto their food products such as the Kellogg Company adding information on the back of cereal boxes claiming consumption would result in a possible reduction in a risk of certain cancers (Symbols et. al, 2010). The FDA tightened its food-label regulations further 1987 and 1990 after several incidents of misinformation on food labels that permitted health claims only if certain criteria were met and approved (Symbols et. al, 2010). These policies were created and

reshaped by the stakeholders of the food-buying process: nutritionists, consumer groups, and the food industry, creating an environment for the decisions to be made in the interests of all groups (Symbols et. al, 2010). These policies therefore helped consumers stay informed in their purchasing decisions with proper and correct nutritional content and claims.

Although the intervention of tobacco companies and food labels had remarkable success, the opioid crisis in the United States continues to plague its citizens. Studying it, the key factors that caused it to balloon to this size was the opioid companies' influence over public health officials, legislators, and patient advocacy organizations. Between 2006 to 2015, opioid companies spent US$ 880 million on lobbying and campaign contributions and over a 5 year period between 2012 and 2017 they donated US$ 9 million to patient advocacy organizations, academy of Integrative Pain Management, and the American Pain Society (Marks et. al, 2020). Not surprisingly, these donations create conflicts of interests as demonstrated in their lobbying against legislation restricting opioid prescribing and downplaying addiction risks (Marks et. al, 2020). Fundamentally, the existence of independent objective opinion on whether or not opioids harm consumers' health cannot be decided within these organizations, even among those for patient advocacy. Therefore, necessary actions to prevent or change how corporate influences spread to organizations that benefit consumers are necessary.

Results and Discussions

STS Framework

When using the lens of Actor-Network theory to understand how stakeholders affect ingredients in product regulation, it becomes clear that this problem is not so black and white. Actor-network theory is an STS theory that encapsulates actors (any object, living or nonliving) in networks of relationships and postulates that all of them should be held in the same terms

(Law 1992). Actor-network theory best encapsulates the relationship between the multiple stakeholders jostling to maintain their wants and needs. Specifically in this case, companies, non-profits, governments, consumers, and the products are all actors in this industry, each fighting to meet more of their own needs which also are actors influencing these relationships. Individual consumers buy products, specifically foods, based on the actors of motivation which include different perceptions, ethical concerns, and wellbeing (Knezevic et al., 2021). These 'product actors' contain a blend of ingredients that have either its intended effect on the consumer or not, whether that be sunscreen applied on the skin or a pack of granola bars. Many companies identify these consumer expectations and build products aligned with these goals to reach profitability. Sometimes harmful ingredients can be included which can cause negative side effects from magnification of addictions or increase probability in certain diseases. Governments and nonprofits also play a role in balancing the needs of companies incentivized to generate revenue with consumers being safe. Yet, as these concerns are identified, misinformation continues to be a problem in the consumer product industry. In certain cases, package labels with information as "natural substances only" are plastered onto products to entice consumers, when in reality, many of these substances could be classified as hazardous carcinogens, mutagens, and toxic to human reproduction (Klaschka, 2016). Even with companies selling explicitly harmful products such as cigarettes, vague labels and warnings such as "may be hazardous to your health" still exist to confuse and make consumers doubt themselves (Noar et al., 2016). Finally, the lack of uniformity across worldwide laws regarding additives, along with conflicting results of studies contributes to more confusion. Molecules and compounds added into products that may be legal in the European Union are allowed in the United States and vice versa (Carocho et al., 2014).

The Future of Legislation

As previously mentioned, many efforts to reform legislation in order to enforce public health policies have gone underway. However, this is not enough. The ongoing presence of various chemicals in the food supply that have been associated with significant health risks indicate that our legislation is not adequate enough to take into account the best available methods and evidence assessing chronic and cumulative effects of ingredients in our products. It is clear that a larger budget in public health legislative bodies such as the FDA and USDA to match the size of food sales would help manage all the products being distributed and sold. For instance, the Center for Food Safety and Applied Nutrition's (CFSAN) budget was US$ 1 billion compared to US $371 billion in packaged food sales (Maffini et. al, 2017). A larger budget would help spur more innovation and reformations as more resources could be pooled in creating solutions to upgrade and fix aspects of the current legislation respectively. Government agencies, non-profit consumer groups, and other consumer advocacy organizations should also stay wary of corporate interests, especially companies that donate funds, lobby, and utilize other tactics to further their profit agendas. As demonstrated from the GRAS status designation and opioid crisis, when production of valid information is required of companies, the idea of 'independent conduct' becomes biased and cannot be trusted. Better legislation and increasing public scrutiny is required to prevent the warping of objective information.

Conclusion

The health crisis in the United States is a pressing issue that cannot be ignored. Widespread chronic diseases such as obesity and high cholesterol are indicative of a flawed product approval process that allows companies to exploit loopholes and add harmful substances

to their products. The responsibility to prevent further harm lies with the United States legislators, who must pay closer attention to consumer health and ensure strict regulation and comprehensive information about products. It is imperative that organizations responsible for product oversight are held accountable for their actions, and efforts are made to solve this pressing issue. With so many products present in our daily lives, it is necessary to scrutinize food, cosmetics, and drug legislation to prevent further harm on citizens.

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