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Exploring the Legal Liability of Genetically Modified Organisms and their Impact on Society

Jarrett Davis
University of Central Florida

EXPLORING THE LEGAL LIABILITY OF GENETICALLY MODIFIED ORGANISMS AND THEIR IMPACT ON SOCIETY

by

JARRETT B. DAVIS

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Thesis Chair: Dr. Gina Naccarato-Fromang

ABSTRACT

Controversy surrounds the use of Genetically Modified organisms (GMOs): whether the process of developing GMOs should be allowed, and if so, how they should be labeled. Efforts by activist groups have caused food associated with GMOs to carry a stigma, but farmers across the nation are fighting to continue to grow GMO crops and maximize their yield. In the 1970's, GMOs were credited for assisting in the attempt to defeat world hunger and had a positive image. However, there has been a recent trend toward political and consumer resistance of food items that contains GMOs. A prediction of an abrupt population increase, combined with sudden climate changes, present further complications for world hunger, and make GMOs even more essential in today's society.

Additionally, farmers must now consider certain potential legal liabilities when buying seed, planting crops, and marketing their crops. This thesis will examine United States federal and state law to review how courts have ruled on tort claims in order to determine the potential and future liabilities that farmers producing GMO crops might face. This thesis will also examine the regulations by the United States Food and Drug Administration (FDA) and the federal laws they must comply with to determine if they need to be increased or if they are sufficient.

Scientific studies will be used to assess the health risks associated with the consumption of GMOs and the impact they have on the environment. This thesis will also examine the First Amendment to determine how GMO foods should be labeled, so as to not interfere with consumers' right to know if their food was genetically modified. Also, it will look at the impact labeling may have on the price of food in the United States, if mandated. Lastly, in order to

understand the role that GMOs might play in the future with an increasing population, this thesis will review the work of Dr. Borlaug and how the implementation of GMOs assisted in alleviating a hunger crises in the 1970's when the supply of food could not meet the demand.

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INTRODUCTION

In the produce section of the local grocery store there are a variety of fruits and vegetables on display for purchase. All are suitable for eating and have a very similar appearance. For instance, Red Delicious apples are just the right shade of burgundy with an almost perfectly oval shape; watermelons are bright green and seedless; and corn is consistently colored without any missing kernels. What consumers may not know is that this produce was most likely grown from a seed that was genetically modified to produce crops that would be visually appealing to consumers. Additionally, the use of genetically modified seeds may allow a crop to grow in certain conditions under which it would not normally have been able to survive, to resist certain pesticides and herbicides, and to produce a high yield. Genetically Modified Organisms (GMOs) have been around for many years, but their presence in foods, is at an all-time high with an estimated 70 percent of items found on grocery store shelves containing a GMO ingredient.[1] In order to get an indication of some of the food products and what ingredients contain GMOs, refer to Table 1.

Grocery store food/product	**GM component**
Pickles	Dextrose from corn, corn syrup
Milk	Recombinant bovine growth hormone
Soda/Soft drink	Corn syrup
Catsup	Tomatoes, corn syrup
Fruit drinks	Corn syrup, dextrose from corn

[1] Grocery Manufacturers Association, *Position on GMOs.*

Grocery store food/product	**GM component**
Bread	Yeast, corn syrup, soybean oil, cornstarch, soy flour, dextrose from corn
Aspirin	Corn starch
Honey	GM enzymes (alpha amylase)
Beer	Corn, yeast, enzymes
Some antibiotics	Corn starch
Tomatoes/peppers	Genes from bacteria and viruses
Breakfast cereals	Corn, corn syrup, soybean oil
Peanuts	Longer shelf-life peanuts
Peanut butter	Peanuts, cottonseed oil, soybean oil, dextrose from corn, corn syrup
Candy and gum	Corn syrup, corn starch, dextrose from corn, soy flour
Chips	Potatoes, cottonseed oil
Sources: BIO 1998, National Corn Growers Association, American Soybean Association. Alliance For Better Foods (www.betterfoods.org).	

Table 1: Grocery store foods and products containing GM ingredients

The current regulations set by the FDA do not require the labeling of Genetically-Modified (GM) foods, because they do not have a different appearance or taste compared to the original version.[2] Some consumers, however, are hesitant about the use of GMOs and believe that food labels should disclose any GMO product in the ingredients. These opponents of GMOs

[2] *FDA's Role in Regulating Safety of GE Foods.*

are trying to encourage legislation that would mandate labeling in the United States. If all farmers who produce crops were required to label, then prices would increase because of associated costs.[3] Additionally, there have been previous cases that indicate labeling is a violation of the First Amendment and these issues will be further discussed in this thesis.[4]

The invention of GM crops has revolutionized farming, however the advent of new technology can cause unforeseen legal issues. Currently, lawsuits are arising over intellectual property rights, contractual agreements, and nuisance claims, and there may be additional potential liabilities. Farmers that produce GMOs should take all preventive steps necessary to reduce future liability.

Significance

This thesis intends to provide an answer to ongoing legal battles and how to prevent potential ones from arising. Additionally, it will evaluate criticisms such as health risks, the consumers' right to know, and the harm to the environment that have led to a resistance of GMOs. It will also review the benefits that GMOs provide such as reducing the overall costs of food and animal feed, the positive effects that they have on the environment, and how they can allow for more efficient land use. It will provide an analysis of the GMO labeling controversy and determine if labeling should be mandated in the United States. Lastly, it will discover how GMOs can assist in the battle against worldwide hunger and how they can factor into a world

[3] Lesser, *Costs of Labeling Genetically Modified Food Products in NY State*.
[4] 92 F. 3d 67 - Court of Appeals, 2nd Circuit (1996).

with an increasing population that is forecasted to grow by approximately one billion people in the next 20 years, accompanied climate change.[5]

[5] Rotman, *Biotech crops will have an essential role in ensuring that there's enough to eat*.

GENECTICALLY MODIFIED ORGANISMS

Farmers have been using breeding techniques for thousands of years to crossbreed crops by exchanging genes from a male (pollen) of one plant to the female organ of another; however, in the 1970's scientists began using biotechnological methods to genetically modify crops. Genetic modification occurs by inserting a desired gene from an organism into the genetic makeup of another organism. The process of chemically cutting and splicing strands of DNA at specific places in the sequence was discovered by Stanley Cohen and Herbert Boyer in 1972, which made it possible for GMOs to be created.[6] This process allows for scientists to alter the genetic makeup of an organism by combining genes with specific characteristics to create one organism.[7] For example, if scientists wanted to genetically modify corn so it would resist pesticides, they would find a specific gene, from a related or unrelated specie, that resists pesticides and transfer it to the corn gene. The traditional method of crossbreeding plants can take many years to complete and is limited to exchanges only between closely related species. Genetic modification is not limited to just closely related species; in fact, scientists can transfer genes from one specie to another. This is because all species, such as humans, plants, animals, and bacteria are made up of the same genetic material; therefore, when genetically modifying, scientists can mix genes from different species.[8] The ability to interchange genes from different species provides scientists with a broader pool of genes to choose traits from when genetically

[6] *GMO Timeline: A History of Genetically Modified Foods.*
[7] *FDA's Role in Regulating Safety of GE Foods.*
[8] Institute for Responsible Technology.

modifying. The greater precision and increased success rate in less time than traditional breeding make GMOs a popular choice amongst farmers.

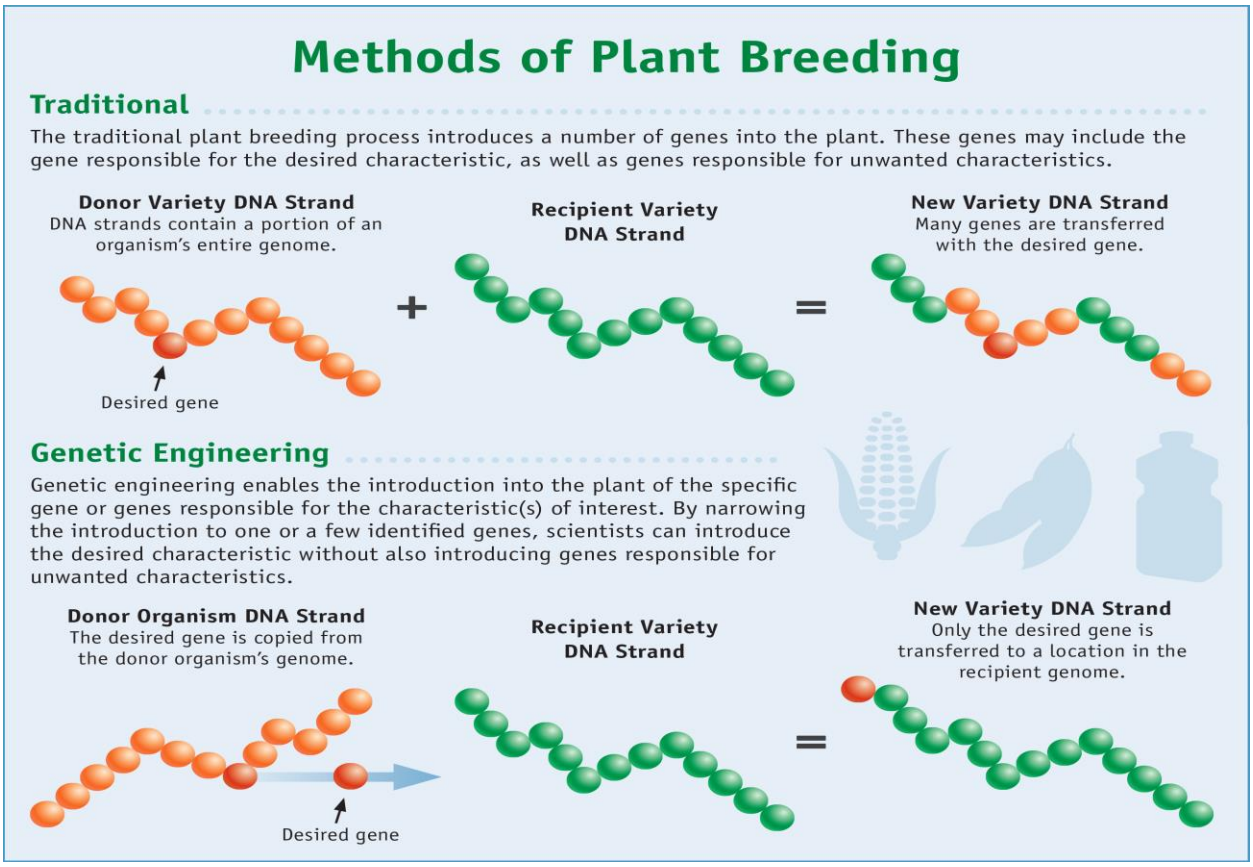


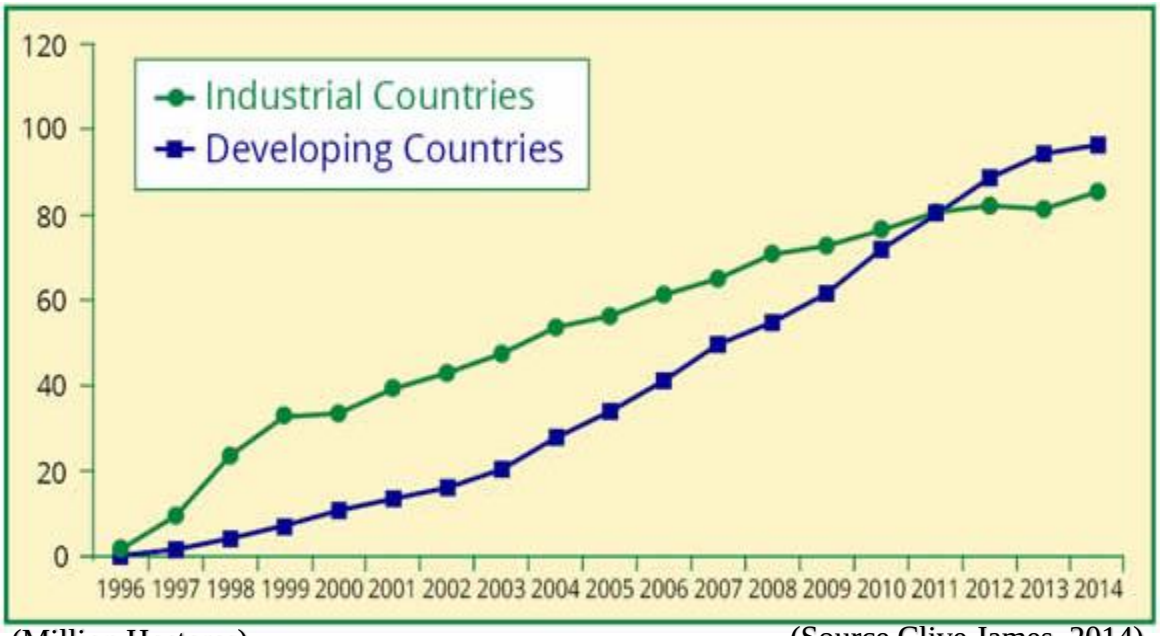
Figure 1: Methods of Plant Breeding (Source: U.S. Food and Drug Administration)

The first GMO product that was available to the public was approved by the FDA in 1982.[9] However, it was not a food product, it was insulin created by scientist Eli Lilly by genetically engineering E. coli bacteria.[10] It was called Humulin and before its discovery, all

[9] White, *Celebrating a Milestone: FDA's Approval of First Genetically-Engineered Product.*
[10] White, *Celebrating a Milestone: FDA's Approval of First Genetically-Engineered Product.*

insulin that was used for human use was gathered from slaughterhouse animals. This medication is still used today and is safe and efficient for human use.

The FDA approved its first GMO food product to the public market for consumption in 1994, which was a delayed-ripening tomato.[11] It was coined the name Flavr Savr because it had a longer shelf life compared to conventional tomatoes. Five years later farmers began to completely embrace the idea of GMOs and over one hundred million acres worldwide were used to plant genetically engineered seeds. Grocery stores became filled with products containing GMOs. Over the last decade, more than 18 million farmers have planted GMO crops on more than a billion acres across the globe.[12] Developing countries accounted for 16.5 million[13].



(Million Hectares). (Source Clive James, 2014)

Figure 2: Global Area of Biotech Crops: Industrial and Developing Countries

[11] GMO Timeline, *A History of Genetically Modified Foods.*
[12] ISAA, *Global Status of Commercialized Biotech/GM Crops in 2014.*
[13] *Id.*

Farmers have supported the biotechnological implementation into agriculture because GM plants offer benefits such as the ability to withstand extreme weather conditions. Some areas of the world are seeing record temperatures and droughts, which affects the crop production significantly. These GM crops are bioengineered to withstand these climate conditions. Also, some GM crops have the trait to be able to resist herbicides and pesticides, such as "Roundup Ready" products by Monsanto. This is beneficial because it increases farmers' yields at a lower cost while aiding the environment by reducing applications of chemical sprays. Figure 3 "Benefits of Genetically Modified Crops" displays the benefits GM crops provide farmers by indicating yield increase accompanied with an upward income trend.

Benefits of Genetically Modified (GM) Crops

Country	Total GM Crop Farm Income Benefits, 1996–2008, in Millions of U.S. Dollars	Average Yield Increase of GM Crops	
		Corn	*Cotton*
United States	$23,268.7	5%	9.6%
Argentina	$9,227.3	7.8%	28.6%
China	$7,599.0	n/a	9.5%
India	$5,142.0	n/a	54.8%
Brazil	$2,820.6	n/a	6.2%
Canada	$2,070.5	5%	n/a
South Africa	$506.9	15.3%	24.3%
Paraguay	$503.2	n/a	n/a
Australia	$224.1	n/a	n/a
Mexico	$91.1	n/a	11.8%
Philippines	$88.3	24.1%	n/a
Bolivia	$83.4	n/a	n/a
Spain	$77.0	7.4%	n/a
Uruguay	$53.3	6.3%	n/a
Romania	$44.9	n/a	n/a
Colombia	$13.9	n/a	5.7%

Sources: PG Economics, "Focus on Yields," October 2009, at *http://www.pgeconomics.co.uk/pdf/focusonyieldeffects2009.pdf* (January 12, 2011).

Table 1 • B 2509 heritage.org

Figure 3: Benefits of Genetically Modified Crops

Dr. Norman Borlaug

Dr. Norman Borlaug was responsible for making GMOs a global phenomenon by using biotechnological methods to aid developing countries that had food deficiencies. He taught these countries how to plant and harvest this new genetically modified seed, which resulted in these countries becoming self-sufficient in producing crops. One of Dr. Borlaug's greatest

achievements took place in India during the 1960's.[14] During this time, Jawaharlal Nehru, the first Prime Minister of independent India died. Nehru focused heavily on industry in an attempt to boost the economy and gave little assistance to the agricultural sector. Food shortages arose after two consecutive droughts, which took place in 1966 and 1967 and predictions began to arise about the supply of food not being able to meet the demand of the increasing population. Biologist Paul Ehrlich wrote in his bestseller of 1968, The Population Bomb, "I have yet to meet anyone familiar with the situation who thinks India will be self-sufficient in food by 1971".[15] He claimed that "India couldn't possibly feed two hundred million more people by 1980."[16] However, what he was not aware of was that Dr. Borlaug was then in Mexico attempting to help solve a similar crisis. He was experimenting with a strain of wheat that produced high yields, but caused the crop to grow too tall and fall over. He crossbred that strain with its antithesis, which caused the plant to shrink in size but still produce a high yield. The new crossbred plant produced high yields of grain and could withstand the harsh environment of Mexico.[17] Many local farmers in Mexico began using Borlaug's genetically modified seed and saw exceptional results. When India's government heard about Dr. Borlaug's discoveries they promptly brought him to the country with 16,000 metric tons of seed in an attempt to save millions of lives.[18] Dr. Borlaug taught the local farmers the proper methods for cultivating this new strain of wheat. The wheat production tripled after implementation of the new genetically modified seed and allowed

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[14] Gillis, *Norman Borlaug, Plant Scientist Who Fought Famine*
[15] Easterbrook, *The Man Who Defused the 'Population Bomb.*
[16] *Id.*
[17] Singh, *Norman Borlaug: A Billion Lives Saved.*
[18] *Id.*

for the country to become self-sufficient in the production of all cereals. Dr. Borlaug received global attention from his discoveries and focused his further studies in developing countries where the population was increasing to a number that the farming production was not able to supply. In 1970, he was awarded the Nobel Peace Prize for his agricultural advances, which were credited with saving hundreds of millions of lives.[19]

[19] Gillis, *Norman Borlaug, Plant Scientist Who Fought Famine.*

UNITED STATES LEGAL ISSUES

Farmers face legal liabilities for buying, planting, and marketing GMOs. Since GM crops are relatively new to the court system, many of the cases that arise do not have precedent. This thesis will analyze the current legal liabilities and determine what potential lawsuits could be filed in the future.

Genetic Drift

Certain crops cross-pollinate through the air and when a farmer who grows GMO crops has a neighboring field it could potentially contaminate the neighboring landowner's crops. This is known as "Genetic Drift".[20] This is a major issue because certain farmers are under non-GMO seed contracts and if their crop becomes contaminated then it could show traces of GMOs. The presence of GMOs in the crops could potentially cause a farmer to face damages for failure to follow through with the contact agreement. Tort claims such as trespass to land, nuisance, negligence, and strict liability could be brought against a landowner as damages.

TRESPASS

The tort claim of trespass to land arises when someone intentionally enters another person's land and causes damage.[21] This claim could arise in a GMO context if a farmer and/or seed company knew that genetic traits from a GMO crop would enter a neighbor's property and genetic drift in fact occurs, causing harm to the neighbor's crop. However, since Genetic Drift is not a direct act that stems directly from a person because it's affected by factors that are out of

[20] Preston, *Drift of Patented Genetically Engineered Crops.*
[21] *Id.* at 15-16.

the control of a farmer, such as wind, it cannot be considered trespass.[22] Another way trespass could arise through GMO use is by pesticides traveling through the air. Many GMO crops are genetically engineered to resist certain pesticides and herbicides, such as Roundup Ready Corn by Monsanto. Farmers are safe to spray a crop with a particular pesticide without it affecting the crop but killing and deterring pests and weeds. Pesticide spray that travels through the air to a neighboring farm could be held liable for trespass charges. Major damage could be done to organic farmers who are under contracts not to use any pesticides or herbicides.

However, after examining a recent ruling by the Minnesota Supreme Court, *Oluf Johnson v. Paynesville Farmers Union Cooperative Oil Co.,* No. A10-1596, A10-2135 (2011), it appears that pesticide drift does not constitute a claim for trespass.[23] In 2007, Organic farmers, Oluf and Debra Johnson filed a contamination complaint to the Minnesota State Department of Agriculture (MDA). They stated that Paynesville Farmers Union Cooperative Oil Company contaminated one of their soybean fields through pesticide drift. The Johnson's were under a contract with the National Organic Program (NOP) that did not allow their crops to use any pesticides for a period of three years before the harvest of the crop. In 2008, the Johnsons filed another contamination complaint with the MDA for one their alfalfa fields. The testing by the MDA revealed that their crops were contaminated by the Paynesville Farmers Union Cooperative Oil Company spraying of pesticide but there were no damages detected. The Johnsons filed a trespass lawsuit and claimed: "(1) loss of profits for fields taken out of organic production for 3 years; (2) loss of profits because they had to destroy approximately 10 acres of

[22] Strauss, *Liability for Genetically Modified Food.*
[23] No. A10-1596, A10-2135 (2011).

soybeans; (3) inconvenience due to increased weeding, pollution remediation, and National Organic Program reporting responsibilities; and (4) adverse health effects".[24]

When making their decision, the Minnesota Supreme Court, examined the Organic Foods Production Act of 1990, 7 U.S.C. §§ 6501-6523 (2006) (OFPA), and the NOP and found that pesticide drift is not trespass.[25] The Supreme Court ruled that pesticide drift is not a "tangible invasion" of the Johnsons' "right to exclusive possession of the land".[26] Since pesticide drift is something that is not visible, it does not apply to the same standards as tangible invasions. The Supreme Court explained that organic farmers cannot meet all of the necessary legal requirements to establish a trespass claim. They additionally reasoned that because trespass is an "intentional" tort, pesticide drift does not fall under the definition of trespass because it was caused by factors outside of the direct control of Paynesville Farmers Union Cooperative Oil Company. The court stated that the Johnsons should have filed a complaint for nuisance and sent the case back to trial court for a rehearing to determine if there was a violation of Minn. Stat. § 18B.07 (2010) by spraying pesticides onto property and having it drift beyond the boundaries of the intended area.[27]

Minn. Stat. § 561.01 (2010) provides that a nuisance is "anything which is injurious to health, or indecent or offensive to the senses, or an obstruction to the free use of property, so as to interfere with the comfortable enjoyment of life or property."[28] The court dismissed the

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[24] Gertsberg, *Is Pesticide Drift Trespass?*
[25] *Id.*
[26] No. A10-1596, A10-2135 (2011).
[27] *Id.*
[28] § 561.01 (2010).

Johnsons' nuisance per se claim because they were unable to prove the negligence per a breach of duty that directly caused damage. The court reasoned that since the crops were not damaged and the pesticide amount found on the crops would not cause them to lose their organic certificate, there were not sufficient damages done and granted the Paynesville Farmers Union Cooperative Oil Company summary judgment.[29]

STRICT LIABILITY

Strict liability arises when someone engages in an abnormally dangerous activity; in such cases, a person harmed by the abnormally dangerous activity can recover damages from the person who engaged in the activity, without having to prove recklessness or negligence. In regards to GMOs, the courts would have to determine if making, planting or selling GM crops is considered to be "an abnormally dangerous activity".[30] The fact that the federal regulatory system has conducted numerous tests on GMOs and approved them for national use, places doubt that a GM company is an abnormally dangerous activity and most likely could not be held liable for Strict Liability. In *Bennet v. Larsen Co.*, 348 N.W.2d 540, 553 (Wis. 1984), the court held that the planting of GM crops does not qualify as an abnormally dangerous activity.[31] In fact, the court ruled that organic farming was "abnormally sensitive character".

PATENT INFRINGEMENT

Another legal issue associated with genetic drift is patent infringement. Many biotechnological companies place patents on their genetically engineered seeds to protect their

[29] *Id.*
[30] Strauss, *Liability for Genetically Modified Food.*
[31] 348 N.W.2d 540, 553 (Wis. 1984)

intellectual property rights. In order to understand the rights of these companies, it is important to look at the case law of patentability of genetic modifications. In *Diamond v. Chakrabarty*, 447 U.S. 303 (1980), Dr. Chakrabarty applied for a patent for a GM oil-eating bacterium and it was rejected by a patent examiner, which was upheld by the Patent Office Board of Appeals on the ground that living things are not patentable subject matter under Title 35 U.S.C. 101.[32] This decision was reversed by the Court of Customs and Patent Appeals, who ruled that the fact that micro-organisms are alive is without legal significance for purposes of the patent law.[33] Diamond, The Commissioner of Patents and Trademarks challenged this ruling and the case was heard by the Supreme Court.[34] The Supreme Court had to decide if living organisms can be patented. The Court affirmed the ruling and concluded that patentable subject matter included "anything under the sun that is made by man", even if it is a living organism.[35] This decision established that GMO plants can be patented and seed producers are afforded the right to protect their engineered seeds. Since this decision, thousands of GMO seeds have been patented.[36] Five major companies in the biotech field hold 71 percent of the patents. Out of those five, the top patent holder is Monsanto, who holds 5,355 GMO patents, which accounts for more than 90 percent of all the GM seeds in the world.[37] Under patent law 5 U.S.C. § 271(a), these companies are entitled to strictly enforce their patent rights against farmers who do not uphold licensing agreements.

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[32] 447 U.S. 303 (1980).
[33] *Id.*
[34] *Id.*
[35] *Id.*
[36] Wilson, *Induced Nuisance: Holding Patent Owners Liable for GMO Cross.*
[37] *Id.*

When GMOs first emerged courts had to decide if the patent rights of GM seed producers expire after the sale of the patented seed. In *Monsanto Co. v. Bowman*, 657 F.3d 1341, 1348 (Fed. Cir. 2011) the court determined that the GM seed producer maintains the patent rights after sale, including in the case of genetic drift.[38] Therefore, when GM crops genetically drift to a non-licensee's land, it constitutes a violation of patent infringement. Patent infringement is a unique claim because it does not require knowledge or intent of use.

One of the most notable cases regarding this type of infringement is in the case of *Monsanto Canada Inc. v. Schmeiser*, 1 S.C. R. 902, (2004) SCC 34, Mr. Schmeiser was found guilty of patent infringement because his non-GMO crops were contaminated by means of genetic drift from a surrounding Monsanto Roundup Ready Canola field.[39] Monsanto sued Mr. Schmeiser for patent infringement and the court awarded Monsanto thousands of dollars in damages. A key aspect to this case was that even though Mr. Schmeiser did not intend to use Monsanto's product, he was found liable. Although, *Monsanto Canada Inc. v. Schmeiser* was a Canadian case, the facts of the case mirror those of numerous United States lawsuits and American jurisprudence suggests that a similar outcome would be reached in United States courts. For example, an analogous case occurred in the United States, in Monsanto Co. v. Trantham, 156 F. Supp. 2d 855, 868 (W.D. Tenn. 2001), Monsanto's patented crops were found growing on the defendants land without authorization.[40] The defendant claimed no intent to use the patented technology. However, the court decided that the defendant's use of patented

[38] 657 F.3d 1341, 1348 (Fed. Cir. 2011).
[39] 1 S.C.R. 902, 2004 SCC 34(2004).
[40] 156 F. Supp. 2d 855, 868 (W.D. Tenn. 2001)

technology constituted an infringement in the plaintiff's patent and that intent is not a required element for patent infringement under U.S. law.[41] Monsanto has won 70 of the 136 lawsuits filed, which total $23,345,821 against farmers.[42]

NUISANCE

Farmers are filing lawsuits against companies that produce GM crops for contamination. As previously mentioned in *Oluf Johnson, et al, v. Paynesville Farmers Union Cooperative Oil Co.,* No. A10-1596, A10-2135 (2011), contamination would fall under the claim of a nuisance, which occurs when someone interferes with another person's use and enjoyment of his or her property.[43] Some farmers advertise their products as organic because of the farming methods they use. When Genetic Drift occurs from a field that has GM crops to a field that is organic, these farmers could potentially suffer economically because their current client base will not purchase their crops. This could be classified as an interference of a person's use of property. As mentioned earlier, Monsanto has clearly established ownership of the seed, even if it travels to a neighboring field, which means if the courts think these claims hold merit they will definitely be held responsible. However, many small organic farmers are hesitant to file a lawsuit because of the fear of a possible patent infringement suit by the patent owner.[44]

NEGLIGENCE

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[41] 156 F. Supp. 2d 855, 868 (W.D. Tenn. 2001)
[42] *Id.*
[43] No. A10-1596, A10-2135 (2011).
[44] Wilson, Induced Nuisance: Holding Patent Owners Liable for GMO Cross at 1.

In order for a claim of negligence, there must be a "breach of duty to exercise reasonable care under the given circumstances".[45] In order for an organic farmer to recover damages from a claim of negligence due to Genetic Drift, there must be proof that the GMO farmer has a duty to control approved GM crops. If a duty of care does exist, it must be accompanied by the failure to act reasonably in handling the GMOs.[46] There are two major issues that could impede a negligence claim. The first is if the GMO farmer abided by the external requirements imposed by the purchase and planting of GMO seeds. This would make proving the failure to act reasonable very difficult. The second would be the organic farmer identifying the source of contamination in order to prove causation.[47] This could be an expensive endeavor that most organic farmers cannot afford.

The proceeding sections illustrate how current United States farmers are being exposed to unforeseen legal liabilities. The United States legal system has primarily ruled in favor of GMOs but have noted that foreseeable risks can be created by noncompliant practices.[48] The United States needs to make changes to the current regulatory framework to balance the interest of all parties involved. Currently, there are small farmers that being taken advantage of by larger corporations. There should be additional rights afforded to small famers, to ensure protection from economic damages from genetic drift contamination at the state and federal level.

Contract

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[45] Preston, *Drift of Patented Genetically Engineered Crops*.
[46] *Id.*
[47] *Id.*
[48] Margaret Rosso Grossman, *Genetically Modified Crops in the United States: Federal Regulation and State Tort Liability*.

Biotechnological companies and seed distributors that market GMO seeds to farmers usually require that farmers sign grower or technology agreements. These agreements generally give the farmer rights to use the GMO seeds in exchange for complying with all of the company's production methods and management requirements. The contract may require the farmer to allow company representatives access to fields to inspect crops and determine if the farmer is in compliance with the contract.

Seed companies invest a great amount of money in research and production of GM seeds; therefore, they usually include a "no saved seed" provision in the contract with the grower.[49] This provision prohibits the saving of 2nd generation seeds from the GM crops they grew with the original GM seed purchased. Companies make this requirement so that annual purchases will be made.

There are many contract issues that arise because of this requirement. For example, In *Bowman v. Monsanto,* 133 S. Ct. 1761 (2013), an Indiana farmer was charged with patent infringement for saving seed produced by Monsanto.[50] Mr. Bowman purchased seeds produced from Roundup Ready Soybean plants from a local grain elevator. The elevator believed that Mr. Bowman was going to use the seeds for livestock feed. Mr. Bowman planted the soybean seeds on his 65 acre farm and for eight years re-used the seeds that the annual crop would produce. Monsanto was notified about Mr. Bowman's illegal farming practices and filed charges. The United States Supreme Court unanimously agreed that Mr. Bowman was in violation of Federal

[49] Dowell, *Texas Agriculture Law. Progressive Forage Grower.*
[50] 133 S.Ct. 1761 (2013).

law and ordered him to pay damages of $84,456.[51] *Bowman v. Monsanto* illustrates how important it is for farmers to be aware of the protections seed companies are entitled to, and the serious penalties that could be enforced if violated.

Prevention

The easiest and most cost-effective way for farmers to reduce the legal liabilities associated with GMOs is exceptional management practices. This applies to both GM producers and non-GM producers. Most of the management practices should take place before the grower even plants their crops.

It is important for all producers to know the traits of the seed they buy and if it has been approved by Federal agencies. Some seeds are pending approval for regulatory status and should not be planted. If a farmer planted a seed that was not approved for release, serious penalties could be enforced. Additionally, if genetic drift occurred from a non-regulated seed to a neighboring field with crops that are intended to be consumed, strict penalties could apply. For example, in *Marvin Kramer v. Aventis Crop Science USA Holding, Inc.*, 212 F. Supp. 2d 828 (N.D. Ill. 2002), StarLink corn, a crop that was approved for animal feed but not human consumption, was detected in Kraft taco shells.[52] The product was immediately pulled from supermarket shelves and all products that could have contacted the contaminated product were recalled.[53] The costs associated with this accident were devastating; farmers were not only impacted by the recall in the United States, but additionally, exports of all United States corn

[51] *Id.*
[52] 212 F. Supp. 2d at 834 (2002).
[53] *Id.*

were rejected, costing farmers "tens of millions of dollars".[54] The StarLink accident displays how important it is to know the regulatory status of seeds before planting them. Lastly, even if a seed is approved for planting, it is important to be informed about the planting regulations set forth by Federal agencies. For example, some GM seed contracts have regulations that require farmers to plant non-GM seeds with the GMO seeds in an effort to delay the development of resistance among target pest.[55]

As mentioned above, there are many licensing agreements issued by biotechnological companies. It is essential for producers to read the entire contract and follow the planting instructions. The seed manufacturer provides information on how far the pollen is likely to travel.[56] Producers should know what farms neighbor them and ensure that contamination is not a possibility. It would be a great idea for farmers to also be in contact with neighboring farmers and discover if they are growing any non-GMO products. If they are in fact growing non-GMO crops, they should inform the neighboring farmer of the measures they are taking to prevent genetic drift.

After the crop is planted, farmers should inspect the equipment used for farming and make sure it is thoroughly cleaned before and after use. This method will ensure that the farmer's crop is not being contaminated and also that future crops will not be contaminated by their crops. This includes trucks that transport crops. Lastly, it is significant to know who you are selling

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[54] *See Du, supra note 28, at 380–81.*
[55] Riddle, *GMO Contamination Prevention What Does it Take?*
[56] *Id.*

your crops to and their expectations. If these practices are followed it will minimize the legal liabilities associated with GMOs.

HEALTH RISKS

In the United States, scientific studies are the determining factor of health risks, instead of fear. GMOs have received a bad reputation in the public's eye because of misinformation. People believe that food products that have been altered in any way cannot be wholesome. However, food today has very little resemblance to its original state because of natural evolution from breeding and cultivation. Furthermore, there have been concerns that GMOs may have a potential toxicity and allergen issues.[57] However, there are not any peer-reviewed scientific studies that have displayed adverse health effects; in fact, the studies indicate that dietary DNA has no direct toxicity itself.[58]

In 2012, the American Association for the Advancement of Science (AAAS) stated: "Contrary to popular misconceptions, GM crops are the most extensively tested crops ever added to our food supply. There are occasional claims that feeding GM foods to animals causes aberrations ranging from digestive disorders, to sterility, tumors and premature death. Although such claims are often sensationalized and receive a great deal of media attention, none have stood up to rigorous scientific scrutiny. Indeed, a recent review of a dozen well-designed long-term animal feeding studies comparing GM and non-GM potatoes, soy, rice, corn and triticale found that the GM and their non-GM counterparts are nutritionally equivalent".[59] This statement explains that up to the date of this thesis, there are no known scientific tests that show conclusive evidence that GMOs are harmful to the public's safety.

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[57] Resnik, *Food Fights Genetically Modified Food and the Law.*
[58] *Id.* at 2.
[59] AAAS, *Labeling of Genetically Modified Foods.*

The idea of using technology on foods that humans consume is frightening for many people, especially with the false information that is available to the public. It is important that the United States continue to test products containing GMOs to ensure public safety; however, as long as scientific studies continue to display no legitimate adverse health effects there should not be any resistance to using them.

LABELING

Supporters of GMO labeling believe that they are afforded the right to know what is in their food and how it was created. Currently, the FDA's guidelines direct what constitutes a labeling requirement. The FDA is provided the authority to regulate labels under the Food, Drug, and Cosmetics Act (FDCA).[60] The FDA tests the end product of an item to determine if it should be labeled, which has been a controversial issue. Proponents of GMO labeling believe that the whole creation process should be taken into account, as opposed to only considering the end product[61]. In 1992, the FDA stated that it would not require special labeling for food products that contain GMOs, because they are not materially different than traditional foods.[62] If the end product is materially different then it must be labeled accordingly.[63] In order for the FDA to rule that a product is materially different, it must fall into one of these three categories:

(1) It poses "special health or environmental risks";

(2) If the product is misleading to the consumer. A product is misleading if it:

> "Fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling or advertising relates under the conditions of use prescribed in the labeling or advertising thereof or under such conditions of use as are customary or usual.";

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[60] U.S. Food and Drug Administration, *Significant Dates in U.S. Food and Drug Law History*
[61] U.S. Food and Drug Administration, *Biotechnology- Genetically Engineered Plants for Food & Feed*
[62] *Id.*
[63] *Id.*

(3) If the product is perceived as having similarities to other items of food, that it does not.

The legal question that arises is whether genetic engineering constitutes a "material" change. The FDA has been clear that they believe that GM products are not "materially" different from conventional food. However, even if a food product is considered to not be materially different, there are four exceptions that could require the food product to still be special labeled:

1. If a product's nutritional value is altered then the label must reflect that;
2. If the product is "significantly different from its traditional counterpart such that the common or usual name no longer adequately describes the new food";
3. If a food product contains an allergen;
4. When "an issue exists for the food or a constituent of the food regarding how the food is used or consequences of its use" because of how the food is used. In this case the issue would have to be clearly stated and described on the label.

If these four exceptions are not met then GM products will be under the same labeling requirement as traditional food.[64] This would include listing items such as the name, nutrients, calories, and ingredients. The FDA is concerned that if labeling was required, consumers would speculate that GM products are inferior to traditional food items because they are not familiar

[64] U.S. Food and Drug Administration, *Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering.*

with the term.[65] The FDA believes that since most consumers are unfamiliar with GM products, they would conclude that they are harmful and not purchase them. The FDA explains this reasoning in their guidelines by stating "a label that implies a food is better than another because it was, or was not, bioengineered would be misleading".[66] However, the FDA does allow for companies to voluntarily label products that do not contain GMOs, but the label must be approved by the FDA.[67] The FDA requires approval to ensure that companies are not implying that their food is superior to foods containing GMOs. Even though the FDA provides example statements for those companies who wish to voluntarily label, they are vague on what companies may display on their label without violating regulations.

The FDA has been challenged in court regarding their decision to forgo labeling, but the courts have always ruled in favor of the FDA. For example in *Alliance for Bio-Integrity International Center for Technology Assessment v. Shalala*, 116 F Supp. 2d 166, 170 (D.D.C. 200), The Alliance for Bio-Integrity International Center for Technology Assessment legally challenged the FDA by stating that they were too presumptive about the GMO health risks and did not fully uphold the FDCA. However, the District court ruled that the FDA's actions were reasonable and not in violation of any laws or regulations.[68] Furthermore, the court stated that

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[65] Timmons, *In Absence of Comprehensive Federal Regulation, Battles Over GMOs Being Fought in States, Localities.*
[66] Robertson, *Finding a Compromise in the Debate Over Genetically Modified Food.*
[67] *Id.*
[68] *Alliance for Bio-Integrity International Center for Technology Assessment v. Shalala*, 116 F Supp. 2d 166, 170 (D.D.C. 200).

since there are not any known health risks, requiring labeling would be strictly for consumer interest and that it is not enough to constitute labeling.[69]

First Amendment

Even if labeling laws were passed by state legislatures, these laws could potentially violate the First Amendment and the Commerce Clause. In the case of *International Dairy Foods Ass'n v. Amestoy*, 92 F. 3d Court of Appeals, (2d Cir. 1996), the federal appeals court denied the enforcement of, 6 V.S.A. § 2754, a law in Vermont that required labeling on milk from cows that were treated with a synthetic growth hormone created by genetically engineered bacteria to increase production.[70] The appellants claimed that 6 V.S.A. § 2754 was in violation of the First Amendment and the Commerce Clause of the United States Constitution.[71] They moved for a preliminary injunction, which would make 6 V.S.A. § 2754 not enforceable.[72] In order for the court to grant an injunctive relief, the claim must satisfy a two-pronged test.[73]

The first requirement of the two-pronged test is to establish irreparable harm. In *Jackson Dairy, Inc. v. HP Hood & Sons,* 596 F. 2d 70 (2d Cir.1979), the court established what constitutes irreparable harm.[74] The court stated that "Irreparable harm is an injury that is not remote or speculative but actual and imminent, and for which a monetary award cannot be adequate compensation." The Second Circuit applied this definition to the *Amestoy case* and determined that a violation of First Amendment rights undoubtedly constitutes irreparable harm.

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[69] *Id.*
[70] 92 F. 3d at 69.
[71] *Id.*
[72] *Id.*
[73] *Id.*
[74] 596 F. 2d 70 (1979).

The second requirement of the two pronged test is for the claim to result in likely success at trial. In order for the court to make this determination, the Second Circuit used a four-part test created in *Central Hudson Gas & Elec. Corp. v. Public Serv. Commission,* 447 U.S. 557 (1980), to conclude if government restriction on commercial speech is permissible.[75] The claim must meeting the following requirements:

(1) whether the expression concerns lawful activity and is not misleading;

(2) whether the government's interest is substantial;

(3) whether the labeling law directly serves the asserted interest;

(4) whether the labeling law is no more extensive than necessary.

After applying this four-part test to the facts of the case, the Second Circuit found that Vermont failed to establish likely success at trial because government's interest was not substantial.[76] It was not substantial because the labeling mandate was based on consumer interest alone, instead of health or safety concerns. The court explained their ruling by stating "Although the Court is sympathetic to the Vermont consumers who wish to know which products may derive from rBST-treated herds, their desire is insufficient to permit the State of Vermont to compel the dairy manufacturers to speak against their will,"[77]. Additionally, they added "Were consumer interest alone sufficient, there is no end to the information that states could require manufacturers to disclose about their production methods."[78] The FDA did various tests on rBST

[75] 447 U.S. 557 (1980).
[76] *Id.*
[77] *Id.*
[78] *Id.*

and they determined "that rBST has no appreciable effect on the composition of milk produced by treated cows, and that there are no human safety or health concerns associated with food products derived from cows treated with rBST."[79] Therefore, Vermont had no grounds for a counter-argument and the Second Circuit denied 6 V.S.A. § 2754, because the claim fulfilled both requirements of the two-pronged test.[80] The legislature subsequently repealed the labeling statue.

The precedent set in *International Dairy Foods Ass'n v. Amestoy*, presents a challenge for GMO labeling advocates. The ruling confirmed that GMO labeling regulation by state legislatures is unconstitutional due to a violation of commercial speech under the First Amendment. If an amendment or new law was enacted at the federal level, then there could be a possibility for a GMO labeling regulation in the United States.

Increased Costs

In 2013, Professor Bill Lesser from Cornell University conducted a study on GMO labeling to find out how much of an annual cost increase would be imposed on an average New York household, if labeling were required. He used proposed bill 3525E in the New York State Legislature for his study. The bill would have required labeling of any product that contains more than .9 percent of a GM ingredient.[81] This would be an estimated 50-58 percent of items available at supermarkets to be labeled. He found that it would cost the average household

[79] *Id.*
[80] *Id.*
[81] Lesser, *Costs of Labeling Genetically Modified Food Products in N.Y. State.*

approximately $800 more annually.[82] In addition, he found that statewide it would be an annual increase of approximately $3.9 billion.[83]

Professor Lesser also found that prices would rise by $1,556, if New York residents were forced to buy organic food at the grocery store, instead of GM foods.[84] His study also assumed that the current products containing GMO ingredients will remain on the shelves with the newly introduced labeled products. The costs associated with the labeling process would be from warehousing costs, supermarket level costs, and labeling costs.

Food products are warehoused at least a few times before they make it to the consumer. Large supermarket chains are able to have their own warehouses to store the products they buy in bulk directly from manufacturers, and smaller stores work with independent distributors who provide the same function. Warehousing produces in-and-out costs, as well as monthly storage costs. If labeling were required, the labeled items would be produced with a new stock keeping unit number in order to differentiate between the labeled and unlabeled products. The labeled product would then be purchased as a new item and warehoused with any existing inventory of the same, but unlabeled, product. This would greatly increase the number of products being warehoused, and therefore the monthly costs of warehousing.[85]

Another associated cost is providing additional space on the shelves at supermarkets. The proposed bill in New York would have introduced approximately 21,000-25,000 newly labeled

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[82] *Id.*
[83] *Id.* at 7.
[84] *Id.* at 4.
[85] *Id.* at 13.

items.[86] Most supermarkets operate on a system called "slotting allowance". This system charges manufactures to provide shelf space for new items.[87] The introduction of newly labeled products would cause prices to increase because supermarkets will have to increase their "slotting allowance".

Lastly, the redesigning and application of the new label would account for a small portion of the price increase. The actual ingredients in the product would not have to be altered, but many manufactures would redesign their label. Professor Lesser predicts that this process would have cost manufactures approximately $6.3 million.[88] The New York labeling requirement bill did not pass during the New York 2013 legislative session.

Solution

An increase in grocery costs in the United States would make it harder for families who are already struggling to provide food for their family. Current regulations allow for farmers to voluntarily grow non-GMO products and label them accordingly. The total population should not suffer because of food preferences of a certain group. The activists for labeling should purchase these foods that are voluntarily labeled, therefore, so the average consumer does not have to suffer. If scientific studies begin to present even the slightest amount of health risks, then this proposal should be amended. However, with the current information available there is not enough compelling information to prove risk to the consumer.

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[86] *Id.* at 13.
[87] *Id.* at 13.
[88] *Id.* at 15.

EUROPEAN LABELING POLICY

The United States has a different perspective on GMOs compared to the European Union. The cause of these differing perspectives is thought to be because of a change in the politics of Europe.[89] During the 1960's, the United States imposed strict regulations on health, safety, and environmental risks. The European Union was opposite with less strict regulations, and was supportive of scientific innovations. However, since that time, the two countries have interchanged viewpoints. Recently, the European Union adopted strict regulations.[90] They are skeptical about the benefits of new technological innovations created by science and biotechnology. Additionally, they have lack of trust in their government officials and industrial companies, which allows non-governmental organizations to influence policy changes.[91] In the early 1990's, England experienced Bovine Spongiform Encephalopathy (Mad Cow Disease), which dramatically raised the suspicion that government regulations are ineffective.[92] By contrast, the United States has adopted the regulatory style of the European Union in the 1960's- one that embraces technological advances and regulators working compliantly with industries.[93] Also, in the United States government there is a widespread trust in public officials and their ability to provide a fair regulation process.

To understand the current politics in the European Union, it is important to look at the history of the European regulation of biotechnology. In 1985, the European Union established

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[89] Runge, *Differing U.S. and European Perspectives on GMOs.*
[90] Lynch, *The Regulation of GMOs in Europe and the United States.*
[91] *Id.*
[92] *Id.*
[93] *Id.*

the Biotechnology Regulations Interservice Committee (BRIC) to develop biotechnology regulations. The BRIC decided to use a precautionary principle approach to risk management, which is, "When an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically."[94] Under this principle, the BRIC determined that GMOs could potentially be harmful and even though there was no scientific evidence to back this claim, they required Member States to label GMO products and provided them with the right to refuse the sale of GMOs altogether if the product poses a "risk to human health or the environment."[95] In contrast, the United States determined that there was not a need for new regulations because current laws provided adequate statutory authority and tested the end result of the product instead of the creation process.

Since the 1960's the European Union has seen an increase in the political strength of civic interests. Political parties such as the Green Party have developed to advocate for stricter regulation policies.[96] Consequently, regulatory policies have become more risk-averse. Another factor is that the European Union has struggled to structure a stable comprehensive regulatory system. Each of fifteen Member States has a regulatory system of their own and is constantly attempting to upgrade the regulatory agenda, which causes an unsound system attempting to balance scientific fear with public opinion. The public is very skeptical of the government

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[94] Science & Environmental Health Network, *Precautionary Principle*.
[95] Adler, *More Sorry Than Safe: Assessing the Precautionary Principle and the Proposed International Safety Protocol.*
[96] Lynch, *The Regulation of GMOs in Europe and the United States.*

agencies in Europe and is advocating for stronger regulations. In fact, only 12 percent of Europeans trust their national regulators compared to 90 percent in the United States.[97]

Since the United States and the European Union each have a different viewpoint on biotechnology, it has caused problems for trade. For example, in 1996, when the United States first exported GM soybean and corn to the European Union, they refused to accept the crops unless they were separated. GM crops made up 2 percent of the total shipment; however, the European Union wanted them separated. The United States exported 20 to 40 percent of its soybean supply to Europe at the time and separating the product cause increased costs and hassle.[98] Trade implications have remained since the emergence of GMOs and have a huge impact on United States exports. A few European companies completely ended trade with United States manufactures that produce GM crops. Proponents of GMO labeling believe this is another reason to label products in the United States.

The United States and European Union's cultural roots also explain their stance on GMOs. European consumers are accustomed to foods that are naturally grown with little technology involved. On the contrary, American consumers have become accustomed to processed foods.[99] Europeans consider food aesthetics more heavily than the United States, whereas quantity is favored more by the United States than quality. Another cultural difference is the viewpoints on agriculture. The European agriculture business is made up principally of small, family farms.[100] The application of technology is very limited and predominantly traditional

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[97] Enriquez, *Transforming Life, Transforming Business: The Life Science Revolution.*
[98] Lynch, *The Regulation of GMOs in Europe and the United States.*
[99] *Id.*
[100] *Id*.

more labor intensive methods are used. As previously mentioned, United States agriculture is made up mostly of large companies and welcomes new technological innovations.

The facts mentioned above display why the European Union was motivated to label GMOs. The United States is currently in a completely different situation culturally and politically. The United Sates only has one regulatory system to satisfy and it has proven to be a system that depends on scientific studies to prove if there is harm to consumers. Therefore, when analyzing the European Union implementation of a labeling policy, it should not be compared to the United Sates.

ENVIRONMENTAL BENEFITS

Imagine 11.8 million cars taken off the road and how huge of an environmental impact that would have on society. In 2012, the amount of carbon dioxide reduced by genetically engineered crops' resistance to pesticides is equivalent to 11.8 million cars taken off the road per year. Genetically engineered crops have reduced pesticide application by 224 million kg., which is a total of a 14 percent overall decrease in the environmental impact associated with pesticides.[101]

Fresh water is essential for life on earth and is a precious natural resource. Seventy percent of fresh water is used globally for agriculture.[102] Since GMOs have the ability to be drought tolerant, they can assist in lowering this number and conserve the water supply. This genetic trait is particularly useful for developing countries, where drought is more common and severe.

Soil conservation is another environmental benefit that GMOs offer. Since some GMOs are herbicide resistant, it requires less plowing of land to remove unwanted weeds. As a result of less plowing, soil is protected from soil erosion and the moisture in the soil is conserved.[103] Soil is sometimes overlooked but it is another necessary aspect needed for agriculture sustainability.

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[101] International Service for the Acquisition of Agri-biotech Applications, *Global Status of Commercialized Biotech/GM Crops: 2012*.
[102] *Id.*
[103] EuropaBio, *Does GM crops have an effect on soil?*

ENIVRONMENTAL CRITICISMS

Opponents of GMOs argue that there are associated environmental risks. They claim that the toxicity that GM crops possess to resist herbicides and pesticides is an issue because it could affect non-target organisms. One recent claim was Monarch butterflies being affected by the toxins of GMO maize plants.[104] The Monarch population has dropped 90 percent over the past 20 years, but GMOs may not be the sole factor.[105]Some of the other factors include: deforestation in Mexico where they migrate in the winter, recent weather patterns, and reduced availability of milkweed (the butterflies' main food source and where their larvae grow).[106] The deforestation in Mexico has affected the Monarch population, because it reduces the area where they migrate.[107] The deforestation is caused by illegal logging in Mexico and the Mexica government has begun placing measures to reduce this action from occurring.[108] During the winter migration to Mexico the Monarch butterflies feed on nectar from plants on the way. A recent drought in Texas has killed many plants they feed on, affecting the lifecycle of Monarch butterflies.[109] The reduced supply of Milkweed is the largest threat. The cause of a decline in Milkweed growth is not yet determined. Some scientist claim that the Milkweed is being killed form herbicide spray that most GMO crops resist, however, there is no direct evidence supporting this claim.[110] It appears

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[104] Glass, *The environmental Impact of GMOs.*
[105] The Center for Biological Diversity, *GE Crops Are Major Driver in Population Crash.*
[106] Carroll, *Are GMOs causing monarch butterflies to become extinct?*
[107] *Id.*
[108] Plumer, *Monarch butterflies keep disappearing. Here's why*.
[109] *Id.*
[110] *Id.*

that GMOs may have contributed to the decline in the Monarch population, however, they are not the sole cause.

Another environmental concern is the spread of "super weeds", which are weeds that have developed a greater resistance to herbicide sprays and become invasive. Some scientist believe that GM resistant plants transfer genes through cross pollination to these weeds. However, this is very unlikely because of pollen incompatibility, varying numbers of chromosomes and other factors that serve as impediments for crops and weeds to cross pollinate.[111]GMOs are not the reason "super weeds" for Weeds; in fact, weeds have exhibited resistance to herbicides long before the creation of GM herbicide resistant crops.[112] The environmental claims made by opponents appear to be more of a correlation instead of a causation.

[111] Hanson, *Dispelling Common Misconceptions about Superweeds*
[112] *Id.*

WORLD HUNGER AND FUTURE BENEFITS

Across the globe, countless deaths are associated with starvation and malnutrition. GMOs have the ability to produce higher yields on smaller pieces of land while adding nutritional value to crops; these could play a key factor in reducing world hunger. Also, recent GM crops have been modified to provide medical and health benefits.

Since 1996, GMOs have increased farmers' income totals by a total of $44.1 billion, half of which is in developing countries. Farmers in developing countries have received $3.74 for each dollar invested GM seeds in 2012.[113] The production of GMOs in developing countries is essential to their survival; however, some government authorities do not permit the planting of GM seeds because of safety concerns.[114] Developing countries battle harsh weather conditions, famine, and pests, which results in a struggle to provide food for their people. These countries do not have the resources to effectively control pests and weeds. GM seeds assist in overcoming these obstacles and are relatively easy for farmers to cultivate because the traits are engineered into the seed.

Although the resources available to developing countries do not effectively deter pests, farmers still spend a great amount of time spraying in an effort to reduce the amount of pests. The use of GM crops that are insect resistant that do not require spraying, will allow the farmer to have more available time for other farming activities or other income earning undertakings.

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[113] Brookes, Graham, and Peter Barfoot, *Focus on Yields*
[114] Azadi, *Genetically modified and organic crops in developing countries: A review of options for food security.*

An insufficient food supply is not the only cause of death in developing countries; malnutrition is also a huge contributor. Approximately two hundred and fifty million children across the globe currently have a Vitamin A deficiency, which is the leading cause of preventable blindness and immunodeficiency; of those, two million are expected to die from the deficiency.[115] A solution to this problem could be a GMO crop such as Golden Rice, which is rice that is genetically modified to consist of high levels of vitamin A. Many countries that are poverty stricken have a dependence on rice, which does not contain Vitamin A, causing a deficiency.[116] Additionally, Golden Rice is a fertile crop, which means it can be grown and the seeds can be used for next year's crop. If these countries could be taught to farm Golden Rice, then the deficiency would decrease.

GMOs may provide potential future benefits; for example, there is currently a GMO tobacco plant that is under testing for a cure to Ebola called ZMapp. It was used to treat two Ebola patients earlier this year before supplies ran out. It has not been approved by the FDA but does show a great potential for medical related research. Also, a GM potato was recently approved for commercial planting by the United States Department of Agriculture. This potato is altered so that it does not contain the chemical acrylamide, which is suspected to be a cause of cancer when the potato is fried.[117]

Population Increase

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[115] Golden Rice Project, *Vitamin A Deficiency-Related Disorders.*
[116] *Id.*
[117] ZMappTM.

In the face of a projected population of nine billion by 2050, GMOs are vital to the battle against world hunger.[118] Even at a time when agricultural productivity has improved dramatically over the past 50 years, the demand for food may be outgrowing the supply. Economists are projecting the need for food to increase by 70 to 100 percent, and almost double in developing countries[119]. It is important for the world to learn from the past and look at Dr. Borlaug's implementation of GMO crops to save billions of lives and how essential GMOs are to providing a food supply that can feed the increased population.

Economic forecasters analyze the gross domestic product (GDP) per capita to determine the per capita food demand.[120] As illustrated in Figure 4, per capita GDP has increased greatly over the past few decades and has been accompanied by a global population increase.[121] This data is significant to the world hunger discussion because population and economic growth drive growth in food demand.

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[118] Rotman, *GMOs Could be an Important Tool in Feeding the World.*
[119] *Id.*
[120] ITIF, *Feeding the Planet in a Warming World*
[121] *Id.*

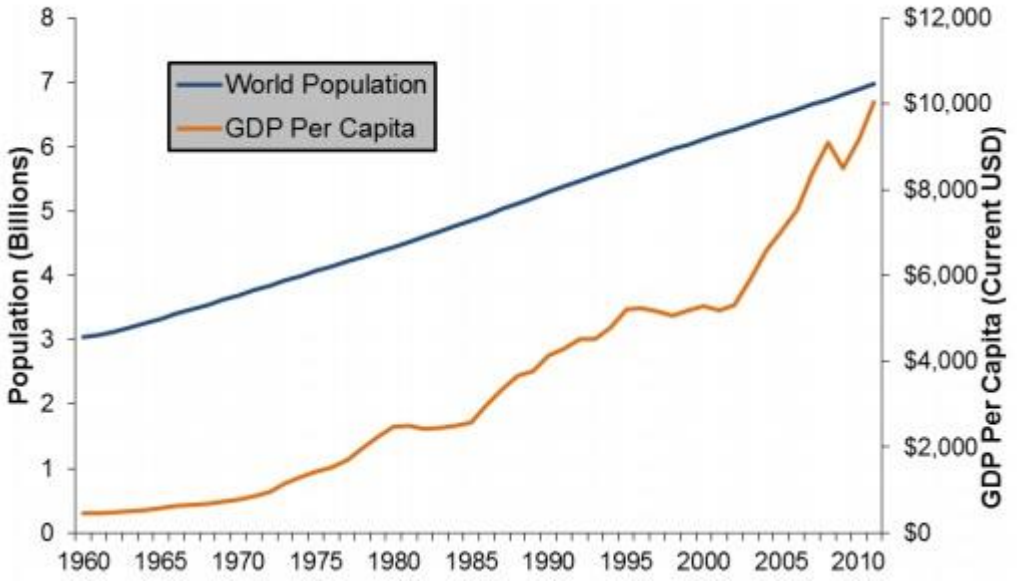

Figure 4: Global Population and GPD Per Capita in Current U.S. Dollars; 1960-2011

Currently, there is already a struggle to provide adequate nutrition to the world population. According to the Food and Agriculture Organization (FAO), 870 million people are starving, 98 percent are in developing countries.[122] For the world to meet the food demand with a growing population and economy, they must implement GMOs into their agricultural practices.

Climate Change

The forecasted population increase will present a great challenge for the food demand to meet the supply, but climate change will bring about further complications. The United States Department of Agriculture released a report that forecasts an upcoming climate change.[123] Temperatures will reach to record highs and lows. These harsh temperatures will be

[122] *Id.at 8*
[123] Walthall et al., *Climate Change and Agriculture in the United States: Effects and Adaptation*.

accompanied by severe storms, droughts, and floods. GMOs will essential during this time period because of the traits that allow them to survive in these extreme conditions. Crops can be genetically engineered to survive in conditions that receive little precipitation and have scorching temperatures.

A sudden climate change for crops, will cause them to die because of the inability to adapt. Genetically modified seeds could play a role if a climate change crisis occurred because of the short time it takes to produce a sustainable seed. It takes less than six months to produce a genetically modified seed, however, it takes at least 15 years to create a new seed by using traditional propagation breeding methods[124].

[124] *Id.*

CONCLUSION

Genetically engineered food is a relatively new discovery but is grown all over of the world and is being consumed by the majority of the population. Any food item used in such a widespread area will inevitably encounter critics and proponents, legal liabilities, and regulation concerns. Farmers who produce GMOs must be aware of the associated liabilities and take all necessary steps to protect themselves from legal action. The United States should amend their regulatory framework so that it provides a balance of rights between the GM seed producer, GM seed grower, and the non-GMO grower. The health risks and labeling issues coincide with each other because if health effects are not present, then labeling should not be mandated. Scientific studies have repeatedly shown that there are not any health effects associated with consuming GMOs. The European Union's recent political change has given GMOs a negative connotation throughout the country. The wealthy European Union can afford to make these restrictions and be selective about what they eat; however, developing countries cannot. Governmental authorities in developing countries are endangering their population by banning GMOs and should reform GMO regulations. The United States government is currently basing their stance on GMOs by analyzing scientific studies. This is the correct way to measure risk and all others should join the United States. Labeling foods that contain GMOs has been a controversy following biotechnology since its emergence in food products. A comprehensive labeling mandate in the United States would raise grocery prices and the public's misconception of GMOs will be furthered. If companies wish to label their food products, this can be done voluntarily, but there is no basis for mandatory labeling of GMOs.

A population increase accompanied by a food shortage has taken place before in history. During the Green Revolution, Dr. Norman Borlaug assisted in defeating this food shortage and saved millions of lives by using GM seeds. A predicted crisis is looming in the future and GMOs are essential to feeding the world, especially developing countries. A second Green Revolution driven by GMOs will need to take place to increase the crop productivity so that it meets the demand of the growing population and can survive in extreme climate conditions.

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