What’s in a name: the Vermont Genetically Engineered Food Labeling Act

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ABSTRACT

On May 8, 2014, Vermont passed the Vermont Genetically Engineered Food Labeling Act (Act) requiring labels on certain genetically engineered foods. Once the bill takes effect July 1, 2016, all Vermont-retailed foods with more than 0.9% of their total weight in genetically modified ingredients must be labeled with language stating, “may be partially produced with genetic engineering.” As genetically engineered food are considered scientifically equivalent to their traditional counterparts and are not subject to federal labeling by the FDA, the Act presents several legal questions. Several of the legal questions have been raised in a recent lawsuit filed by the Grocery Manufacturers Association that claims the Act violates the First Amendment, Supremacy Clause, and Commerce Clause. This paper will discuss why the Second Circuit could strike down the Act as unconstitutional as to each claim.

KEYWORDS: genetic engineered, food, Vermont, labeling, pre-emption, FDA

On May 8, 2014, Governor Peter Shumlin signed the Vermont Genetically Engineered Food Labeling Act (Act) into law, requiring most genetically engineered (GE) foods sold in Vermont to be so labeled beginning in July 2016. Although Vermont is the first

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1 An Act relating to the labeling of food produced with genetic engineering, No. 120, § 6, 2014 Vermont Acts [codified at 9 V.S.A. §§ 3041, 3048 (2014)].
state to pass this type of legislation, it is not the first state to try. More than 25 other states have attempted similar actions through legislative and voter initiatives. Three states have passed ‘restrictive’ food labeling statutes—Alaska has mandatory labeling laws for GE fish, and Maine and Connecticut have labeling laws that are triggered once additional states pass corresponding laws. Vermont, therefore, does not stand alone on the edge of food labeling, but its Act presents a unique opportunity to analyze the policy, politics, and merits of the broad GE food labeling about to come into force. This paper will address the debate and noise surrounding GE labels by discussing why GE foods should not require special labeling, and why the Act may be struck down as unconstitutional.

I. SHOULD GE PRODUCTS REQUIRE SPECIAL LABELING REQUIREMENTS?

A. The Vermont Act

Effective July 1, 2016, any food produced, licensed, imported, processed, or distributed for sale in Vermont containing GE food will need to be appropriately labeled. The Act broadly regulates any ‘food intended for human consumption’ and distinguishes labels for raw or processed food. If the food is a GE raw agricultural commodity, it must be labeled with the words ‘produced from genetic engineering’ either on the packaging or with a label on the retail shelf. If the food is processed and contains greater than 0.9% GE materials by aggregate weight, its packaging must contain the words ‘partially produced with genetic engineering’, ‘may be produced with genetic engineering’, or ‘produced with genetic engineering’. The Act does not require specific ingredient identification or the placement of the term ‘genetically engineered’ immediately before any common name or primary product descriptor of a food.

B. Defining GE Foods

In the Act, ‘genetically engineered’ refers to any food or food ingredient that is produced from an organism or organisms in which the genetic material has been changed through the application of in vitro techniques (including recombinant DNA and injection of nucleic acid) or through the fusion of cells. It also prohibits any food produced entirely or partially from genetic engineering techniques from being labeled or advertised with words such as ‘natural’, ‘naturally made’, ‘naturally grown’, etc.

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2 Alison V. Eenennaam et al., The Potential Impacts of Mandatory Labeling for Genetically Engineered Food in the United States, CAST ISSUE PAPER, Apr. 2014, at 3, https://www.cast-science.org/file.cfm/media/products/digitalproducts/CAST_Issue_Paper_54_web_optimized_29B2AB16AD687.pdf (last accessed June 29, 2014) (the student would like to recognize that this paper provides an excellent and comprehensive source of legal and scientific analysis on GE labeling.)

3 Id.

4 Id. at 3, 4.


6 9 V.S.A § 3042(3).

7 9 V.S.A § 3044(b)(1).

8 Id. at § 3044(b)(3).

9 9 V.S.A § 3043(d).

10 9 V.S.A § 3042(4)(A).

11 9 V.S.A § 3043(3)(C).
C. Labeling Exceptions in the Statute

Despite the labeling requirements for GE products, several food products are exempt.\(^{12}\)

1. Animals or animal products that are not themselves genetically modified but might be injected or fed with genetically modified products.
2. Milk products, until the attorney general reports on or before January 2015.
3. Alcoholic beverages.
4. Processed foods that would be labeled solely because of a processing aid or enzyme produced with genetic engineering.
5. Raw agricultural commodity or processed food that has been grown, raised, or produced without the knowing or intentional use of food or seed produced with genetic engineering.
6. Food served, sold, or otherwise provided in a restaurant or other food establishment.
7. Food certified by an independent organization as not having been knowingly or intentionally produced from or commingled with food or seed produced with genetic engineering; unpackaged processed.
8. Processed food that is not packaged and intended for immediate human consumption.
9. Medical food.

D. Legislative Motivations for Requiring Labeling

The Vermont legislature asserted that ‘there is a lack of consensus regarding the validity of the research and science surrounding the safety of genetically engineered foods’ and that ‘genetically engineered foods potentially pose risks to health, safety, agriculture, and the environment’.\(^{13}\) This reflects attitudes of the precautionary principle, which caution that ‘if a course of action carries even some remote chance of irreparable damage, then one should not pursue it, no matter how great the benefits may be’.\(^{14}\) The Act also states that ‘labeling food as produced from genetic engineering will reduce consumer confusion and deception regarding the food they purchase’.\(^{15}\)

E. Assessing Vermont’s Justifications

1. Safety of GE Products

Although the Act tracks public opinion about health and environmental concerns, public opinion often ignores the ‘already established and solid basis for a science based discussion on GMO biosafety’.\(^{16}\) As recognized in the European Union 2010 report on GE foods, science is better suited to ‘certify the existence of danger, not its absence’.\(^{17}\) The report instead called for an abandonment of the precautionary principle in favor

\(^{12}\) 9 V.S.A. § 3044; an Act relating to the labeling of food produced with genetic engineering, No. 120, § 6.

\(^{13}\) An Act relating to the labeling of food produced with genetic engineering, No. 120, § 1, 2014 Vermont Acts.


\(^{15}\) 9 V.S.A. § 3041 (3).

\(^{16}\) European Commission, supra note 14, at 246.

\(^{17}\) European Commission, supra note 14, at 22.
of ‘striking’ a balance between the advantage and disadvantages’ of agro-genetic technologies.\(^1\)

Yet even though not proving the impossible—that there exists no possible risk—the overwhelming body of scientific literature confirms that the use of GE techniques in agriculture is safe for humans and the environment.\(^2\) The American Medical Association and the National Academies of Science agree that foods derived from genetic engineering are just as safe as foods with ingredients produced from other methods.\(^3\) Since 1996, the FDA has found no safety or nutritional problems of GE crops when compared to their ‘natural’ counterparts.\(^4\) The American Association for the Advancement of Science considers GE crops the most ‘extensively tested crops ever added to our food supply’.\(^5\) There have been no differences observed between animals fed conventional or biotech crops or their products.\(^6\) For more than a decade, ‘hundreds of millions of people’ have eaten GE food without proof of any verifiable harm to consumers or the environment.\(^7\) Finally, over one hundred peer-reviewed, independent studies have confirmed that there are no adverse effects from the ‘consumption of currently available biotech crops’.\(^8\)

Further, the Act itself undermines its claimed safety concerns; if something is inherently wrong with genetically modified foods, why are there so many labeling exceptions?\(^9\) For example, hard cheeses (currently an exempt food) are often produced by adding rennet to coagulating milk.\(^10\) The active ingredient in rennet is the enzyme chymosin, which until 1990 was produced from the stomach of slaughtered calves.\(^11\) Since then, rennet has been produced using GE bacteria. It has been widely used in both Europe and the USA because consumers valued humane substitutes.\(^12\)

(2) Consumer ‘Confusion and Deception’

By specifying which forms of GE techniques must be labeled, the Act attempts to pronounce that GE is ‘unnatural’. With the widespread use of GE technology over the past 20 years, Vermont’s decision seems both anachronistic and more likely to confuse consumers.

The concept of what is ‘natural’ changes over time. For example, 200 years ago it was common belief that organic compounds derived from living organisms were ‘fundamentally different’ than products derived from inorganic compounds.\(^13\) This notion was overturned in the 19th century, when chemists were able to synthesize urea,
previously considered a natural/organic compound, from inorganic sources.\textsuperscript{31} As urea could then be produced independently, outside the kidneys of animals, organic chemistry was no longer ‘the study of substances from living sources’, but the ‘study of carbon compounds’ regardless of production techniques.\textsuperscript{32}

Similarly, it is now understood that genetic modifications occur spontaneously in nature.\textsuperscript{33} Since the development of agriculture, farmers have deliberately selected, improved, and cultivated crops with desired characteristics.\textsuperscript{34} The success of breeding has relied on genetic variation, artificial selection, and direct cross-pollination to create favorable genetic combinations.\textsuperscript{35} More so, genetic mutations are often created by exposing seeds to radiation or chemicals, which do not require GE labeling under Vermont’s statute.\textsuperscript{36} Therefore, the main difference is that traditional breeding depends on phenotypic selection, while genomic engineering depends on deliberate manipulation based on the relationship between genotypes and phenotypes.\textsuperscript{37}

GE foods have been found to be equivalent to their traditional counterparts and have been confirmed safe after 30 years of use in humans. The precautionary principle should not be undertaken in Vermont; debate should be centered over which foods and food production techniques should be introduced to generate greater overall benefits while minimizing risks.

\textbf{II. CAN VERMONT LEGALLY REQUIRE GE LABELING?}

\textbf{A. The Legal Battles}

On June 12, 2014, the Grocery Manufacturers Association, combined with the Snack Food Association, International Dairy Foods Association, and the National Association of Manufacturers, filed suit against Vermont asserting that the Act violates the First, Third, and Fourteenth Amendments, the Commerce Clause, and the Supremacy Clause.\textsuperscript{38} Considering that the recombinant bovine Somatotropin (rBST)-labeling fight was waged in Vermont 20 years ago on similar grounds, the plaintiffs and causes of actions were not surprising.\textsuperscript{39} Therefore, the Act also creates a GE Food Labeling Special Fund ‘to pay the costs and liabilities’ incurred by the attorney general in implementing the requirements of the Act.\textsuperscript{40}

\textbf{B. Federal Pre-emption}

The Grocery Association complaint asserts that the Federal Food, Drug, and Cosmetic Act (FDCA), the Nutrition Labeling and Education Act, and the Federal Meat Inspection Act (FMIA) all pre-empt Vermont’s legislation.\textsuperscript{41} The federal pre-emption doctrine is rooted in the Supremacy Clause of the US Constitution, which holds that

\begin{itemize}
\item \textsuperscript{31} Id. at 56.
\item Id.
\item \textsuperscript{33} Eenennaam et al., \textit{supra} note 2, at 5, 6.
\item Id.
\item \textsuperscript{35} Pérez-de-Castro et al., \textit{Application of Genomic Tools in Plant Breeding}, 13 CURR. GENOM. 179 (2012).
\item \textsuperscript{36} Eenennaam et al., \textit{supra} note 2, at 6.
\item \textsuperscript{37} Pérez-de-Castro et al., \textit{supra} note 35, at 179, 180.
\item \textsuperscript{38} Grocery Manufacturers Ass'n v. Vermont, Case 5:14-cv-00117-cr, filed June 12, 2014, Compl. § 34.
\item \textsuperscript{39} Int'l Dairy Foods Ass'n v. Amestoy, 92 F.3d 67 (2d Cir. 1996).
\item \textsuperscript{40} An Act relating to the labeling of food produced with genetic engineering, No. 120, § 4, 2014 Vermont Acts.
\item \textsuperscript{41} Grocery Manufacturers Ass'n v. Vermont, \textit{supra} note 38.
\end{itemize}
the laws of the federal government are the ‘supreme law of the land’. Under the Supremacy Clause, federal law can pre-empt state law through (a) express pre-emption or (b) implied pre-emption, which is further classified as either field pre-emption or conflict pre-emption. Field pre-emption occurs when Congress has reserved a field for federal regulation, ‘leaving no room for state regulation’. Implied conflict pre-emption instead occurs when it is impossible to comply with both state and federal regulations.

In 1990, Congress amended the FDCA with the passage of the National Labeling and Education Act Act (NLEA) to strengthen the FDA’s authority to add nutrition labels on foods. The NLEA contains an express pre-emption provision that prohibits any labeling requirement that is ‘not-identical’ to federal regulations. However, it also directs courts to not find implied pre-emption in any provision, such that pre-emption can only occur in products explicitly listed under at least one category in 21 U.S.C. § 343–1. These expressly pre-empted categories can be broken down into three main areas: (1) standard of identity, (2) food nutrition labeling, and (3) nutrition levels and health claims.

The FDCA contains no mention of genetic labeling. From this, Vermont will argue that there is no congressional intent to regulate in the genetic labeling area. With regard to each category of activities under the NLEA, Vermont will assert that genetic labeling (1) does not change the ‘identity’ of the product as ‘bread’ would still be labeled bread, (2) does not state nutrition information, and (3) does not constitute a health claim.

The Grocery Manufacturers may point to the FDA’s express consideration, and decision not to make labeling a requirement, as evidence that the FDA already acted. This argument is weak—the FDA’s draft guidance is explicitly non-binding and the pre-emption doctrine turns on congressional intent as articulated through the language of the NLEA, rather than the FDA’s interpretation of the NLEA. Therefore, it seems unlikely that courts would find congressional intent to pre-empt state law from any explicit category within the FDCA.

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43 Id.
44 Id. at 335.
45 Id. at 339.
47 See Pub. L. No. 101–535, [the NLEA (Public Law 101–535) and Section 403A of the FDCA expressly pre-empt inconsistent state labeling laws and provides that ’[n]o subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce; (2) [a]ny requirement for the labeling of food of the type required by [the sections related to misbranded articles] that is not identical to the requirement of such section. ’].
48 Holk, 575 F.3d at 336.
50 Id. at 532, 536.
51 See United States v. Locke, 529 U.S. 89, 107 (2000) (stating that the court must ‘start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress’).
The Grocery Manufacturers’ argument that the FMIA pre-empts state action is stronger. The FMIA contains specific pre-emption language and broadly defines ‘labeling’ to include all ‘written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article’. The Acts’ labeling requirements—‘produced or partially produced with genetic engineering’—are demonstrably different than those labeling mandated under 21 U.S.C. § 678. Further, Vermont’s prohibition of ‘natural’ claims on GE products is in direct conflict, as the United States Department of Agriculture (USDA) definition of ‘naturally raised’ only refers to the absence of growth promotants, antibiotics, and animal by-products fed, not genetic engineering.

Although no GE animals have yet been approved for food consumption, the Act’s broad inclusion of animal products should be pre-empted by the FMIA. In 2012, the Supreme Court overturned the Ninth Circuit’s more lenient interpretation of the FMIA’s slaughterhouse inspection requirements that allowed California to regulate the treatment of ‘nonambulatory animals’. The Court noted that the ‘FMIA’s preemption clause sweeps broadly’ to prevent one state from substituting its own regulatory scheme for the federal regulatory scheme.

C. First Amendment Rights

Perhaps the more controversial and timely issue is whether the Act violates the First Amendment. Although the Supreme Court has noted that there is a difference between ‘compelled speech and compelled silence’, it has ruled that ‘the difference is without constitutional significance’.

Courts first consider whether the speech is ‘commercial or non-commercial’ in nature. Because of the dramatic difference in standards applied to each type, the classification adopted by the court can often determine the outcome. For non-commercial speech, courts apply the highest level of scrutiny to state restrictions or mandates. States must show that the regulation ‘is necessary to serve a compelling state interest and is narrowly drawn to achieve that end’. Alternatively, state restrictions or mandates to compel speech that is purely commercial must only meet a less rigorous, four-part
Central Hudson test:

At the outset, commercial speech enjoys no First Amendment protection at all unless it is not misleading (and relates to lawful activity). If the speech passes that test, it is nonetheless subject to regulation if the government has a substantial interest in regulating the speech, the regulation directly advances that interest, and it is no more intrusive than necessary to accomplish its goal.64

The Grocery Manufacturers Association will argue that Vermont’s law is forcing manufacturers to convey a non-commercial, government message, and should be subject to strict First Amendment Scrutiny. Under strict scrutiny, it would surely be struck down for lack of compelling state interest.

However, any court analyzing whether GE and ‘natural’ labeling constitute ‘commercial or non-commercial speech’ would most likely apply the more lenient standard first. In International Dairy, the Second Circuit declined to specifically rule on whether labeling milk products produced with rBST constituted non-commercial speech. As the court found that the labeling law did not even meet the intermediate scrutiny test, it didn’t need to reach the merits of whether it could be subject to the strict scrutiny test as well.65

The law struck down in International Dairy required dairy manufacturers to choose between four labeling options for dairy products containing milk from cows treated with rBST.66 The Second Circuit held that with regard to the state interest, ‘consumer curiosity alone’ was insufficient to justify the labeling requirement.67 For GE labeling, Vermont has been careful to point out health, environmental, religious, and consumer reasons, but the lack of substantial evidence that GE products are different than traditionally grown food weakens these proposed interests.68

There are potential challenges for GE labeling under other parts of the Central Hudson test as well. Unlike rBST labeling, which would accurately identify the use of hormone injections in dairy animals, ‘genetically engineered’ or ‘natural’ could be construed as misleading because there are no standards for these terms.

Further, as the law will affect ‘70–80% of the packaged foods in the supermarket’,69 the state action should not be considered ‘narrowly tailored’ following the Supreme Court’s decision in Brown v. Entertainment Merchants Association.70 In Brown, the Court held that if there is ‘publicly available information’ that is sufficient to alert consumers to the state’s concern, additional labeling requirements are unjustified.71 As argued by the

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65 Id. at 71, 74.
66 6 V.S.A. § 2754; Int’l Dairy Foods Ass’n, 92 F.3d at 73, 74.
68 An Act relating to the labeling of food produced with genetic engineering, No. 120, § 1, 2014 Vermont Acts.
69 Id.
70 Brown v. Entm’t Merchants Ass’n, 131 S. Ct. 27, 29 (2011); Vermont Senate Committee on Judiciary, May 6, 2013 (testimony from Karin Moore, Vice President and General Counsel, Grocery Manufacturers Association).
71 Brown, 131 S. Ct. at 29; Vermont Senate Committee on Judiciary, May 6, 2013 (testimony from Karin Moore, Vice President and General Counsel, Grocery Manufacturers Association).
Grocery Manufacturers Association General Counsel during the legislative hearings, ‘consumers can already make the assumption that if they’re picking up a product in the supermarket, and that product is not labeled “organic,” it contains an ingredient derived from genetic engineering’.  

Vermont will argue that the more lenient test used in Zauderer should be applied rather than the Central Hudson test. In Zauderer, the Second Circuit stated that regulations compelling commercial ‘factual disclosures’ were subject to a lower standard of judicial review—the ‘rational basis test’.  

When deciding which standard of review to apply to the mandatory labeling of calorie content in New York City restaurants, the Second Circuit concluded that the rational approach was more appropriate than the Central Hudson test because International Dairy should be read as ‘limited to cases in which a state disclosure requirement is supported by no interest other than the gratification of “consumer curiosity”’. As the law compelled the disclosure of purely factual calorie information, New York City only had to demonstrate a ‘reasonable relationship’ between the purpose of the statute and the means employed to achieve that purpose. As New York City had strong interests in reducing consumer confusion and obesity, the court found that additional calorie labels were a valid means to those ends.  

Therefore, whether Vermont’s law violates the First Amendment may depend on whether GE labeling is closer to rBST hormone or to restaurant calorie content labeling. On the face of the arguments, GE labeling is closer to rBST labeling for three reasons. Unlike the obesity epidemic, the problems with GE foods as an integral part of the food system have not been established, public opinion about GE products highlights the notion that consumer curiosity is driving the legislation, and the FDA has regulated calorie labeling in other packaged foods, whereas the FDA declined to mandate rBST or GE labeling because there is no ‘material difference’ between the modified products and traditional food products. Further, the terms ‘natural’ or ‘genetically engineered’ do not have a fixed definition that can be confirmed through truly factual bases. Courts may also consider whether, like calorie information, requiring GE labels promotes the public policy goals of giving consumers tools to make informed decisions about food consumption. The weight of the scientific evidence indicates it does not.

D. Dormant Commerce Clause

‘For the same reason that a state cannot prohibit interstate commerce, a state cannot impose an unreasonable burden on it.’  The Dormant Commerce Clause is the recognition that the Commerce Clause limits the ability of states to pass legislation that

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72 Vermont Senate Committee on Judiciary, May 6, 2013 (testimony from Karin Moore, Vice President and General Counsel, Grocery Manufacturers Association).
73 See generally, Zauderer v. Office of Dist. Counsel, 471 U.S. 626 (1985) (the court found that because the extension of First Amendment protection to commercial speech was justified by the value to consumers of the information such speech provides, the State may require a commercial actor ‘to provide somewhat more information than they might otherwise be inclined to present’).
75 Id. at 134 (quotation omitted, citing Sorrell, 272 F.3d at 115 no. 6.)
76 Id.
77 Id.
78 8 Witkin, Const Law, § 1300, Summary 10th (2005) at 1000.
threatens the flow of interstate commerce.\textsuperscript{79} The Dormant Commerce Clause works under a two-tiered approach. Tier-one laws that give ‘differential treatment of in-state and out-of-state economic interests that benefits the former and burdens the latter’ receive strict scrutiny.\textsuperscript{80} To survive strict scrutiny, the law must demonstrate the existence of a ‘legitimate, non-protectionist local purpose and the absence of nondiscriminatory alternatives’.\textsuperscript{81} Vermont will claim that there are no facial distinctions between the in-state and out-of-state products under the statute.\textsuperscript{82} The manufactures will point to the language in the statute ‘that promotion and protection of Vermont agriculture is a purpose of the legislation’.\textsuperscript{83}

Tier-two laws are afforded a ‘less-rigorous balancing test’—the \textit{Pike} balancing test—in which the law will be upheld unless the ‘burden imposed on such commerce is clearly excessive in relation to the putative local benefits’.\textsuperscript{84, 85} The manufacturers will argue that the lack of local benefits is clearly outweighed by the distribution and manufacturing effects on out-of-state food systems.\textsuperscript{86} Again, the statute could only withstand the \textit{Pike} test if the court recognized the public health, environmental, and safety reasons of the legislation.

Finally, courts could strike down the statute if it is considered ‘extraterritorial’ in that the practical effect of ‘regulating commerce occurring wholly outside the borders of the regulating state’.\textsuperscript{87} Courts have inconsistently decided whether to apply the \textit{Pike} balancing or extraterritorial standard to many laws, even though the standard applied is often outcome determinative.\textsuperscript{88} As there is little case law regarding the Dormant Commerce Clause, it seems that a court would not strike it down on the Commerce Clause unless it felt that Vermont’s interests were solely self-interested and discriminatory.

**CONCLUSIONS**

The Act should not withstand constitutional scrutiny. First, it will most likely be preempted as applied to the FMIA. Second, Vermont’s legal authority depends on the inherent scientific and policy merits of GE labeling—the conclusion that GE products pose no immediate public problem should mean that there is insufficient state interest under the First Amendment or Commerce Clause. This type of legislation could also be deemed discriminatory as most of the GE crops are inherently produced out of the state. Like rBST labeling, courts should decline to allow Vermont to legislate in an area that has only become controversial for the private interests at stake, rather than a valid public interest.

\textsuperscript{79} Id.  
\textsuperscript{80} Id.  
\textsuperscript{81} Id.  
\textsuperscript{82} Vermont Senate Committee on Judiciary, Mar. 19, 2014 (testimony by Laura Murphy, Associate Director, Environmental and Natural Resources Law Clinic, Vermont Law School).  
\textsuperscript{83} Vermont Senate Committee on Judiciary, May 6, 2013 (testimony from Karin Moore, Vice President and General Counsel, Grocery Manufacturers Association).  
\textsuperscript{86} Vermont Senate Committee on Judiciary, Mar. 19, 2014 (testimony by Laura Murphy, Associate Director, Environmental and Natural Resources Law Clinic, Vermont Law School).  
\textsuperscript{87} Sears, supra note 85, at 166.  
\textsuperscript{88} Id. at 189.