Preparing California for Genetically Engineered Salmon

University of California, Hastings College of the Law
Center for State and Local Government Law
Eric Dang and Itak Moradi, J.D. Candidates

December 2014

This report does not represent the views or policies of UC Hastings College of the Law, its Board of Directors or Faculty
Executive Summary ................................................................. 1
Background ............................................................................. 4
Introduction ............................................................................. 6
California’s Seven Policy Options and their Legal Impediments ......................... 7
An Overview of What Works and What Doesn’t .................................................. 7
I. Preemption ............................................................................ 9
  A. Express Preemption: The NLEA ........................................... 11
  B. Implied Preemption: The NLEA, NADA AND “Field” PREEMPTION .......... 16
     “All-Natural Snapple” Case Study for Implied Preemption: ....................... 16
  C. CONFLICT Preemption: THE NLEA and Beyond ......................... 20
     HIGHLIGHTS OF THE PREEMPTION DOCTRINE & ANALYSIS ........... 23
II. First Amendment: Compelled Commercial Speech ........................................ 25
    Applying The Doctrine ................................................................ 27
    A. The difficulty of determining the appropriate test .................................. 28
    B. Deciding On an Appropriate State Purpose ........................................ 30
       The Necessity for a “Factual and Uncontroversial” Label – Distinguishing ........ 33
       CTIA—The Wireless Ass’n v. San Francisco ......................................... 33
       HIGHLIGHTS OF THE FIRST AMENDMENT DOCTRINE & ANALYSIS .... 34
III. Dormant Commerce Clause .......................................................... 35
    Applying The Doctrine ................................................................ 35
    A. Discrimination Against Interstate Commerce ................................... 36
       Washington State Apple: A Case Involving Discriminatory Intent: ......... 37
       Boggs: A Case Without Discriminatory Intent .................................... 38
    B. Extraterritorial Effect ................................................................... 40
       Foie Gras: A Case Without Extraterritorial Effect ............................... 40
       California’s Greenhouse Gases: A Case Without Extraterritorial Reach .... 41
    C. Pike Balancing ......................................................................... 43
       Mercury Labeling: A Case that Survives the Pike Balancing Test ............ 43
       Imitation Cheese: A Case that Survives Pike Balancing ....................... 44
       Revisiting the Boggs Case and its Application of the Pike Test ................ 45
       Another Look at the Foie Gras Case and its Application of the Pike Test .... 45
       HIGHLIGHTS OF THE DORMANT COMMERCE CLAUSE DOCTRINE & ANALYSIS .... 47
IV. Drafting Tips for GMO Legislation .................................................................. 48
V. California’s Other Policy Options: Why They Don’t Work .................................. 50
Executive Summary

The U.S. Food and Drug Administration (FDA) is on the verge of deciding whether to approve AquAdvantage transgenic salmon as the first genetically engineered (GE) animal product sold for human consumption in the United States. Because the FDA concluded in 2010 and 2012 that AquAdvantage salmon 1) is not materially different from Atlantic salmon; 2) is safe for human consumption; and, 3) poses no U.S. environmental threat, experts believe it likely the FDA will grant approval.

The popular debate over GE foods is far from settled, however. While the FDA has found GE salmon to be “as safe as” conventionally farmed salmon, lingering concerns remain as to the allergenicity of GE salmon. The scientific community is still uncertain whether GE salmon poses a risk to health and the environment. While the FDA’s pending regulatory approval will probably be premised on findings that GE salmon is generally recognized as safe, the lack of definitive scientific evidence at once concerns consumers, legislators and activists.

Assuming the FDA allows GE salmon to enter U.S markets, can California act independently to address concerns about the salmon’s safety and its environmental impacts? This Report explores options available to California: these options range from 1) an independent California approval process to supplement the FDA’s; 2) inspections outside of California; 3) environmental regulation; 4) importation bans based on an unhealthy standard; 5) mandatory GE labeling; 6) point-of-sale caution signage; and 7) an outright ban on the sale of GE salmon in California. This report concludes only two are feasible, legally: a **GE labeling requirement** or an **outright ban**.

California must, however, craft legislation carefully to meet exacting standards, or any legislation will be vulnerable to being overturned by the courts. As an overarching matter, the lack of scientific proof about GE salmon’s health risks imperils the legislature’s ability to protect Californians’ health.

**Product Labeling**

The legislature could pass a law require GE salmon producers to label their products as genetically engineered. For a labeling requirement to be valid, it needs to be premised on a strong state interest. Because the FDA approval is likely to be based on a finding that GE salmon is safe for consumers and the environment, the labeling requirement would need to be premised on state interests other than health and safety.

Because the FDA does not regulate moral, ethical or socioeconomic issues related to new foods and drugs, legislation premised on avoiding consumer confusion, or on ethical or moral values like preventing animal cruelty stands a better chance of

---


2. FDA Center for Veterinary Medicine, “Briefing Packet” at 102, 133.
meeting with judicial approval.

In addition, to help ward off a legal challenge, a labeling requirement should:

- Reflect interests other than protecting California’s salmon industry, because laws aimed at economic protectionism are presumptively unconstitutional.
- Be consistent with other states’ labeling requirements, because requiring producers to conform to different standards in different states can unconstitutionally burden interstate commerce.
- Be limited to requiring producers to include substantiated facts, not opinions, on their labels.
- Require all GE salmon to be labeled, not just salmon produced out of state.
- Allow sellers of non-GE salmon to label their salmon as “non-GE,” as long as the labels do not misleadingly suggest that there are differences without scientific evidence to support the claim.

Banning the Sale of GE Salmon

Alternatively, California could ban the sale of salmon created through a recombinant DNA process. Courts generally disfavor product bans, requiring that the legislation meet a high standard of necessity. Courts have been more lenient, however, when states ban a particular process -- as when California banned force feeding ducks to produce foie gras – rather than banning a product itself. Along these lines, California could prohibit the use of a recombinant DNA process altering the growth hormone to produce salmon products for sale.

Once again, it is important that economic protectionism not be evident in the purposes behind the legislation. California should avoid appearing to be protecting California’s salmon industry. And as with the labeling option, California should draft language consistent with that of other states, to maintain uniformity and lessen the compliance burden on producers.

Laying the foundation for regulation

For any California legislation to withstand judicial scrutiny, two steps are crucial: establishing a legitimate state interest in regulating GE salmon, and ensuring the legislation is not seen as a form of economic protectionism. To establish a legitimate state interest, the state should conduct public health, economic and environmental impact studies to document the dangers of GE salmon, or at a minimum, uncertainty about GE salmon’s effects.

To avoid charges of economic protectionism, legislation should be drafted to treat in-state and out-of-state producers uniformly. Legislative history plays a critical role in demonstrating that protectionism did not motivate the legislation. The State should seek broad coalitions, including garnering support from businesses outside California, to signal that legislation is not intended to protect California’s salmon industry. Conversely, opposition from businesses inside California would send a similar message.

In sum, California has an opportunity to quell the guessing game that its citizens may otherwise soon face in grocery stores. While California must navigate numerous legal shoals, California can fight the currents to protect its citizens and ready itself for the introduction of genetically engineered salmon.
Background

The advent of genetically modified organisms has stirred up an increasingly contentious debate about their impacts on consumer health and the environment. Supporters of GMOs contend that GMOs can meet future global demand for food by means of production efficiency, be engineered to resist pathogens and drought, have better nutrient profiles, and reduce fishing pressure on wild stock. Opponents express concern about the objectivity of regulators, and unknown long-term effects on the environment, human health, and markets.

These controversies raise questions about the role of government regulation, the necessity for objective scientific research on a range of possible consequences of market-ready GMO foods, and the suitability of labeling foods as genetically engineered. Labeling foods as genetically modified is currently required in 64 countries, but not in the United States.

Federal legislation has recently been introduced. In 2011, a bill was introduced in Congress that would have prohibited the FDA from approving AquAdvantage salmon, based on concerns over a hasty, insufficient FDA review and approval process. This bill did not pass. Senator Boxer introduced a bill in 2013, that would mandate that the FDA require the labeling of a broad class of genetically modified foods. In April 2014, Congressman Mike Pompeo (R-KS) introduced a H.R 4432, entitled the “Safe and Accurate Food Labeling Act.” This legislation would amend the Federal Food, Drug and Cosmetic Act to give the FDA sole authority to require mandatory labeling, and thereby prohibit states from passing any labeling legislation. Passage of this, or a similar bill in the next Congress, would greatly constrain California’s policy options.

The states have also begun to regulate GMO foods. In May 2014, Vermont became the first state in the nation to enact a law that would require the labeling of genetically engineered foods. The law, H.112, includes a legal defense fund to pay for costs associated with liabilities in implementing the law. Maine and Connecticut have also passed labeling bills, to take effect once a threshold number of regional states pass similar legislation. The citizens of Colorado and Oregon voted down mandatory GMO labeling propositions in November 2014; the preliminary margin in Oregon was fewer than one thousand votes, triggering an automatic recount that is pending as of December 2014.

In early 2014, California State Senator Noreen Evans introduced S.B. 1381, entitled the “California Right to Know Genetically Engineered Food Act.” The legislation would have required that food produced with genetic engineering shall be labeled as such. The bill was voted down in committee 19-16 on May 29, 2014. Additionally, Governor Brown signed into law Assemblymember Wes Chesbro’s A.B. 504, prohibiting transgenic salmon aquaculture in California waters, going beyond the existing restriction against transgenic fish aquaculture in Pacific Ocean waters subject to California jurisdiction.3

---

3 Fish & Game Code §15007. Also, California defines “transgenic” in the Administrative Code. 14 CCR 1.92. 14 CCR 671.1(a)(8) requires a Fish and Game Commission permit before the import, export, transport, maintain, sale, disposal, or use of transgenic aquatic animals. The Chesbro bill codified the regulatory definition of “transgenic.”
Amidst these concerns, AquaBounty Technologies, Inc. (ATI) has been seeking FDA approval for a genetically engineered salmon product, called AquAdvantage salmon (or colloquially, “Frankenfish”), since 1995. This salmon is engineered to exhibit a rapid-growth phenotype that allows it to reach market-size in 16 to 18 months, instead of the usual 30 months. The method to produce this all-female triploid species uses recombinant DNA molecules, or DNA molecules genetically recombined in order to join genetic material from different sources, and gynogenesis, which is a process that requires both sperm and an egg to produce offspring but occurs without the two fusing, so the offspring only expresses the female’s genes.

First, the synthetic genome is created in vitro, and contains an inserted growth hormone gene from Pacific Chinook salmon and a protein gene from ocean pout that helps salmon survive in near freezing temperatures. The resulting eggs are then subject to gynogenesis. Sperm from Arctic char salmon are exposed to radiation, so that the DNA from the sperm is not present in the gynogen population, introduced to the eggs, and then a pressurized treatment results in diploid or “twin” offspring. The female population is then subject to a “masculinization” process, where they become “neo-males,” or genetically female fish that produce sperm instead of viable eggs. Upon sexual maturity, the neo-males are bred with non-GE Atlantic salmon females. Then, the resulting eggs are subjected to more pressure shock treatment so that triploids result – one set of chromosome from the neo-male GE salmon and two sets of chromosomes from the non-GE female salmon. The resulting fish, female triploids with the recombined growth construct, are the actual AquAdvantage salmon intended for commercialization. Triploids are incapable of reproduction, and ATI asserts that this process will ensure an exclusively triploid population.

Generally, the FDA has authority under the Federal Food, Drug & Cosmetic Act to regulate GE foods. The FDA considers GMO foods to be “generally recognized as safe” and does not regard methods used to develop GMOs as “material information” that would be required to be disclosed on labels. Specifically, the FDA considers AquAdvantage salmon to be both biologically and physically contained, meaning it accepts that the fish is both sterile and that the facilities in which the fish is bred is guaranteed against escape. These conclusions are significant, as they are the driving force behind the FDA’s preliminary finding of “no significant impact” in the draft Environmental Assessment produced in 2012. Though the environmental report for AquAdvantage salmon regards the sterility method as 99% effective, the validity of this claim, as well as the physical containment claim, have been contested.

---

4 H.R. 4432 (Safe and Accurate Food Labeling Act of 2014).
**Introduction**

While the FDA has its authority pursuant to the Federal Food, Drug & Cosmetic Act, California also has statutory and regulatory authority over certain aspects of food inspection, importation, manufacturing, production, and sale. Generally, California’s food laws under the Sherman Food, Drug, and Cosmetic Law (Sherman Food Law) are administered and enforced by the California Department of Public Health (CDPH).

On the assumption that California is dissatisfied with the FDA’s ultimate approval of and/or labeling requirements for GE salmon, our analysis begins by looking at potential ways that California could inject itself into the regulatory picture for GE salmon, by utilizing existing authority, or enacting new laws. This report assumes that the FDA will not require labeling of GE salmon, and further, that the FDA will not affirmatively bar states from requiring GE labeling, either.

First, we provide a general overview of the conceivable means of regulation. While we identified seven policy options for California regulatory initiatives, this report focuses mainly on the two most powerful and defensible policy options (labeling and prohibition). We briefly discuss why the other five options are not viable at the end of the report.

Second, in sections I through III, we provide a general overview of legal doctrines that could challenge California’s initiatives: Preemption Doctrine, First Amendment Commercial Speech Doctrine, and Dormant Commerce Clause Doctrine. During the doctrinal discussions, we: 1) provide a general overview of each doctrine; 2) highlight several cases illustrating the law; and 3) explain practical aspects of each doctrine that are relevant to the policy initiatives. It should also be noted that not every doctrine (or sub-doctrine) is implicated in a particular policy option.

Third, in section IV, we examine the two most viable policy options in fuller detail and outline the specific course of action the Legislature should take if it chooses to enact the policy into law. The policy discussion also highlights the pitfalls and legal ambiguities that the law presents.

Lastly, in section V, we briefly discuss why the other five policy options are unavailing. Generally, the other five policy options either pose significant legal problems, or are likely ineffective in helping the Legislature prepare California markets for genetically engineered salmon.

All seven options are explained on the next page, and we used a key to a delineate our level of confidence in the viability of each: stop signs indicate impracticable options; yield signs indicate that an option is possible to pursue but ultimately would be an ineffective route; and, arrows indicate the two we find to have the most likelihood of success.

It should be noted that the “arrow” options are subject to substantial concerns, as well. Our analysis has not produced any easy and certain solutions for California’s concerns about the introduction of GE salmon into the marketplace.
California’s Seven Policy Options and their Legal Impediments

An Overview of What Works and What Doesn’t

Option One: GE Salmon Approval
Before a new food product enters the market, the FDA must determine whether the food is “safe and effective.” Since GE salmon is a new food product, the FDA must approve the product through the company’s submission of a New Animal Drug Application (NADA). Option One asks whether California could create its own food approval process, similar to the FDA, if it disagrees with an FDA action. The Preemption Doctrine and the Supremacy Clause would squarely prevent California from attempting to undermine the FDA’s approval process.

Option Two: Inspections Outside of California
When the FDA reviews products for food safety, the FDA regularly sends health inspectors to determine whether the producer or manufacturer is in compliance with Federal laws. Option Two asks whether California could send its own health inspectors to hatchery or processing facilities outside of California so that food intended for California would meet California standards. The Dormant Commerce Clause (particularly the Foreign Dormant Commerce Clause doctrine) is likely to be a legal barrier if California sought to send its own health inspectors into other jurisdictions, such as Panama where the AquAdvantage grow out facilities are located.

Option Three: Environmental Regulation
The California Environmental Quality Act (CEQA) is a potential mechanism for inspecting out-of-state facilities, for examining the environmental ramifications of GE salmon production. CEQA requires state and local agencies to perform an environmental impact report (EIR) when they engage in an action that results in significant environmental impacts. Current California regulations largely bar the consideration of impacts on environments outside of California. Option Three contemplates changing those CEQA regulations to permit California agencies to consider the impacts of actions on the environment outside of California. The Dormant Commerce Clause and Preemption Doctrine are unlikely to be legal barriers, but the problems with applying CEQA are likely to be more prosaic, rooted in the fact that there is no obvious California agency “action” relative to GE salmon to trigger CEQA’s environmental assessment procedures.

Option Four: Importation into California
California requires seafood importers to abide by certain regulations – e.g., inventory and documentation requirements -- before their products may be brought into the California marketplace. Additionally, California law allows state public health inspectors to seize and embargo food products that are unsound, unsafe, or deleterious to health. Option Four is the idea of applying the same regulatory structure to GE salmon imported into California. Importation regulations are not a reliable framework to regulate GE salmon, as the documentation requirements are easily met. Additionally, while it is unlikely that the Dormant Commerce Clause would prevent California public health

officials from seizing or embargoing unsafe or unsound GE salmon, this option is not sufficiently robust to stop GE salmon as a general matter. Indeed, immediate or potentially serious injuries to human health would be required before the Department of Public Health could invoke this authority.

**Option Five: Product Information Labeling**

The Federal Nutrition Labeling and Education Act (NLEA) requires that food products contain certain information for consumers. **Option Five** explores whether California could impose a labeling requirement supplementing those of the Federal NLEA. Labeling is an oft-utilized regulatory option, but it triggers **Preemption, Compelled Commercial Speech**, and **Dormant Commerce Clause** concerns. See the **Preemption, Compelled Commercial Speech**, and **Dormant Commerce Clause** sections for the legal discussions, and the **Policy Recommendation: Labeling** for suggestions on how to craft a labeling regulation that would best withstand legal challenge.

**Option Six: Caution Signs**

When food poses a potential public health hazard, States may require a retailer to post a caution sign near and around the food product for sale. **Option Six** is the requirement of mandating California retailers to post point-of-sale caution signs around genetically engineered salmon. The First Amendment, in particular the **Compelled Commercial Speech** doctrine, would likely pose a legal barrier, as does **Preemption**. See the **Compelled Commercial Speech** and **Preemption** sections for the legal discussion.

**Option Seven: Outright Ban**

7 States may prohibit the sale of certain food products into their markets; California (and other states) already ban the sale of force fed foie gras, and California prohibits the sale of shark fins. **Option Seven** explores whether California could prohibit the sale of GE salmon. While prohibition does seem to be a viable regulatory option, it triggers significant **Dormant Commerce Clause** concerns, as well as **Preemption Doctrine** concerns. See the **Dormant Commerce Clause** and **Preemption** sections for the legal discussion, and the **Policy Recommendation: Outright Ban** for drafting recommendations.

---

7 While an outright prohibition on the sale of GE salmon goes beyond the scope of the initial project request, the thought experiment of a potential ban surfaces numerous critical questions. What is more, in 1986 the Supreme Court noted that “the greater power to completely ban casino gambling necessarily includes the lesser power to ban advertising of casino gambling.” *Posadas de Puerto Rico Assocs. v. Tourism Co. of Puerto Rico*, 478 U.S. 328, at 346 (1978). Similarly, the power to ban GE fish entirely from California might suggest an ability to control the information that appears on GE salmon labels. The general *Posadas* principle has attracted its fair share of criticism in academic circles, and has not been followed strictly by the Supreme Court itself. *See Greater New Orleans Broad. Ass’n v. United States*, 527 U.S. 173, 193 (1999) (striking down a ban on all broadcast advertising of casino gambling).
Overview of the Doctrine:

I. Preemption

Conclusion: A California labeling or other regulation of GE salmon could potentially withstand the preemption challenges posed by Federal law, but stronger scientific evidence would greatly buttress the validity of California legislation.

Preemption, a principle emanating from the Supremacy Clause of the Federal Constitution, holds that Federal law will trump state law whenever the two conflict. Implementation of the doctrine is fraught with nuance, as it requires sussing out Congressional intent, delimiting the scope of the Federal and state law schemes, as well as delimiting the extent of express preemption clauses themselves.

The mere existence of a Federal regulatory scheme, even if expansive, does not by itself imply preemption. The Supreme Court has identified two guiding principles for determining whether preemption exists: Congressional purpose in enacting the law, and the "presumption against preemption," which means that preemptive clauses are read narrowly. This narrow reading is especially operative in areas of traditional state regulation, such as "the proper marketing of food," where courts require "clear and manifest" Congressional intent before trumping a state law.

A California GE salmon labeling requirement raises preemption concerns because the Federal government has broad food safety and food labeling authority under the Federal Food, Drug and Cosmetic Act (FDCA). Congress amended the FDCA in 1990 to include the Nutrition Labeling and Education Act (NLEA), which strengthened FDA regulatory scope by mandating more detailed labeling and by adding express preemption provisions.

An California outright ban on GE salmon also stirs up preemption concerns because it could undermine the FDA approval of the New Animal Drug Application (NADA) for the recombinant DNA construct used in GE salmon. Below, we discuss an outlying case, Provimi, where a court decided that the the FDA’s approval of

---

8 The US Constitution’s Supremacy Clause mandates that federal law is “the supreme law of the land.” U.S. Const. Art. VI, §2.
11 In re Farm Raised Salmon Cases, 42 Cal.4th1077, 1088 (2008)(The NLEA does not preempt state law suits brought by private parties under state laws identical to the NLEA).
subtherapeutic antibiotics for veal preempted a state-based lawsuit, including the requested injunctive relief for consumer warnings.\textsuperscript{14}

Preemption can occur in three ways:

1. **Express preemption** - Congress enacts a statute that explicitly preempts state law.
2. **Implied preemption** - Federal law ‘occupies’ a legislative field to such an extent that it is reasonable to conclude Congress did not want to leave room for additional state regulation in that field.
3. **Conflict preemption** - State law conflicts with Federal law, either by:
   a. Making it impossible for a private party to comply with both state and Federal requirements,\textsuperscript{15} or
   b. When state law stands as an obstacle to the accomplishment of the Congressional purpose behind the Federal statute.\textsuperscript{16}

Both Federal statutes and regulations promulgated through notice and comment rulemaking may preempt state laws.\textsuperscript{17}

**APPLYING THE DOCTRINE**

Of the Seven Policy Options, the Preemption analysis applies to:

**Option Five: Product Information Labeling**

**Option Six: Caution Signs**

**Option Seven: Outright Ban**


\textsuperscript{15} English, 496 U.S. at 78 (1990).

\textsuperscript{16} Hines v. Davidowitz, 312 U.S. 52, 67 (1941).

Preemption: The Analysis

A. EXPRESS PREEMPTION: THE NLEA

The NLEA contains 13 express preemption provisions. The three that typically apply to state labeling laws are: 1) standards of identity, 2) nutrition information, and 3) nutrient levels and health-related claims. A fourth, concerning labels that have no representation of standards of identity, is also implicated in the first. If a state labeling regulation is not identical to the Federal labeling regulation in one of the covered categories, the state regulation is preempted. Other issues with compelling producers to label GE salmon as “Genetically Engineered” will be discussed in the First Amendment: Compelled Commercial Speech section.

The boldest California labeling requirement would bar GE salmon producers from using the term “salmon” on labels to identify the fish being sold. The courts increasingly disfavor this kind of “standard of identity” labeling requirement as preempted by the NLEA. On the other hand, legislation that would require manufacturers to disclose that the product has been genetically modified would accomplish a similar goal and would likely circumvent those three express preemption provisions of the NLEA, as long as the label requirements are truthful and not misleading. The independent implied and conflict preemption issues will be discussed in sections B and C.

1. A “Standard of Identity” for Salmon

Under Federal law, food does not conform to the definition and standard of identity if it:

- Contains an ingredient for which no provision is made in the definition and standard of that food; or
- If it fails to contain any one or more ingredients required by such definition and standard; or
- If the quantity of any ingredient or component fails to conform to the limitation, if any, prescribed by that food’s definition and standard.

The FDA writes standards of identity for particular foods at the national level. Products that are not identical to those standards, by either composition or by how they are labeled are considered “misbranded.” State labeling requirements that conflict with the FDA standard of identity are preempted and similarly invalid. Further, § 343(i) requires that foods without a Federal standard of identity must bear the “common or usual name of the food.” While there is a formal definition and standard of identity for canned

---

19 21 C.F.R. § 130.8; 21 U.S.C. §§ 343-1(a), 343(g).
21 Where no “standard of identity” exists, § 343(i) of the FDCA declares a food misbranded “[u]nless its label bears (1) the common or usual name of the food, if any there be, and (2) in case it is fabricated from two or more ingredients, the common or usual name of each such ingredient...” 21 U.S.C. § 343(i); in parallel, 21 U.S.C. § 343-1(a)(3) preempts state law labeling requirements that conflict with the “common or usual name of the food.”
Pacific salmon, the FDA has not created a standard of identity for salmon, GE salmon, or GE foods in general. Hence this preemption provision will not apply to states attempting to regulate the labeling of GE salmon, although prohibiting GE salmon sellers to use the term "salmon" for their product raises some potential problems, as seen in the "honey" cases.

The “Honey” Standard in California: Brod and Perea

Whether California could create its own standard of identity for salmon is not a first impression question. A well-litigated analogous example is honey, specifically honey that has had its pollen removed. A handful of states prohibit the removal of pollen from honey, and restrict the use of the term “honey” to honey products that have not had their pollen removed. As with salmon, the FDA has not promulgated a formal standard of identity for honey. Nevertheless, a “growing body of case law hold[s] that labeling claims regarding pollen-removed honey are preempted by the FDCA,” specifically, the FDCA’s requirement that food bear its “common or usual name.”

In Guerrero, a Florida district court decided the issue the other way: the Florida state honey standard of identity withholding the term “honey” from honey without pollen did not violate the preemption provisions of the NLEA because there was no Federal standard with which it could conflict: the FDCA’s express preemption clause only applied if there were no standard of identity at all. In Brod, the court held that “California simply cannot under § 343(i) ban the use of the label “honey” for products which are commonly and usually called honey,” although the court relied on conflict preemption for this holding. The court found §343(i) to apply in the absence of a Federal standard of identity: again, section 343(i) mandates that, for "label[s] where no representation as to definition and standard of identity" exists, the label must bear its common or usual name. Similarly, the Perea court explicitly rejected

---

23 While FDA has not established a formal standard of identity by notice and comment rulemaking, the FDA considers that the “ABT [the AquAdvantage] salmon meet[s] the standard of identity for Atlantic salmon established by FDA’s Reference Fish Encyclopedia.” FDA Center for Veterinary Medicine, “Briefing Packet” supra note 1 at 61.
24 California law makes it unlawful to label any honey product as “honey” if it does not conform to the requirements of the chapter, including the mandate that “no pollen or constituent particular to honey may be removed except where unavoidable in the removal of foreign inorganic or organic matter.” California Food & Agric. Code §§ 29671, 29413 (West).
26 Guerrero v. Target Corp., 889 F. Supp. 2d 1348, 1361 (2012). The Guerrero court interpreted the preemptive clause as applying only there is no standard of identity, state or Federal; as Florida had established its own standard of identity for honey, there could be no express preemption in the case. Id.
Guerrero’s analysis by reasoning that § 343-1(a), the express preemption provision of the NLEA, applies regardless of whether a Federal standard of identity exists.

An additional, weighty factor in a court’s analysis is the presence of Federal definitions around a food product, even if the definition does not rise to the level of a formal “standard of identity.” And in the case of salmon, the FDA has given its imprimatur to the use of “salmon” as the acceptable market name for Atlantic salmon.\(^{28}\) which is the type of fish AquAdvantage salmon purports to be. Also, the FDA specifically considers that the “ABT [the AquAdvantage] salmon meet[s] the standard of identity for Atlantic salmon established by FDA’s Reference Fish Encyclopedia.”\(^{29}\) An FDA regulation explicitly states that FDA advisory opinions may be used in court to illustrate acceptable standards, not legal requirements,\(^{30}\) but guidance and other agency actions still often have effect on a court’s analysis, as discussed in more detail under Implied Preemption.

In short, developing a standard of identity for salmon to exclude GE salmon does not seem to be California’s safest route for regulating the labeling of GE salmon. For present purposes – i.e., California’s requiring “Genetically Engineered" to appear on a GE salmon label -- it is important to note that the Brod court went on to observe “that its finding of preemption does not imply that California is powerless to act in this arena. For instance, if California required disclosure on its labels that the honey was e.g., ‘filtered’ or ‘pollen free,’ that would appear not to conflict expressly with § 343(i).”\(^{31}\)

In the following paragraphs, we address whether the other express preemptive provisions (“nutrition” and “health claims”) of the NLEA might impede California’s mandating that GE salmon be labeled “Genetically Engineered.”

2. Express preemption provisions concerning nutritional and health information

a) Nutrition Information.

Nutrition labels must contain information about:
- Serving size
- Number of servings
- Total calories per serving
- Amount of fat, cholesterol, sodium, carbohydrates, sugars, fiber and protein per


\(^{29}\) FDA Center for Veterinary Medicine, “Briefing Packet” supra note 1 at 61.

\(^{30}\) 21 C.F.R. § 10.85.

\(^{31}\) Brod v. Sioux Honey Ass’n Co-op., 895 F. Supp, at 981.

In a later proceeding, a second court affirmed these dicta. Brod v. Sioux Honey Ass’n Co-op., 927 F. Supp. 2d 811, 823 (N.D. Cal. 2013), citing Freightliner Corp. v. Myrick, 514 U.S. 280, 288 (1995), for the proposition that “an express definition of the pre-emptive reach of a statute 'implies'- i.e., supports a reasonable inference - that Congress did not intend to pre-empt other matters.”
serving.
- Amount of trans fat,
- Any vitamin, mineral or other nutrient required on the label prior to 10/1/1990.  

No nutrients or food components other than those listed may be included on a state nutrition label, or it will be preempted. “Genetically Engineered” does not constitute “nutrition information” as described above, and it therefore seems that this provision would not be triggered.

b) Nutrition Content and Health-Related Claims.

Nutrient content and health-related claims are claims that:
- Expressly or implicitly characterize the level of a nutrient to be on nutritional labeling;
- or,
- Expressly or implicitly characterize the relationship of any substance to a disease or health-related condition.  

These provisions govern voluntary statements about a food product made anywhere on the product label that is either an express claim (e.g. “contains 100 calories”), implied claim (e.g. “high in oat bran,” which is implied because it suggests presence of the actual nutrient, fiber), or a health-related claim (e.g. “helps lower cholesterol”).

A GE label would provide no information about the nutrient content of the salmon, so neither the express nor implied claim provisions should be triggered.

Unlike nutrient content claims, health claims must be reviewed and approved by the FDA, and they operate to link a nutrient in a food to the mitigation or treatment of a condition or disease.  

A GE label would not attempt to link any nutrient in the food to a disease or condition, so there is no preemptive concern with the health-claims provision either. Even without identifying a link to a disease, however, a GE label should not make health-related claims just to be safe, particularly as the FDA has taken the position in general that there are no health-related concerns with GMO foods. FDA guidances might not be considered to have the “force of law” such that they would confer preemptive effect, but a court will look at the fairness and deliberation behind the administrative procedure that produced that opinion to decide whether it should.  To skirt this concern, it would be safest to make no health-related claims – while consumer health and safety can be a state purpose behind a regulation, as explained in the First Amendment discussion, the type of label that this provision calls into question would be overly specific. Given the lack of scientific evidence on GE foods, a court could consider a health-related claim on a label an “opinion,” which would infringe on the distributor or manufacturer’s rights.

-------------------------------

The NLEA portion of the FDCA is not the only font of preemption concern for our purposes, however: the New Animal Drug Application approval process itself could block

state regulatory efforts. Throughout the preemption discussion we will highlight ways that a court could find an unexpected means of foiling California’s efforts. For present purposes, however, NADA does not contain express preemption clauses, and need not be discussed further.  

Preemption: The Analysis

B. IMPLIED PREEMPTION: THE NLEA, NADA AND “FIELD” PREEMPTION

In the absence of express preemption language, state law is still subject to scrutiny under an implied or “field” preemption analysis to determine whether a state law regulates within a field Congress intended for the Federal government to occupy exclusively. Again, preemption guiding principles control this analysis – Congressional purpose and a presumption against preemption. When state law traditionally governs the field in question, Congressional purpose to occupy the field must be “clear and manifest” for a court to apply field preemption.\(^{37}\) Fortunately for California’s regulatory ambitions, food labeling and consumer health and safety have been recognized as areas that state law historically governs. As far back as 1872, the Supreme Court noted, “If there be any subject over which it would seem the states ought to have plenary control … it is the protection of the people against fraud and deception in the sale of food products.”\(^{38}\)

The NLEA contains a “savings clause,” which states that the Act can only be construed to preempt any state law that is expressly preempted.\(^{39}\) In other words, the NLEA itself prohibits implied preemption interpretations. In order to find a California labeling regulation impliedly preempted, a court would have to do so based on provisions of Federal law other than the NLEA that suggest Congress intended to leave no room for state regulation.\(^{40}\) Indeed, the NLEA expressly preserves implied preemption claims based on other provisions of Federal laws.\(^{41}\) In other words, the NLEA would not impliedly preempt a CA labeling regulation, but that does not mean that other laws could not, such as the NADA approval process itself.

“All-Natural Snapple” Case Study for Implied Preemption:

After being sued for the deceptive use of the word “natural” on its labels, Snapple argued that the FDCA (before it was amended to include the NLEA) so broadly addressed the labeling and misbranding of food that its regulations “occupied the field.” The lower court agreed with Snapple’s argument, but the Third Circuit Court of Appeals reversed that decision, and ruled that it was clear Congress had not intended to fully occupy the field of food and beverage labeling.

The court reasoned that the original FDCA included no preemption provisions, preserving state authority, and that the subsequent NLEA amendment only created limited exceptions. Expressly providing for instances of preemption would serve no

---


\(^{39}\) Uncodified section 6(c)(1) of the NLEA that “[t]he [NLEA] shall not be construed to preempt any provision of State law, unless such provision is expressly preempted under [section 343–1] of the [FDCA].” Pub.L. No. 101–535, § 6(c)(1) (Nov. 8, 1990), 104 Stat. 2364.

\(^{40}\) See Holk v. Snapple Beverage Corp., 575 F.3d 329, 336 (3d Cir. 2009) (“if we are to find that Holk’s claims are impliedly preempted, we must do so based on provisions of federal law other than NLEA”).

\(^{41}\) “§ 343-1 shall not be construed to affect preemption, express or implied, of any such requirement of a State or political subdivision, which may arise under the Constitution, any provision of the [FDCA] not amended by section [343–1], or ... any Federal regulation, order, or other final agency action.... ” Pub. L. No. 101–535, § 6(c).
purpose and be redundant if Congress had intended to occupy the entire field. NLEA’s legislative history also demonstrates that Congress intends to preserve state authority in the food and beverage labeling. Thus, the court not only found a lack of “clear and manifest” Congressional intent to occupy the field, it also found that Congress was cognizant of state labeling authority when enacting the NLEA.

Only two months earlier, a district court noted that the mere fact that the NLEA permits state regulations identical to Federal regulations means that the FDCA contemplates state regulation and enforcement, substantiating the argument against “field” preemption by the FDCA.

Even though the Court found no preemption in the Snapple case, it raises noteworthy points for our purposes. Express preemption was not an issue because the FDA did (and does) not have a formal definition for “natural,” but the court hinted that an FDA failure to identify or define a term through rule making does not automatically mean that Congress intended states to supplement the area. That is, the court took into consideration the FDA informal policy that contemplated the use of the word “natural.” Ultimately, part of the court’s reasoning to deny preemption was that the FDA repeatedly acknowledged the ambiguity of the word and how a Federal definition would abate confusion, but still declined to create one for lack of resources needed for rulemaking. This signified the FDA’s intent to stay out of the regulatory realm on the definition of “natural,” leading the court to eschew traditional deference to “reasonable” agency pronouncements. While the difference between formal rules and interpretive rules can be less than clear, reasonable agency interpretations are nonetheless entitled to judicial consideration.

In the matter of genetically engineered food, these two factors cut the opposite way: 1) the FDA has issued guidance on GE foods (as well as preliminary findings on GE salmon), which likely would be judicially relevant, and 2) the definition of “genetically engineered” is not controversial, at least with respect to the GE salmon. It is more controversial when it comes to non-genetically modified animals that are fed genetically engineered crops, but this is not a factor in the GE salmon scenario.

We found only the case of Provimi Veal suggesting that the FDCA, specifically the NADA provisions, led to field preemption of a scope sufficient to block labeling regulations outside of the original area of legislation.

“Adulterated Veal,” Field Preemption, and Co-Existing Federal & State Regulations:

In Massachusetts, a non-profit filed a state law-based consumer protection lawsuit against Provimi Veal Corporation for selling veal adulterated by FDA NADA-approved antibiotics, among other claims. The court ruled that “the comprehensive federal

---

42 Holk, 575 F.3d at 338.
43 Holk, 575 F.3d at 339.
45 Gerace, 755 F.2d at 1002.
statutory and regulatory scheme pre-empts any injunctive relief under [the Massachusetts state law]” in noting that “antibiotic use is thoroughly regulated by the FDCA. When Congress has fully occupied a field of regulation, even non-conflicting state regulation is pre-empted.”47 Specifically, the court noted that “[t]he FDCA and its regulations establish complicated procedures by which new drugs proposed to be used in treating animals both subtherapeutically as feed additives and therapeutically, are approved before they can be marketed. Human safety is specifically considered, because it is in animals raised for food that these drugs and feeds will be used.”48 What is more, plaintiffs “cannot escape the pre-emptive reach of the federal statutory and regulatory scheme by asking for an injunction simply obligating Provimi to tell consumers that the calves it buys are fed antibiotics subtherapeutically.”49

The equivalencies to the NADA approval process for GE salmon cannot be ignored, but as troubling as the Provimi decision might appear, it has not been followed by other courts. What is more, a California GE labeling requirement would be distinguishable. Unlike the Federal Meat Inspection Act (FMIA), the NLEA’s express preemption provisions do not prohibit additional disclosure. The court noted that the preemption of a consumer warning on veal stemmed from both the FMIA, not the only FDCA.50 The NLEA simply requires that labeling be truthful, not misleading, and include all information otherwise required.51 Further, the comprehensiveness of antibiotic animal feed regulation was found through the intersection of Federal meat regulation and antibiotic drug pre-market approval, which amount to much more than the breadth of Federal regulation of genetically engineered animal products. And finally, as the Supreme Court has noted in Riegel v. Medtronic, state tort suits are more likely to be preempted than state regulations, as “one would think that tort law, applied by juries under a negligence or strict-liability standard, is less deserving of preservation [against preemption]. A state statute, or a regulation adopted by a state agency, could at least be expected to apply cost-benefit analysis similar to that applied by the experts at the FDA.”52

---------------

Despite the sweeping field preemption holding of the outlier Provimi case, just because an area is heavily regulated by the FDCA does not mean that state regulation governing the same area is automatically preempted. For instance, a California court held in Reese v. Payless Drug Stores Northwest, Inc. that a plaintiff could still bring a state law based tort claim, notwithstanding the fact that the FDCA expressly reserves enforcement authority to the Federal government.53 Accordingly, even if the NLEA heavily regulates labeling, a California regulation that imposes labeling requirements

50 Provimi Veal Corp 626 F.Supp. at 285. FMIA, 21 U.S.C. § 678, explicitly preempts labeling regulations that are in addition to those mandated by Federal law. Id.
53 Reese v. Payless Drug Stores Northwest, Inc., 40 Cal.Rptr.2d 75, 80 (1995); see also, Osborn v. Anchor Laboratories, Inc., 825 F.2d 908, 912 (5th Cir. 1987)(holding no preemption of a state law that required more extensive labeling than FDA approved drug and label, especially because the FDA allowed manufacturers to add more warnings to the label). Somewhat similarly, the FDA already allows manufacturers to voluntarily label GE foods.
beyond the FDCA’s, with perhaps a different purpose than the FDCA purpose of promoting health and safety, is not automatically preempted.

Moreover, uncodified section 6(c)(2) of the NLEA specifies that the express preemption provisions “shall not be construed to apply to any requirement respecting a statement in the labeling of food that provides for a warning concerning the safety of the food or component of the food.” This savings clause fits the purposes of a “genetically engineered” label perfectly, although it remains subject to the familiar point that the scientific justification for the warning will likely be the pivot point for a broad variety of judicial decisions on the legality of California regulatory initiatives. As will be discussed in the Compelled Commercial Speech section, the Amestoy court held that “consumer curiosity alone is not a strong enough state interest to sustain the compulsion of even an accurate, factual statement.”

Preemption: The Analysis

C. CONFLICT PREEMPTION: THE NLEA AND BEYOND

A California regulation focused on labeling or outright ban could trigger conflict preemption, which occurs when a regulation 1) obstructs Congressional purpose, or 2) makes it impossible for a private party to comply with both state and Federal requirements.

The first prong --- obstruction of Congressional purpose --- is oftentimes a subjective inquiry. One factor in deciding Congressional purpose is the aspect of government in question, and whether it is traditionally a Federal power or state power. Health and safety issues, which include food labeling and branding, have traditionally fallen within the province of state regulation.\footnote{Plumley v. Massachusetts, 155 U.S. 461, 471 (1894).} In fact, one court used state food labeling laws as an illustration of a legislative area that does not demand broad Federal authority in contrast to one that does, like international relations,\footnote{Hines v. Davidowitz, 312 U.S. 52, 68 (1941).} and courts have repeatedly acknowledged the traditional state power to regulate food. Courts often look to legislative history as well, and the NLEA’s demonstrates that Congress intended to preserve state authority for food labeling. A complicating factor in the Federal role, however, is other statutory authority, such as the Federal government’s primary role in regulating international trade (the GE salmon product might come from Panama), as well as the FDA’s central role in approving new animal drugs.

The second prong --- impossibility of compliance with two distinct laws --- is not an issue with respect to labeling for there are no Federal labeling requirements for GE salmon (as of this writing) with which a state law could conflict. Parties should be able to comply with both regulatory frameworks. In Brod honey labeling cases, the court noted “if California required disclosure on its labels that the honey was e.g., “filtered” or “pollen free,” that would appear not to conflict expressly with § 343(i). California simply cannot under § 343(i) ban the use of the label “honey” for products which are commonly and usually called honey.”\footnote{Brod v. Sioux Honey Ass’n Co-op., 895 F. Supp. 2d 972, 981 (N.D. Cal. 2012).}

More guidance as to the interplay of Federal and state laws in the GE context may be found in FDA’s own writings. In 2008, the FDA issued and opened for public comment \textit{Guidance for Industry #187: Regulation of Genetically Engineered Animals Containing Heritable rDNA Constructs}.\footnote{FDA Center for Veterinary Medicine, \textit{Guidance for Industry #187: Regulation of Genetically Engineered Animals Containing Heritable rDNA Constructs}, available at http://www.fda.gov/downloads/animalveterinary/guidancecomplianceenforcement/guidanceforindustry/ucm113903.pdf (May 17, 2011)(last visited 11/2/14).} The FDA response to those comments made several salient points:

- Developers may be subject to other state requirements that apply to their products,
- Whether those requirements would be preempted by FDA requirements depends on the nature of the particular law; conflict preemption could be a driving force

\textit{Guidance for Industry #187: Regulation of Genetically Engineered Animals Containing Heritable rDNA Constructs}
[where a state law requirement makes compliance with both Federal and state law impossible, or frustrates Federal objectives\textsuperscript{60}], and

- A state law is more likely to be preempted if it is misleading by suggesting that GE food is materially different from its non-GE counterpart, given that the Guidance explicitly concluded the opposite, and doing so would therefore conflict with FFDCA misbranding provisions in § 343.\textsuperscript{61}

California could avoid NLEA preemption by not interfering with any standard of identity definitions, and, instead, by compelling disclosure that avoids suggesting material differences that cannot be documented between GE salmon and non-GE salmon while still providing information about the process by which the product was created. An analogy is how orange juice from concentrate is labeled without the implication that the product is deleterious to consumer health.\textsuperscript{62} To make sure that any disclosure does not violate the NLEA, it must be truthful and not be misleading. Labeling is misleading under the NLEA if it fails to reveal facts that are material in light of what the label represents, or material with respects consequences that could result from consuming the food.\textsuperscript{63} The FDA interprets “materiality” to mean information about the attributes of the food itself, which is in line with its assessment of AquAdvantage salmon – it looked at the nutrient profile of the resulting product to determine whether there were any differences, and found none. Therefore, any label should emphasize the process through which the product was made, not necessarily any differences posed by the end-product itself. Of course, if California is able to produce research that does in fact show differences between non-GE salmon and GE salmon, then that avenue can be more safely pursued.

One way of minimizing the misleading nature of a barebones “Genetically Engineered” label requirement would be to adopt language similar to Vermont’s rBST signage requirement, specifying:

“\textit{The United States Food and Drug Administration has determined that there is no significant difference between milk from treated and untreated cows. It is the law of Vermont that products made from the milk of rBST-treated cows be labeled to help consumers make informed shopping decisions.”}\textsuperscript{64}

Although the Vermont rBST signage law was struck down on Compelled Commercial Speech grounds, this language could help circumvent a misleading implication for preemption purposes.

A brief note on the possibility of conflict preemption under NADA: this threat is largest in the unlikely event that California sets up a parallel approval process for genetically engineered animals. Even an outright ban might make it past a conflict with


\textsuperscript{62} 21 C.F.R. § 146.145.

\textsuperscript{63} “FDA’s Response to Public Comments on Guidance for Industry #187,” \textit{supra} note 61.

\textsuperscript{64} 6 V.S.A. § 2754.
NADA if it is premised on legitimate state interests other than health and safety. Several are suggested in a subsequent section of the report: **First Amendment: Deciding on a State Purpose.**
HIGHLIGHTS OF THE PREEMPTION DOCTRINE & ANALYSIS

- Preemption is a constitutional doctrine that mandates that Federal law will invalidate state law wherever the two conflict. There are three kinds of preemption: express, implied, and conflict, and courts use two principles to determine whether a conflict exist: Congressional purpose and the “presumption against preemption.”

- The NLEA provides broad Federal authority for labeling, and it includes express preemption provisions.

- The NADA provides the process to approve new animal drugs, but it has no express preemption provisions.

- For implied preemption analysis to be persuasive regarding the NLEA or NADA, Congressional intent to occupy the field must be “clear and manifest.” The NLEA’s legislative history, at least, does not indicate that intent. See Snapple.

- The NLEA would not impliedly preempt a California GE labeling regulation because it includes a “savings clause” that states the Act should only be construed to preempt state law where it is expressly noted.

- However, the NLEA expressly preserves implied preemption claims based on other provisions of Federal law. It does not seem as though other provisions in the FDCA bear on GE foods closely enough for preemption to be implied. Further, the NADA does not contain any express preemption provisions. Our research did not reveal any other Federal laws that labeling legislation might conflict with.

We conclude:

- The NLEA would not expressly preempt California GE labeling regulation.
  - An emerging trend in the courts points to the difficulties a new state-based standard of identity (withholding the use of the term “salmon” for GE salmon products) would face. See Guerrero, Brod, and Perea.
  - The express provision that prohibits state deviations from Federal standards of identity would not be triggered because the FDA has not set out a formal standard of identity for GE salmon.
  - The express provision that prohibits non-identical nutrient content would not be triggered because a GE label would provide no information about the nutrient content of the claim.
  - The express provision that prohibits non-identical health-related claims would not be triggered because a GE label would not attempt to link any nutrient in the food to mitigating a disease or condition.

- The NLEA and NADA are also unlikely to block California GE regulation (both outright ban and labeling) on the basis of implied field preemption, although an outlier court could surprise.

- The NLEA and NADA present a slight risk of implied conflict preemption.
Overview of the Doctrine:
II. First Amendment: Compelled Commercial Speech

Conclusion: When a regulation compels information from a party rather than restricting their speech with the state purpose of preventing consumer deception, and that information is factual and controversial, the regulation likely is constitutional. Other state purposes are valid as well, and first deciding on the appropriate one then substantiating it with evidence is the most important ingredient in withstanding a legal challenge.

Labeling legislation raises First Amendment concerns in several ways. The Constitution provides less protection for commercial speech than for other guaranteed forms of expression because of the importance of advertising in accurately informing the public about lawful activity. In other words, the government can ban certain forms of communication if it is likely to deceive the public, and likewise it can compel certain forms of communication if it is likely to better inform the public.

Depending on how the commercial speech is regulated (i.e., whether compelling or prohibiting certain language), courts apply different levels of scrutiny, although courts have not fully settled on the proper standard to apply.

The Rationale Behind Protecting Commercial Speech

One of the core purposes of the First Amendment is to protect the right to “receive information and ideas.”65 The intent in protecting commercial speech66 is less about protecting the speaker/seller’s business, and more about furthering the societal interest in the free flow of information. Thus, while the protection extends to both companies and consumers, a company’s protected interest in not providing factual information is subordinate to a consumer’s interest in knowing that information.67 The rationale supporting this distinction is that the “free flow of commercial information is indispensable to … a free enterprise system because it informs the numerous private decisions that drive the system.”68

Commercial speech is protected if it is truthful, non-deceptive information that proposes a lawful commercial transaction.69 While the precise bounds of the definition are unclear, courts have considered the following to be commercial speech: beer labels; mandatory labeling for growth hormones in milk; mandatory labeling for mercury levels in

66 Central Hudson, 447 U.S. at 561-62 (1980)(commercial speech defined as “communication (such as advertising and marketing) that involves only the commercial interests of the speaker and the audience”).
69 Pruett v. Harris County Bail Bond Bd., 400 F.Supp.2d 967 (5th Cir. 2007).
a product; and, disclosure of calorie information. A GE label requirement would be considered commercial speech.

The Possible Tests Applied to Commercial Speech: Central Hudson & Zauderer

Once established that the commercial speech is truthful and doesn’t concern illegal activity, courts accord varying levels of protection depending on the type of commercial speech at issue and the method of regulation. The Supreme Court has provided two possible tests, often called the Central Hudson and the Zauderer tests.

In the 1980 case Central Hudson Gas & Elec. Corp. v. Public Serv. Comm’n of New York, the Supreme Court struck down an advertising ban imposed on electric utility companies as a violation of the First Amendment. The Court established an intermediate-scrutiny four-part test for First Amendment protection of commercial speech:

1. The commercial speech must concern lawful activity and not be misleading (as noted),
2. The asserted governmental interest in regulating the speech must be substantial,
3. The regulation must directly advance the governmental interest asserted, and
4. The regulation may not be more extensive than is necessary to serve that interest.

The asserted state interest in Central Hudson was energy conversation and preventing inequitable rates, which the court acknowledged as two substantial government interests. However, the court did not find a strong enough link between the prohibition and the second asserted interest. This is an important cautionary note for California: the state interests in regulating GE salmon must flow be clearly connected to the actual regulation, including the labeling language. Moreover, the accompanying restriction should be narrowly crafted to serve the State’s purposes: restrictions that are more extensive than necessary to serve the state interest will be held unconstitutional.

Five years later, in Zauderer v. Office of Disciplinary Counsel of the Supreme Court of Ohio, an attorney faced disciplinary action from the state for his advertising methods, and tried to argue that the rules imposed violated his First Amendment rights. The U.S. Supreme Court decided that the state limitations on what was allowed in attorney advertising were unconstitutional, but also that compelling disclosure of the structure of contingent fee costs was appropriate. Significantly, the court applied the Central Hudson test to the prohibitions on advertising, and created a different test for the requirement for compelled disclosure on contingent fees, noting a material difference between outright prohibitions and disclosure requirements. Compelled disclosure for contingent fees was not a state attempt to prevent attorneys from conveying information to the public, but instead a requirement to provide more factual information than they might otherwise be inclined to present, supporting the consumer right to information that is intrinsic to the

71 New York State Restaurant Ass’n v. New York City Bd. of Health, 556 F.3d 114, 132 (2009).
73 Central Hudson, 447 U.S. at 572.
74 Zauderer, 425 U.S. at 650.
First Amendment. It is important to note that the Court premised this distinction on the fact that the compelled disclosure involved “factual and uncontroversial” information that was meant to quell consumer deception. *Central Hudson* also noted that warnings or disclaimers may be required for that purpose.  

*Central Hudson* established a rational-basis test that looked at whether there was a rational connection between factual, uncontroversial compelled disclosure and a reasonable state purpose. The Court in *Zauderer* found that the regulation and preventing consumer deception “easily pass[ed] muster” under this test.

**APPLYING THE DOCTRINE**

Of the Seven Policy Options, the First Amendment analysis applies to:

Option Five: Product Information Labeling  
Option Six: Caution Signs

---

75 *Central Hudson*, 447 U.S. at 565.  
76 *Zauderer*, 425 U.S. at 652.
Compelled Commercial Speech: The Analysis

A. THE DIFFICULTY OF DETERMINING THE APPROPRIATE TEST

Label language requirements are likely to be considered compelled speech and not prohibitions, in that it compels speech rather than restricting it. Despite the reasoning posed in Zauderer, it remains unclear whether Zauderer (mere rational basis) or Central Hudson (intermediate scrutiny) is the appropriate test to apply to a label: Federal appellate courts are not unified (known as a “circuit split”). While the following analysis will explain the discrepancies, we believe that California could argue, in the event of litigation, that the Zauderer test should apply and that a GE labeling regulation passes its standard. We also believe, with less confidence, that a compelled commercial speech requirement could meet the Central Hudson standard should that apply, but success would likely rest on the substantive evidence regarding the differences of GE salmon.

The confusion begins with the 1996 Second Circuit case International Dairy Foods Association v. Amestoy. Vermont passed legislation requiring manufacturers to label products from cows treated with growth hormone. The court subjected the label to a Central Hudson test, and found that it failed the prong requiring a substantial state interest. The legislation did not claim health or safety concerns, surely substantial state interests, but instead defended it on the basis of a strong consumer interest and the public’s “right to know,”77 and the court found this insufficient.

While the court did not explain why it subjected the label to the test in Central Hudson instead of Zauderer, it alluded to it by citing non-commercial cases that demonstrated how the First Amendment protects both the right to speak and the right to refrain from speaking, in effect equating disclosure with prohibition. However, those cases are distinguishable on their facts, and were in fact also cited by the Zauderer court in order to establish the importance of the “factual and uncontroversial” standard. The cited cases involved a New Hampshire requirement that drivers display the state motto “Live Free or Die” on their license plates, and a West Virginia requirement that students salute the American Flag. In all three cases, including Zauderer, the Supreme Court noted the unconstitutionality of requiring citizens to endorse what amounted to the state’s opinion or political ideology.78

Perhaps as result, later cases in the same circuit have limited Amestoy’s application.79 In National Elec. Mfrs. Ass’n v. Sorrell, the court held that Zauderer was broad enough to encompass non-deceptive disclosure requirements. The court reaffirmed the difference between disclosure and restriction, and again justified why less exacting scrutiny was appropriate for the former.80 “The compelled disclosure [requiring mercury labeling] was not intended to prevent consumer confusion or deception per se,

77 International Dairy Foods Ass’n v. Amestoy, 92 F.3d 67, 72 (2d Cir. 1996).
79 National Elec. Mfrs. Ass’n v. Sorrell, 272 F.3d 104 (2d Cir. 2001) (concerning a Vermont regulation that required manufacturers of mercury-containing products to disclose the presence of mercury on the label); New York State Restaurant Ass’n v. New York City Bd. of Health, 556 F.3d 114 (2d Cir. 2009).
80 Id. at 114.
but rather to better inform consumers about the products they purchase.\textsuperscript{81} It ruled that the state’s interest in raising consumer awareness about mercury levels products, with the indirect purpose of reducing mercury pollution, was a constitutionally valid state purpose.

Sixth Circuit cases have also upheld the Second Circuit reasoning that \textit{Zauderer} could apply to a broader base of state purposes. Two Eleventh Circuit cases have not. Ultimately, the confusion seems to turn on whether \textit{Zauderer} should apply to any disclosure requirement controversies, or only those aimed at combating the problem of otherwise inherently misleading speech. In other words, it is unclear whether \textit{Zauderer} can be used for disclosure that has a purpose other than preventing consumer deception.

Recently, the Ninth Circuit applied the \textit{Zauderer} standard to purely factual and uncontroversial compelled disclosure, where the state interest was public health and access to information. This case, \textit{CTIA—Wireless Ass’n v. City and County of San Francisco}, is discussed under: \textbf{The Necessity for a “Factual and Uncontroversial Label”} below.

\textsuperscript{81} \textit{National Elec. Mfrs. Ass’n v. Sorrell}, 272 F.3d at 115
Compelled Commercial Speech: The Analysis

B. DECIDING ON AN APPROPRIATE STATE PURPOSE

In *Thornhill v. Alabama*, the Court observed that “freedom of discussion, if it would fulfill its historic function in this nation, must embrace all issues about which information is needed or appropriate to enable the members of society to cope with the exigencies of their period.”

The advent of genetically modified food would be one such exigency, as it entails an entirely new method of changing the nature of food. Nonetheless, the more support a state can show to authenticate its intended purpose, the better chance that a court will recognize that purpose as valid. The following is a small selection of state purposes that have and have not worked in the past.

<table>
<thead>
<tr>
<th>VALID</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Action required</strong></td>
<td><strong>Purported state purpose</strong></td>
<td><strong>Reason for validity</strong></td>
</tr>
<tr>
<td>Compelled disclaimer on green tea product regarding health claims</td>
<td>Prevent consumer confusion and protect public health</td>
<td>Legislating health claims is desirable and necessary because of the great potential for defrauding consumers</td>
</tr>
<tr>
<td>No promotional advertising[^83]</td>
<td>Energy conservation Prevent prince inflation</td>
<td>Country’s dependence on energy resources supports interest in conserving Important to regulate economic fairness for consumers</td>
</tr>
</tbody>
</table>

[^82]: 310 U.S. 88, at 102 (1940).
[^83]: *Central Hudson*, 447 U.S. 557.
<table>
<thead>
<tr>
<th>ideological message</th>
</tr>
</thead>
<tbody>
<tr>
<td>Requiring newspapers to publish replies from candidates the paper criticized(^a)</td>
</tr>
<tr>
<td>Press responsibility to promote debate and serve as public forum</td>
</tr>
<tr>
<td>Conflicts with the First Amendment’s guarantees of a free press and free discussion of governmental affairs by mandating dedication of space that could be used otherwise</td>
</tr>
</tbody>
</table>

While none of the above cases are quite analogous to the issue at hand, they present a number of important points that will help guide the drafting of a new labeling regulation:

- Ensure that the disclosure only requires factual information
- Do not require any disclosure that could be construed as opinion
- Do not require disclosure that could be construed to infringe on another distinct right
- Lend force to the state interest with the requisite support, whether in the form of legislative history, research, or emphasizing the long-established state regulatory power for consumer protection

Developing a legitimate state interest may be difficult in light of the fact that scientific evidence on GE salmon is scarce, and what evidence there is, has led the FDA to find that GE salmon is not materially different from Atlantic salmon, and is safe for human consumption.\(^b\) While we strongly recommend that California sponsor research to substantiate health or safety concerns. Again, health and safety are within the ambit of traditional state regulation, and they have been established as legitimate state interests. Given the FDA’s stance on GE foods as generally healthy, the stronger the evidence here, the better – otherwise, the preemptive force of the FDA’s stance on health might trump California regulatory initiatives.

As noted above, other state interests that could buttress GE labeling legislation would avoid treading on FDA’s health and safety terrain, and might be more readily defensible. These areas include:

- Allergens, toxicity, and antibiotic resistance (potentially blocked by FDA findings, however, as within the FDCA’s values of health/safety)
- Adverse social consequences such as increased industrialization, harm to small producers, harm to the organic industry
- Religious food restrictions
- The collection of data to better identify and monitor GE foods consumption to detect long-term effects on human health

\(^b\) FDA Center for Veterinary Medicine, “Briefing Packet” for AquAdvantage Salmon, Prepared for the Veterinary Medicine Advisory Committee” at 109 (September 20, 2010) (available at http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/VeterinaryMedicineAdvisoryCommittee/UCM224762.pdf (last visited 6/2/14)).
• Animal welfare concerns\textsuperscript{87} and
• Environmentalism.

We left out the state interest in preventing consumer deception, even though it is a legitimate state interest. Preventing consumer deception can be a problematic interest in this context, because it can resemble an intent to accommodate consumer curiosity, which is not a valid interest under the \textit{Amestoy} ruling.\textsuperscript{88} That said, identifying the prevention of consumer deception as the state purpose for labeling regulation need not depend on definitive research. For example, when the court in \textit{International Dairy Foods Ass'n v. Boggs} (discussed in the \textbf{Dormant Commerce Clause} section below) struck down a ban on “rBST free” claims on milk for being more restrictive than necessary, it made an important point for California purposes.\textsuperscript{89} The FDA’s statement that there was no significant difference between milk treated with rBST and untreated milk signaled to the court that there was some appreciable difference, and that the acknowledgment that there was no way to differentiate analytically between the two left open the possibility that a method could one day exist.\textsuperscript{90}

Courts have noted that evidence or empirical data is not necessary to demonstrate the rationality of mandated disclosures in the commercial context.\textsuperscript{91} Even when advertising communicates only an incomplete version of the relevant facts, the First Amendment presumes that some accurate information is better than no information at all.\textsuperscript{92} The more credible evidence California can marshal regarding the harms that GE salmon could pose, the stronger the legislative record will be if it is addressed in court.

\textsuperscript{88} \textit{Amestoy}, 92 F.3d 67, 74. Later Second Circuit decisions limited \textit{Amestoy}’s holding “expressly limited to cases in which a state disclosure requirement is supported by no interest other than the gratification of consumer curiosity.” \textit{National Elec. Mfrs. Ass’n v. Sorrell}, 272 F.3d at 115.
\textsuperscript{89} \textit{International Dairy Foods Ass’n v. Boggs}, 622 F.3d 628, 659 (6th Cir. 2010); elsewhere \textit{Boggs} makes the interesting point that “it seems peculiar to deny the consumer, on the ground that the information is incomplete, at least some of the relevant information needed to reach an informed decision.” Id. at 636, \textit{citing Bates v. State Bar of Ariz.}, 433 U.S. 350, 374–75 (1977).
\textsuperscript{90} \textit{Boggs}, 622 F.3d at 636-37.
\textsuperscript{91} \textit{NY Restaurant} at 134; \textit{Conn. Bar Ass’n}, 620 F.3d at 97-98.
In addition to identifying a legitimate state interest, mandatory labeling requirements must only include factual, uncontroversial information.

In 2011, a cell phone trade group sued San Francisco over an ordinance that required cell phone retailers to display informational posters, provide customers with a fact sheet, and paste display stickers that would all disclose facts and recommendations about radiofrequency (RF) energy emissions to customers. Despite the lack of definitive studies, the materials expressed that it was City policy to adhere to the “Precautionary Principle, which provides that the government should not wait for scientific proof of a health or safety risk before taking steps to inform the public of the potential for harm.”

Using the Zauderer standard, the district court reasoned that although the fact sheet’s statements were in isolation all factual, in conjunction, it was misleading in two ways. First, the court held that the entirety of the fact sheet not only left a reader with the impression that the phones sold were not vetted by the Federal Communications Commission, but that the sheet cited to FCC’s website as though it would mirror the fact sheet’s message. Second, it was misleading to omit an explanation of “possible carcinogen,” which was the classification the World Health Organization [the authority cited on the sheet] gave to RF emissions. The court mandated that San Francisco could enforce the ordinance only if it edited the fact sheet to correct the misleading assumptions, and to exclude the poster and sticker.

However, on appeal, the Ninth Circuit ruled that even with the edits the fact sheet was still not factual and uncontroversial, on the basis that the fact sheet also included the City’s recommendations as to what consumers could do to reduce their chances of exposure. The court found that this could be construed as expressing the city’s opinion that using cell phones was dangerous, which extended beyond purely factual information because the science behind the dangers that RF emissions pose is inconclusive.

This case underscores that any California-mandated label for GE salmon should eschew debatable or leading statements about health effects, sharpening the need for the setting out a strong, defensible roster of state interests undergirding the regulation.

93 CTIA—The Wireless Ass’n v. City and County of San Francisco, 827 F.Supp2d 1054 (2011); Ordinance 165-11 §1.
Although the Constitution provides less protection for commercial speech than for other guaranteed forms of expression, society has an important interest in the free flow of information in the commercial realm.

In light of that qualified protection, the government can ban certain forms of communication if it is likely to deceive the public, and government can compel certain forms of communication if they are likely to better inform the public.

A company’s interest in not providing factual information is minimal compared to the consumer’s interest in knowing that information.

For commercial speech to be protected, it must be truthful and non-deceptive.

The Supreme Court has two possible tests that a court could apply to challenges to state regulations that impact commercial speech.

Where the law restricts speech, and the speech is not misleading and does not refer to illegal activity, the courts apply an intermediate scrutiny.

For laws that compel disclosure of information in pursuit of achieving a valid state purpose, courts have evaluated the regulation under a more lenient rational-based scrutiny. Whether this scrutiny only applies when the state purpose is prevention of consumer deception is unclear. There is a circuit split.
Overview of the Doctrine:

III. Dormant Commerce Clause

Conclusion: California’s attempt to protect consumers from risks surrounding genetically-engineered salmon would likely withstand a dormant commerce clause challenge, in part due to the fact that no in-state interests are protected.

The dormant commerce clause doctrine is a judicial interpretation of the Commerce Clause that limits a state’s authority from burdening interstate commerce, even in the absence of Federal legislation.\(^\text{94}\)

Generally, the dormant commerce clause prevents states from erecting barriers to interstate trade. State and local laws that impose an undue burden on interstate commerce are unconstitutional.

To determine whether a state law violates the dormant commerce clause, a court performs a \textit{two-tiered analysis}. Under the \textit{first tier of analysis}, a court looks at whether the state law is discriminatory against interstate commerce or extends its authority extraterritorially beyond the boundary of the state. If the state law is discriminatory or extraterritorial in reach, the law is generally deemed invalid.

If the law survives scrutiny under the first tier, a court moves onto the \textit{second tier of analysis}, where courts look at whether the state law excessively burdens commerce in relation to its local benefits. This has traditionally been called the \textit{Pike Balancing Test}. If the state law is excessively burdensome under the \textit{Pike} balancing test, the law is deemed invalid.

If the law survives both tiers of analysis, the law does not violate the dormant commerce clause.

\textbf{APPLYING THE DOCTRINE}

Of the Seven Policy Options, the analysis of the Dormant Commerce Clause applies with greatest force to Option Five & Option Seven.

Option Five: Product Information Labeling

Option Seven: Outright Ban

\(^{94}\) \textit{United Haulers Ass'n, Inc. v. Oneida-Herkimer Solid Waste Management Authority}, 550 U.S. 330, 338 (2007).

\(^{95}\) \textit{See Lewis v. BT Inv. Managers, Inc.}, 447 U.S. 27, 35 (1980).
Dormant Commerce Clause: The Analysis

A. DISCRIMINATION AGAINST INTERSTATE COMMERCE

To determine whether a state law violates the dormant commerce clause, a court performs a two-tiered analysis.

A. First Tier

Under the first-tier of dormant commerce clause analysis, a state law is considered invalid if: (1) the statute clearly discriminates against interstate commerce in favor of in-state commerce; or (2) the statute has the practical effect of extraterritorial control of interstate commerce.

Initial Question of “Similarly Situated” Entities

As an initial matter, the court looks at whether an out-of-state entity that is alleging discriminatory effect or intent is “similarly situated” to an in-state entity.

In Alaska v. Arctic Maid, the Supreme Court upheld Alaska’s 4% license tax imposed on the value of salmon carried by freezer ships, which froze salmon on-ship and transported the fish for later canning in Washington.96 The freezer ships argued that the tax was discriminatory because Alaska only imposed a 1% tax on the value of salmon carried by vessels that transported salmon to on-shore processors for the fresh-frozen market.97 The Court held that the freezer ships competed in different retail markets from the vessels that froze fish on-shore.98 Because the consumer markets were different, the Washington freezer ship and the Alaskan vessel were not similarly situated.99 Thus, the dormant commerce clause was not implicated.

Similarly, a court might find that there are different markets for “GE salmon,” and the wild caught salmon, apparently the only comparable in-state fish product,100 blocking the possibility that a California law would discriminate against out-of-state producers in favor of in-state entities, just as the Supreme Court found that canned wild salmon was a different market than fresh-frozen salmon. Given that the answer to this notion of “similarly situated” cannot be surmised definitively, and that courts have found discrimination in a variety of circumstances, however, we proceed to step through the discrimination analysis below.

Discrimination

97 Id. at 204.
98 Id.
99 See also Rocky Mountain Farmers v. Corey, 730 F.3d 1070, 1101 (9th Cir. 2013) (holding that “entities are similarly situated for constitutional purposes if their products compete against each other in a single market.”)
100 Fish & Game Code § 15007(a) bans salmon aquaculture in Pacific Ocean waters under California’s jurisdiction (“In the waters of the Pacific Ocean that are regulated by this state, it is unlawful to spawn, incubate, or cultivate any species of finfish belonging to the family Salmonidae, transgenic fish species, or any exotic species of finfish”); moreover, a self-reported list of aquaculturalists in California contains no record of salmon aquaculture in the state. California Dept. of Fish & Game, “Registered Aquaculturalists,” available at https://nrm.dfg.ca.gov/FileHandler.ashx?DocumentID=3265&inline=true (last visited 6/2/14).
A law is considered discriminatory if it treats an in-state economic interest differently from an out-of-state economic interest by benefiting the in-state interest while burdening the out-of-state interest. Laws motivated by economic protectionism are generally deemed invalid. For example, a state law that imposes a surcharge on the disposal of out-of-state waste at a higher rate than waste generated in-state is considered facially discriminatory because the law explicitly and specifically targets a company who is out of state.

Even when laws are not facially discriminatory, a state law that has discriminatory intent or has a discriminatory effect may be struck down as invalid.

**Washington State Apple: A Case Involving Discriminatory Intent:**

In *Hunt v. Washington State Apple Advertising Commission*, the Supreme Court struck down a North Carolina law that prohibited the sale or importation of apples bearing any grade “other than the applicable U.S. grade.”

While the statute was not explicitly (or “facially”) discriminatory against Washington apples, Washington State argued that the law was discriminatory because it prohibited Washington apple growers and dealers from using “Washington State grade” to distinguish their products in the marketplace. Washington argued that its grades had “gained substantial acceptance in the trade, [and] are the equivalent of, or superior to, the comparable grades and standards adopted by the United States Department of Agriculture.” Indeed, Washington spent over $1 million in marketing and developing the system.

In defense of the statute, North Carolina argued that the law was not discriminatory because it was not directly aimed at Washington, but instead, aimed at helping consumers avoid confusion and deception.

The Supreme Court agreed with Washington, finding that the law was discriminatory. The Court held the law would: (1) raise the costs on Washington apple growers while leaving North Carolina counterparts unaffected; (2) require Washington apples growers and dealers to re-market their apples with the less superior USDA-grade, creating an advantage for North Carolina apple producers; and (3) take away a competitive and economic advantage that Washington had earned through an expensive inspection and grading system. Ultimately, the Supreme Court was concerned about economic protectionism.

101 *United Haulers Ass'n, Inc. v. Oneida-Herkimer Solid Waste Management Authority*, 550 U.S. 330, 338 (2007).
102 *Id.*
105 *Id.* at 354.
106 *Id.* at 336.
107 *Id.*
108 *Id.*
109 *Id.* at 340.
110 *Id.* at 350.
111 *Id.* at 350-52.
The Supreme Court also reviewed the legislative history to determine whether there was economic protectionism at play on the part of North Carolina.\textsuperscript{112} When the North Carolina Commission was debating about whether it would create a legislative exemption for Washington State, a Commissioner said that he had to check with the state’s apple producers since they were “mainly responsible” for the legislation being passed.\textsuperscript{113} The Washington State Apple Court found this probative of economic protectionism because it suggested that an in-state entity was intentionally trying to burden an out-of-state entity.\textsuperscript{114}

\textbf{Boggs: A Case Without Discriminatory Intent}

In 1993, the FDA approved Posilac, a recombinant bovine growth hormone (also known as rbGH or rBST) injected into dairy cows to increase milk production.\textsuperscript{115} The FDA concluded that rBST was safe and effective and that “there was no significant difference between milk from treated and untreated cows.”

After the FDA approved rBST to enter commerce, the FDA issued a Guidance to inform States on how to properly enforce rBST-labeling claims to avoid misleading consumers.\textsuperscript{116} The FDA issued the Guidance after several States, and industry and consumer representatives requested FDA direction.\textsuperscript{117} While milk processors could “voluntarily inform consumers” that its milk does not come from cows treated with rBST, the FDA intended “to rely primarily on the enforcement activities of the interested States to ensure that rBST labeling claims are truthful and not misleading.”\textsuperscript{118}

In the Guidance, the FDA signaled what labels might be considered false and misleading. Specifically, the Guidance focused on labeling claims made from milk processors who supplied milk from cows not treated with rBST.\textsuperscript{119} The FDA signaled that claims like “BST-free” or “From cows not treated with rBST” \textit{alone} were considered misleading because it could confuse consumers into thinking that milk from cows treated with rBST was less safe or less nutritious.

Instead, the FDA approved the following voluntary claim:

\begin{quote}
“From cows not treated with rBST”.\textsuperscript{1}
\end{quote}

\textsuperscript{1}No significant difference has been shown between milk derived from rBST-treated and non-rBST-treated cows.”

After the FDA Guidance, the Ohio Department of Agriculture promulgated a rule that prohibited dairy processors from making the stand-alone claim that its milk was “rBST Free.”\textsuperscript{120} Soon after, the International Dairy Foods Association (IDFA) filed suit against Ohio.

\begin{flushleft}
\textsuperscript{112} Id. at 352; see also Kassel v. Consolidated Freightways Corp. of Delaware, 450 U.S. 662, 677 (1981) (finding hints of economic protectionism within a Governor’s veto message).

\textsuperscript{113} Id. at 352.

\textsuperscript{114} Id.

\textsuperscript{115} Animal Drugs, Feeds, and Related Products; Sterile Sometribove Zinc Suspension, 58 Fed. Reg. 59946 (Nov. 12, 1993) (to be codified at 21 C.F.R. § 510.600(c); 21 C.F.R. § 522.2112) [hereinafter Animal Drugs, 58 Fed. Reg. 59946].

\textsuperscript{116} Animal Drugs, 58 Fed. Reg. 59946.

\textsuperscript{117} Id.

\textsuperscript{118} Id.

\textsuperscript{119} Id.

\textsuperscript{120} International Dairy Foods Ass’n v. Boggs, 622 F.3d 628, 634 (6th Cir. 2010).
\end{flushleft}
In *International Dairy Foods Association v. Boggs*, IDFA argued (among other theories) that Ohio’s rule was discriminatory because “Ohio dairy farmers and Monsanto . . . were the driving force behind the proposals.” According to the IDFA, traditional Ohio dairy farmers and Monsanto wanted to stop Ohio dairy processors from using milk from rBST-free cows. The IDFA contended that out-of-state milk processors committed to using milk from cows not given rBST would be “stripped of any competitive advantage they had developed from advertising their nonuse of such milk in Ohio.”

The Sixth Circuit rejected these arguments because there was no discriminatory intent or effect. The court held that since “traditional Ohio dairy farmers and Monsanto lobbied for the Rule in an effort to prevent other Ohio dairy processors from converting to products made with milk from cows not treated with rBST . . . the rule [was not] aimed at favoring Ohio economic actors at the expense of out-of-state interests” (original emphasis).

The *Boggs* court also held that notwithstanding the FDA’s Guidance, the composition claim “rBST free” was not inherently misleading. The Sixth Circuit indicated that the FDA’s Guidance stated that, “there is no significant difference between milk from treated and untreated cows because ‘there is currently no way to differentiate analytically’” between milk from treated and untreated cows (original emphasis). Thus, the FDA “appears to have left room for the fact that some compositional difference between the two types of milk may exist, leaving open the possibility that one day a method might exist to detect whether rBST is in fact present in conventional milk.” Accordingly, “[t]he composition claim ‘rBST free’ is therefore demonstrably true as applied to this milk.”

---

121 *Id.* at 648.
122 *Id.*
123 *Id.*
124 *Id.*
125 *Id.*
126 *Id.* at 626.
127 *Boggs*, 622 F.3d at 637.
128 *Id.*
129 *Id.*
Dormant Commerce Clause: The Analysis

B. EXTRATERRITORIAL EFFECT

To determine whether a state law violates the dormant commerce clause, a court performs a two-tiered analysis.

A. First Tier

Under the first-tier of dormant commerce clause analysis, a state law is considered invalid if: (1) the statute clearly discriminates against interstate commerce in favor of in-state commerce; or (2) the statute has the practical effect of extraterritorial control of interstate commerce.

Extraterritorial Effect

A law has extraterritorial effect if the statute has the practical effect of controlling conduct beyond the boundary of the state. To determine whether a law has extraterritorial effect, a court examines the direct consequences of the statute, and how the statute may interact with other States’ regulations. Generally, courts have narrowly applied the extraterritorial principle, typically only invalidating state laws that tie the cost of a product outside the state. For example, a State law that requires a product’s price in the State to be no higher than the price outside the state would be invalid.

One example of the limited reach of the extraterritorial doctrine is Cotto Waxo Co. v. Williams. The Cotto Waxo court reviewed Minnesota’s ban on the sale of petroleum-based compounds. Cotto Waxo, which sold the petroleum throughout the Midwest, argued that the Minnesota law imperiled its ability to market the product in the rest of the Midwest by using Minnesota distribution facilities. Although the Minnesota law affected Cotto Waxo’s business model, the court held that the ban did not have extraterritorial reach because the Minnesota law did not “require[] out-of-state commerce to be conducted according to in-state terms.” Similarly, sales of GE salmon outside of California are unaffected by regulations on labeling or restrictions on sales within California.

Foie Gras: A Case Without Extraterritorial Effect

In Association des Eleveurs de Canards et d’Oies du Quebec v. Harris, the Ninth Circuit upheld California’s ban on foie gras. In upholding the law, the Ninth Circuit rejected all of the dormant commerce clause arguments proffered by the foie gras producers.

California’s foie gras law contains two critical parts. Under California Health and Safety Code, Section 25981 provides that: “[a] person (in California) may not force feed a bird for the purpose of enlarging the bird’s liver beyond normal size, or hire another

---

131 Rocky Mountain Farmers Union v. Corey, 730 F.3d 1070, 1101 (9th Cir. 2013).
133 Cotto Waxo Co. v. Williams, 46 F.3d 790, 794 (8th Cir. 1995).
134 Id.
135 Id. at 792.
136 Id. at 794.
person to do so.” Section 25982 provides that: “[a] product may not be sold in California if it is the result of force feeding a bird for the purpose of enlarging the bird’s liver beyond normal size.”

The Ninth Circuit rejected the foie gras producers’ discrimination arguments. The foie producers argued that California’s law discriminated against interstate commerce because Section 25982 specifically targeted out-of-state entities: since Section 25981 is aimed at California businesses, Section 25982 must be limited to, and targeting, out-of-state producers. The Court disagreed, holding that Section 25981 is focused on the conduct, while Section 25982 is focused on the product.

The foie gras producers also argued that California’s law violated the extraterritorial doctrine because: (1) the ban stops the free flow of foie gras between states; and (2) the ban controls conduct outside of the State. The foie gras producers relied on Schollenberger v. Pennsylvania, where the Supreme Court struck down Pennsylvania’s ban on margarine because it violated the extraterritorial doctrine.

However, the Ninth Circuit held that California’s foie gras ban was distinguishable from Pennsylvania’s margarine ban. First, the Ninth Circuit reasoned that in Schollenberger, Pennsylvania was banning a product, whereas California was banning a process. Indeed, the Ninth Circuit explained that, “Section 25982 only precludes a more profitable method of operation — force feeding birds for the purpose of enlarging their liver — rather than affecting the interstate flow of goods.”137 Second, the Ninth Circuit reasoned that Congress “actively regulated” the margarine industry, whereas foie gras producers could not demonstrate “that a nationally uniform foie gras production method” was required to produce foie gras.138

Additionally, the Ninth Circuit held that California’s law did not control conduct outside of the State. The Ninth Circuit reasoned that California’s law did not fix the cost structure of foie gras products outside of the state, nor did the law tie California’s liver products prices to out-of-state prices.139

California’s Greenhouse Gases: A Case Without Extraterritorial Reach

In 2007, in response to the Governor’s Executive Order, the California Air Resources Board (CARB) developed a carbon fuel standard, which sets the carbon intensity value of different transportation fuels used by consumers in California.140 The carbon fuel standard is intended to spur the development of low-carbon fuels and reduce overall emissions.141 The carbon intensity is determined by the amount of greenhouse emissions produced throughout the lifecycle of the fuel.142 Accordingly, the amount of greenhouse gases emitted or the level of energy used during the production, transportation, and use of a particular fuel affects CARB’s valuation of a fuel’s carbon intensity.143 Consequently, the geography of where a fuel is produced generally has an effect on the carbon intensity.144

138 Id. at 950.
139 Id. at 951.
140 Rocky Mountain Farmers Union, 730 F.3d at 1070.
141 Id. at 1080.
142 Id.
143 Id. at 1081-83.
144 Id. at 1083-84.
Soon after, Rocky Mountain Farmers Union (Rocky Mountain) filed suit, arguing that CARB’s fuel standard discriminated against out-of-state producers and had extraterritorial reach. The 9th Circuit rejected both of Rocky Mountain’s arguments.

The 9th Circuit rejected Rocky Mountain’s discrimination argument. Rocky Mountain argued that its ethanol has the same physical and chemical properties as California ethanol, and that the CARB discriminated against its ethanol on the basis of origin by imposing a higher carbon intensity value. The Circuit held that “if producers of out-of-state ethanol actually cause more GHG emissions for each unit produced, because they use dirtier electricity or less efficient plants, CARB can base its regulatory treatment on these emissions.” Thus, an out-of-state producer was burdened not because the producer was out-of-state — but because of environmental reasons.

The 9th Circuit also rejected Rocky Mountain’s extraterritorial reach argument. Rocky Mountain argued that CARB’s carbon intensity valuation was an attempt at controlling out-of-state conduct, and that if every state “enacted a regulation similar to the Fuel Standard, it would result in economic Balkanization.”

The 9th Circuit disagreed, holding that a firm could meet California’s standard if “they wish to gain market share” but no firm was required to do so. Indeed, no firm needed to “adopt a particular regulatory standard for its producers to gain access to California.” While California may consider transportation, farming practices and land use as factors for its valuation in carbon intensity, California was not controlling producers. While California’s laws may create market incentives for fuel producers to create cleaner fuel, California law was not dictating that market.

Additionally, the 9th Circuit held that to show the threat of Balkanization, Rocky Mountain must “present evidence that conflicting legitimate legislation is already in place or that the threat of such legislation is both actual and imminent.” The Court cited to a few states considering legislation, but noted that the other pieces of legislation were complementary to California’s law.

In sum, the lessons of Rocky Mountain are twofold: 1) an insistence on the environmental values as a state interest can immunize restrictive legislation; and 2) an even-handed regulation can permissibly result in changing the terms of industry’s engagement with the California marketplace.

145 Id. at 1086-87.
146 Rocky Mountain Farmers Union, 730 F.3d at 1088.
147 Id. at 1090.
148 Id. at 1101.
149 Id.
150 Id.
151 Id. at 1103.
152 Id.
153 Id. at 1104-05 (citing S.D. Myers v. City of San Francisco, 253 F.3d 461, 469-70 (9th Cir. 2001)).
154 Id.
Dormant Commerce Clause: The Analysis

C. PIKE BALANCING

To determine whether a state law violates the dormant commerce clause, a court performs a two-tiered analysis.

B. Second Tier

When a law is not discriminatory and the law only has indirect effects on interstate commerce, the court conducts a balancing test set out in by *Pike v. Bruce Church*. The *Pike* test requires a court to examine whether a state regulation imposes a burden upon interstate commerce that is clearly excessive in relation to the local benefits. The inquiry depends upon “the nature of the local interest involved, and on whether it could be promoted as well with a lesser impact on interstate activities.”

Unless the balancing test reveals that the burden on interstate commerce is excessive, the law survives. For example, a statute that causes some businesses to shift from predominantly out-of-state to in-state business is not necessarily an excessive burden if goods can continue to move freely.

Mercury Labeling: A Case that Survives the Pike Balancing Test

In *National Electrical Manufacturers Association v. Sorrell*, the Second Circuit upheld a Vermont labeling law requiring manufacturers of mercury-containing products to inform consumers that their products contained mercury and that upon disposal the products should be recycled or disposed of as hazardous waste. The National Electrical Manufacturers Association (NEMA) argued that the labeling law was excessively burdensome compared to the State’s interest. The 2nd Circuit panel disagreed.

The crux of the Second Circuit’s analysis was whether Vermont was shifting the costs of its regulation onto other States. NEMA argued that if it wanted to continue selling in Vermont, it would be “forced as a practical matter to label lamps sold in every other state.” The Second Circuit disagreed, holding that the Vermont law did not pass costs onto other states because the manufacturers could “modify their production and distribution systems to differentiate between Vermont-bound and non-Vermont-bound lamps.” Indeed, the Circuit panel stated that the lamp manufacturers could arrange its systems so that higher prices would be shifted onto Vermont consumers instead of other states. The Circuit even reasoned that “a decision to abandon the state’s market rests

---

156 Id.
157 Id.
158 Id.
159 Id.
162 Id. at 110.
entirely with individual manufacturers,” not with the state legislature. Essentially, when a state law affects a product market, the state does not bear the burden in bouncing the market back to its condition before the legislative enactment.

The Circuit also rejected NEMA’s argument that Vermont’s law would expose its manufacturers to “multiple, inconsistent labeling requirements imposed by other states.” The Second Circuit found that no other states had conflicting laws, and that even some states had laws consistent with Vermont. Thus, Vermont’s law was not excessively burdensome.

The Circuit also found that Vermont had legitimate interests that outweighed any burden on interstate commerce. The Circuit reasoned that, “Vermont’s interest in protecting human health and the environment from mercury poisoning is a legitimate and significant public goal.” The Circuit noted that this interest was more than just preventing “consumer confusion or deception.” Rather, the Vermont law was about “better [informing] consumers about the products they purchase.”

**Imitation Cheese: A Case that Survives Pike Balancing**

In 1985, the Grocery Manufacturers Associations filed suit against a New York state law that required that alternative cheese products (cheese where the milkfat content was removed or replaced with substitutes) be labeled as “imitation” cheese, controverting Federal labeling requirement which allows imitation cheeses that are not “nutritionally inferior” to be natural cheese to be labeled as “cheese.” The New York law also required retailers and restaurants that sold or used the “imitation” cheese to post retail signs or list its use on menus. In *Grocery Manufacturers Association v. Gerace*, the Second Circuit struck down the law’s labeling provisions under preemption grounds, but upheld that retail sign and menu requirements against a dormant commerce clause challenge.

Applying the *Pike* balancing test, the *Gerace* court held that the state had a legitimate state interest for the retail signs and menu requirements, in spite of the FDA regulations requiring that imitation cheese not nutritionally inferior be labeled as “cheese.” The court highlighted the fact that the disagreement among nutritionists over the health impact of imitation cheese products itself was relevant: “[t]he very existence of this controversy persuades us that New York’s nutritional concerns are not unreasonable.” This argument suggests a potential strategy in rebuffing the argument

---

163 *Sorrell*, 272 F.3d at 111.
164 *Id.* at 112. *See also Bibb v. Navajo*, 359 U.S. 520, 526-30 (1959) (finding that evidence of conflicting regulation in neighboring states is a factor in dormant commerce clause analysis).
165 *Id.*
166 *Id.* at 115.
167 *Id.*
168 *Id.*
170 *Id.* at 997.
171 *Id.* at 1003.
172 *Id.* at 1003-04.
173 *Id.*
that FDA approval of GE salmon ends the possibility of state regulation based on health and safety of consumers: the mere existence of a contrary scientific viewpoint might serve to ground California regulation of GE salmon. What is more, the Gerace court pointed to state interests exogenous to health and safety – the prevention of deception and unfair competition, to promotion of honesty and fair dealing and the goal of permitting consumers to clearly discern whether they are buying real cheese or not. This paper has repeatedly counseled finding the broadest portfolio of state concerns in backing regulation – e.g., the discussion in the Compelled Commercial Disclosure.

The Gerace court then examined the economic impact of the cheese law. Combing through the record, the Circuit noted that there was not much evidence on economic impact. In fact, the only availing evidence was from one business that loss sales in imitation cheese amounting $7,500 a week. While the Gerace court noted that the law would reduce the sale of cheese alternatives, the court found that the burden was relatively minor considering the importance of the state interest. Thus, if the economic or monetary impact was greater, the Second Circuit might have decided the case the other way.

**Revisiting the Boggs Case and its Application of the Pike Test**

Although the Boggs Circuit struck down key provisions of Ohio’s rule relating to rBST, the Circuit found that remaining provisions of Ohio’s law survived under the Pike balancing test. The Circuit found that “Ohio has a reasonable basis to believe that the Rule’s intended benefit—consumer protection—is significant.” Indeed, States “have always possessed a legitimate interest in the protection of their people against fraud, deception in the sale of food products.” While the key provisions of Ohio’s law were struck down, the Circuit held that the remaining provisions of the Ohio law outweighed any burden that it imposed on interstate commerce.

**Another Look at the Foie Gras Case and its Application of the Pike Test**

In addition to rejecting the foie gras producers’ discrimination and extraterritorial arguments, the Ninth Circuit also rejected the foie gras producers’ arguments under the Pike test. The Ninth Circuit held that the statute did not burden interstate commerce.

---

174 In contrast to the FDA’s findings, an expert panel has written that "unintended genetically based changes to an organism’s phenotype associated with the introduced gene construct .... has been manifested by changes to enzyme activity, gross anatomy, behaviour and, in all likelihood, hormonal activity" of transgenic fish. Royal Society of Canada, “Expert Panel Report on the Future of Food Biotechnology, Elements of Precaution: Recommendations for the Regulation of Food Biotechnology in Canada” at (2001), available at http://www.rsc.ca/sites/default/files/pdf/GMreportEN.pdf (last visited 6/2/14).
175 Id.
176 Id. at 1004.
177 Id.
178 Gerace, 755 F.2d at 1005.
179 Boggs, 622 F.3d at 649.
excessively in relation to the local benefits.

The Ninth Circuit noted that burdensome statutes are usually discriminatory, or result in inconsistent regulation of activities that are inherently national or require a uniform system of regulation. Since the Circuit held that the statute was not discriminatory, the court examined the foie gras producers’ other arguments.

The Ninth Circuit held that the foie gras producers were unable to show that the “foie gras market is inherently national or that it requires a uniform system of regulation.” The foie gras producers also argued that the regulation was burdensome because it would lose over $5 million in sales, and that California’s interest in preventing animal cruelty was not sufficient when weighed against the financial interests of the foie gras industry. Moreover, the producers argued that the ban does not achieve California’s interest in preventing animal cruelty and that less burdensome alternatives were available.

Again, the Ninth Circuit disagreed with the foie gras producers. The Ninth Circuit concluded that the producer’s sales estimate was overestimated, and that California interest in preventing animal cruelty was legitimate. Additionally, the Ninth Circuit stated that the foie gras producers failed to present evidence that California’s ban “is an ineffective means of advancing the goal.” Indeed, the Circuit held that the presence of less burdensome alternatives is only important if there is a significant burden on interstate commerce. Given that there was no excessive burden on interstate commerce, the court found the California statute valid.

\[181\] Association des Eleveurs de Canard, 729 F.3d 937, 952 (2013); see also CTS Corp. v. Dynamics Corp. of America, 481 U.S. 69, 88-89 (1987) (holding that recent Commerce Clause cases have invalidated statutes subjecting activities to inconsistent regulation); Cooley v. Board of Wardens, 53 U.S. 299, 319 (1851) (holding that the Commerce Clause prevents states from regulating subjects that “are in the nature national, or admit only of one uniform system, or plan of regulation”).

\[182\] With respect to GE salmon, these two factors are relevant, suggesting that early regulation, before a market can develop, might be regarded as less burdensome, and also, that moral and other ideological objections might resonate with a court.
HIGHLIGHTS OF THE DORMANT COMMERCE CLAUSE DOCTRINE & ANALYSIS

- When a law only affects out-of-state producers because there are no comparable in-state producers, the dormant commerce clause is not triggered. See Arctic Maid; Rocky Mountain Farmers Union.

- A law will likely be struck down if it furthers economic protectionism. In other words, a law is discriminatory if it creates a significant advantage for in-state producers to the detriment of out-of-state producers. See Washington State Apple.

- The language of a statute does not need to be explicitly discriminatory to violate the dormant commerce clause. A court may find discriminatory intent or effect in the text of the law, or through legislative history. See Washington State Apple.

- Even if the immediate costs of a law may appear to be minor, a court may determine long-term costs by examining the economic ripple effect of a law on other states. See Washington State Apple.

- In passing legislation, the Legislature must be circumspect in terms of stakeholders of mobilizing in support or in opposition against the bill. If the legislative history reveals that in-state interests are driving the legislation for its own economic benefit or protection, a court will find that effort highly suspect of discriminatory intent. See Washington State Apple; Kassel.

- However, if there are in-state and out-of-state interests each set to win and lose, a court is less likely to find discriminatory intent. See Boggs.

- If the State pursues legislation, the Legislature should be conscious of whether the State’s regulation will pass the true costs of the regulation onto consumers outside the State. Given California’s large market, any new standard could cause a ripple effect in the national market, and make the standard vulnerable to a dormant commerce clause challenge. See Rocky Mountain Farmers Union; Sorrell; Gerace. However, the smaller the economic value of a market segment, the less likely that the court will find it to be burdensome. See Foie Gras; Sorrell.

- California should couch its interest in regulating GE salmon in terms of consumer protection, public health, environmental, and even a concern for animal cruelty/morality. Moreover, California should highlight the existence of an unsettled scientific certitude about the safety of GE salmon and California’s precautionary concern over public health. See Dormant Commerce Clause cases, specifically Gerace at 1005.

- When businesses are required to comply with a variety of different rules from different jurisdictions, courts are solicitous about the effect on the free flow of the goods. See Foie Gras; Washington State Apple. California should look to other states’ regulatory efforts to maintain uniformity. See Sorrell.
IV. Drafting Tips for GMO Legislation

The State should keep the following in mind in considering legislation on product labeling:

- The State could authorize businesses to voluntarily label their products as “non-genetically-engineered salmon.” However, since the FDA has found no appreciable difference between GE-salmon and non-GE-salmon, businesses should indicate that the FDA has found no appreciable difference between the two products; this might help insulate the label from the claim that it is misleading (and violative of FDA labeling regulations. See Boggs.

- If the State enacts mandatory GE labeling legislation, the Legislature should narrowly tailor the legislation so that costs are not shifted onto other states. For example, legislative intent could specifically indicate that the labeling requirement is only on products sold in California, and not for products that are merely passing through the state. Indeed, the more likely that only Californians will bear the costs associated with a labeling requirement, the less likely the labeling requirement will trigger a dormant commerce clause problem. See Foie Gras; Mercury.

- If the State pursues labeling legislation, the Legislature should seek to mirror similar requirements in other states, such as the recent Vermont law requiring genetically engineered commodities and products to be labeled as “genetically engineered.” A State’s labeling rules are more likely to be burdensome if it forces businesses to comply with multiple inconsistent labeling requirements. See Mercury.

- If the State pursues labeling legislation, the Legislature should show how labeling is the best option in protecting consumers. See Gerace. The legislative history should try to convey that a more burdensome alternative, such as banning the transgenic fish, is not pragmatic, and that conversely, less burdensome alternatives like public service announcements, and voluntary labeling will not achieve the state’s interest in informing consumers. See Foie Gras.

- Ultimately, legislation should be tailored to achieve the state’s interest. For example, a ban on transgenic salmon would not likely achieve the state’s interest in consumer awareness, whereas a ban might achieve the state’s interest in protecting Californians from consuming transgenic animals.

The State should keep the following in mind in considering legislation on banning the sale of GE salmon in California:

- If the State enacts a ban on GE salmon, the Legislature should signal that it is not controlling a product, but regulating a process (and hence, less likely to be interfering with interstate commerce). California could “ban the sale of salmon that is created by a genetically-engineered process involving other species’ DNA to achieve a high growth rate.” See Foie Gras.
• If California bans salmon produced by genetic engineering, the Legislature should clearly indicate that California is not preventing other consumers in other states from gaining access to GE salmon. *See Foie Gras.*

• If California enacts legislation banning the sale of GE salmon in California, the Legislature should signal that the product does not require nationally uniformity, but rather is confined to traditional and parochial California interests. Similar to California’s bans on abalone and foie gras, couched in terms of animal cruelty and morality, a ban on transgenic salmon could rely on similar grounds.
V. California’s Other Policy Options: Why They Don’t Work

Option One: GE Salmon Approval

The Preemption Doctrine and the Supremacy Clause would prevent California from instituting a parallel approval process for genetically engineered salmon similar to FDA’s approval process expected to approve the domestic sale of genetically engineered salmon.

Although California has statutory and regulatory authority over certain aspects of food inspection, importation, manufacturing, production, and sale under the Sherman Food, Drug, and Cosmetic Law (Sherman Food Law), the Food and Drug Administration has ultimate authority over New Animal Drug Applications. Any attempt to undo an FDA approval would likely meet with a quick and certain judicial invalidation on Supremacy Clause grounds; in fact, as written in the body of the FDA’s report, the preemptive force of the NADA approval itself might suffice to preempt some of California’s regulatory options.

Option Two: Inspections Outside of California

Although California law allows CDPH agents to enter, inspect, and secure a food sample or specimen from “any factory, warehouse, or establishment in which any food [ . . . ] is manufactured, packed, or held,” California’s statutory authority generally stops at its borders.

Moreover, the Dormant Foreign Commerce Clause could present a legal barrier if California sought to send its own health inspectors into other jurisdictions, particularly Panama or Canada. Under the Dormant Foreign Commerce Clause, the Supreme Court applies “a more extensive constitutional inquiry” to determine whether a state law interferes with foreign commerce. Unlike the dormant commerce clause which is focused on how a state law affects commerce amongst the various states, dormant foreign commerce clause is concerned with how a state’s action may interfere with the nation’s ability to engage in its foreign affairs. The Supreme Court has said that “the Federal Government must speak with one voice when regulating commercial relations with foreign governments.” Given that AquaBounty’s hatcheries are in Canada, and grow-out facility is in Panama, a court might find that independent state action prevents the United States from speaking with one voice.

Option Three: Environmental Regulation

While the Dormant Commerce Clause is unlikely to be a legal barrier should California seek to invoke the California Environmental Quality Act (CEQA), this option is

183 California Health and Safety Code §§ 109875 et seq.
186 Id. at 450.
187 Id. at 449.
not possible under current California regulations (14 CCR 15277). These regulations state that CEQA does not apply to a non-California project which is otherwise subject to Federal environmental review under the National Environmental Policy Act (NEPA). The FDA’s review of the new animal drug application for GE salmon already includes a draft Environmental Assessment. Even if the California Office of Planning and Research should rescind this CEQA exemption, a challenge remains in isolating a California agency action with respect to the mere importation of GE salmon products, the necessary predicate for a CEQA analysis. Of course, the permit review process for a GE salmon hatchery located in California would trigger CEQA analysis, but current law already bars aquaculture of salmon and transgenic fish in California’s jurisdiction.

Option Four: Importation into California

While the Dormant Commerce Clause would not prevent California public health officials from seizing or embargoing genetically-engineered salmon upon the Department of Public Health’s finding that the salmon was unsound, unsafe, or deleterious to health, this option is not viable because the standard is high. Immediate or potentially serious injuries to human health are required before the Department could invoke this authority.

Under California law, a CDPH agent who finds food that is unsound, decomposed, putrid, poisonous, or “deleterious to health or otherwise unsafe, may declare the food to be a nuisance.” If the food is considered a nuisance, CDPH “shall condemn or destroy it, or render it unsalable as human food by decharacterization.” To date, there has been no court cases defining what amounts to being “deleterious to health or otherwise unsafe.”

Also, a CDPH agent who finds food that is adulterated, misbranded, or falsely advertised may tag the food, embargoing the food from being sold. Court proceedings are required to determine whether the food should be condemned, or simply corrected with proper labeling.

While the State could develop legislation to define “deleterious to health” to include food products developed through genetically engineering, a court may find the definition to be plagued by the same problem of an inadequate scientific basis for considering GE salmon as inimical to human health.

| Potential Legislation: The Legislature could develop a “deleterious to health or otherwise unsafe” standard that would give more discretion to public health officials to seize or embargo genetically engineered foods. |

Option Six: Caution Signs

This Option is of dubious utility due to the arguments made in the Compelled Commercial Speech section, and specifically, the CTIA case: an absence of scientific

---

188 California Health and Safety Code § 111890.
189 Id.
190 Id.
evidence would likely transforms point of sale signage into the California’s “opinion” that GE salmon is dangerous, rather purely factual information. California stands a better chance of defending labeling legislation, given the relatively more robust precedents for state additions to package labeling. Also, given that package labeling and point of sale signage are considered one and the same for purposes of preemption analysis, in the event that the labeling option should fall, any caution signs at the point of sale would be similarly flawed.\footnote{A California court held that the National Meat Inspection Act’s express preemption clause that prohibits state labeling requirements “in addition to, or different than” the labeling required by the FMIA trumped Proposition 65 warning sign requirements. \textit{Am. Meat Inst. v. Leeman}, 180 Cal. App. 4th 728, 761, (2009). Most significantly for purposes of GE salmon regulation, the court cited \textit{Kordel} for the assertion that “labels” are broadly interpreted to include material that accompanies a product in the sense that it “supplements or explains it,” but is not necessarily physically attached. \textit{Leeman}, 180 Cal. App. 4th at 757, citing \textit{Kordel}, 335 U.S. 345, 350 (1948).}