

TO: Sierra Club, Rocky Mountain Chapter, Genetic Engineering Committee

FROM: Gillian Dale

DATE: May 1, 2002

RE: **Constitutional Challenges to State Food Labeling Laws**

## I. INTRODUCTION

We have been informed that several state legislators are considering introducing legislation in the next session requiring labeling of foods that contain genetically engineered ingredients. However, there is some question as to whether such legislation would be vulnerable to a constitutional challenge. This memo discusses the possible avenues for a constitutional challenge to state food labeling laws, and assesses the likelihood of success of such a challenge.

There are two avenues by which an opponent of state food labeling laws might challenge the laws as being in violation of the United States Constitution. The first is under the doctrine known as the “dormant commerce clause,” which states that the mere fact that the federal government has explicit authority to regulate interstate commerce restricts states from passing laws that unduly burden interstate commerce. The second is under the federal preemption doctrine, which prevents states from passing laws that conflict with federal laws on the same subject. This discussion focuses on potential challenges based on the Fair Packaging and Labeling Act and the Federal Food Drug and Cosmetic Act.

## II. DORMANT COMMERCE CLAUSE

Under the Constitution, the United States Congress has been expressly delegated the authority to regulate commerce between the states. See U.S. Const. art. I, § 8, cl. 3. As a result, the courts have held that the authority of states to impose additional burdens on interstate commerce is restricted. See Lewis v. BT Investment Managers, Inc., 447 U.S. 27, 35 (1980)(“Although the Clause thus speaks in terms of powers bestowed upon Congress, the Court has recognized that it also limits the power of the States to erect barriers against interstate trade.”) This common law limitation on state regulation of interstate commerce has become known as the “dormant commerce clause.” However, this limitation is not absolute, and “the States retain authority under their general police powers to regulate matters of ‘legitimate local concern,’ even though interstate commerce may be affected.” Id. at 36; see also Maine v. Taylor, 477 U.S. 131, 151 (1986)(“As long as a state does not needlessly obstruct interstate trade or attempt to ‘place itself in a position of economic isolation,’ it retains broad regulatory authority to protect the health and safety of its citizens and the integrity of its natural resources.” (citation omitted)).

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In determining whether a state law violates the dormant commerce clause, the courts will first assess whether the law addresses a matter of legitimate local concern. If it does, the court will perform a balancing test, weighing the state's interest in addressing the local matter against the burden that the law imposes on interstate commerce. Generally speaking, "[w]here the statute regulates evenhandedly to effectuate a legitimate local public interest, and its effects on interstate commerce are only incidental, it will be upheld unless the burden imposed on such commerce is clearly excessive in relation to the putative local benefits." Pike v. Bruce Church, Inc., 397 U.S. 137, 142 (1970).

### A. Matters of Legitimate Local Concern

A law is most likely to be viewed as addressing a matter of legitimate local concern where the state is acting to further health, safety, or general welfare objectives, also referred to as the state's "police power."<sup>1</sup> The Supreme Court has stated that "the supervision of the readying of foodstuffs for market has always been deemed a matter of peculiarly local concern," Florida Avocado Growers v. Paul, 373 U.S. 132, 144 (1963), and, more particularly, it has noted that the field of food labeling has traditionally been occupied by the states. See Jones v. Rath Packing Co., 430 U.S. 519, 548 (1977). In addition, the proposed legislation at issue addresses a potential danger to the state's natural environment. The Supreme Court has acknowledged the states' interest in protecting its citizens from environmental hazards even where the nature and extent of any potential environmental damage has not been conclusively established.

For example, in Maine v. Taylor the Supreme Court reviewed a state statute prohibiting the importation of live baitfish from other states, enacted to protect native species against potential risks from parasites that could be carried in baitfish.<sup>2</sup> Quoting the district court decision in that case, the Supreme Court noted that "the constitutional principles underlying the commerce clause cannot be read as requiring the State of Maine to sit idly by and wait until potentially irreversible environmental damage has occurred or until the scientific community agrees on what disease organisms are or are not dangerous before it acts to avoid such consequences." Id. Rather, the court found that the state had "a legitimate interest in guarding against imperfectly understood environmental risks, despite the possibility that they may ultimately prove to be negligible." Id. at 148.

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<sup>1</sup> By contrast, the protection of in-state businesses from competition by out-of-state businesses "is almost never a legitimate local purpose, and state laws that amount to 'simple economic protectionism' consequently have been subject to a 'virtually per se rule of invalidity.'" Maine v. Taylor, 477 U.S. 131, 148 (1986)(citations omitted).

<sup>2</sup> This is one of the rare cases in which state legislation that affirmatively discriminated against out-of-state businesses has been upheld.

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In this case, the people of the state of Colorado have expressed concern that genetic engineering poses risks to the health of consumers and the environment, and that genetically engineered products and processes have not been adequately tested in order to assess these risks. Therefore, the commerce clause should not be read as requiring the State of Colorado to sit idly by and wait until potentially irreversible environmental or health-related damage has occurred or until the scientific community assesses the dangers of genetic engineering before it acts to protect its citizens from such consequences.

An analogy can also be drawn to the case of Plumley v. Commonwealth of Massachusetts, 155 U.S. 461 (1894), in which the Supreme Court reviewed a state law prohibiting the sale of margarine colored to make it look like butter. The court found that it was a legitimate state interest to “prevent the sale of articles manufactured in or brought from another state, and subjects of traffic and commerce, if their sale may cheat the people into purchasing something they do not intend to buy, and which is wholly different from what its condition and appearance import.” This situation is analogous to the sale of genetically engineered foods, because many consumers do not believe a genetically engineered product to be the equivalent of a naturally-occurring product, and many consumers would not knowingly purchase a genetically engineered product. By inserting genetically engineered foods into the market without any form of labeling, food distributors are arguably fraudulently inducing consumers to purchase something that they did not intend to purchase.

In Plumley, the manufacturers had argued that margarine was as palatable and wholesome as pure butter, and therefore should not be subject to the state laws. The Supreme Court responded that if they thought the product to be as good as butter, they should sell it in its natural state rather than attempting to practice a fraud upon the public by coloring it to make purchasers believe they are purchasing butter. Similarly, any food manufacturer that wishes to assert the genetically engineered foods are no different from their naturally-occurring counterparts are free to sell the genetically engineered foods, but should not be allowed to practice a fraud upon the public by failing to label them as genetically engineered and thereby inducing customers into believing that they are purchasing the naturally-occurring product. See Hebe Co. v. Calvert, 246 F. 711, 718 (S.D. Ohio 1917), aff’d 248 U.S. 297 (1919)(“The Constitution of the United States does not secure to any one the privilege of manufacturing and selling an article offered in such manner as to induce purchasers to believe they are buying something which is in fact different from that which is offered for sale.”)

Although a manufacturer of genetically engineered foods may argue that it is not committing a fraud because it has made no affirmative statements regarding the nature or origin of the product, the authority to regulate in furtherance of the general welfare

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authorizes a state to “prescribe all such regulations as, in its judgment, will secure or tend to secure them against the consequences of *ignorance and incapacity as well as deception and fraud.*” Dent v. State, 129 U.S. 114, 122 (1889)(emphasis added). Therefore, the state of Colorado should be allowed to protect its inhabitants from an inability to distinguish between genetically engineered and non-genetically engineered foods that results from the manufacturers’ failure to inform its customers about the nature of the foods they are consuming. See also Corn Products Refining Co. v. Eddy, 249 U.S. 427, 431 (1919)(“[I]t is too plain for argument that a manufacturer or vendor has no constitutional right to sell goods without giving to the purchaser fair information of what it is that is being sold.”)

The following cases provide additional examples of legislation found by the Supreme Court to address a matter of legitimate local concern: Patapsco Guano Co., 171 U.S. at 358 (state law requiring inspection of all fertilizers sold in the state and imposing a fee to cover the cost of such inspection); Wisconsin Public Intervenor v. Mortier, 501 U.S. 597 (1991)(local ordinance requiring permits for the application of pesticides to public lands or for the aerial application of pesticides to private lands); Savage v. Jones, 225 U.S. 501 (1912)(state law regulating the sale of domestic animal feed, including labeling requirements); Robertson v. People of the State of California, 328 U.S. 440 (1946)(state law requiring out-of-state insurance brokers to be licensed before practicing in the state); Reid v. People of State of Colorado, 187 U.S. 137, (1902)(state law prohibiting import of diseased cattle and requiring cattle imported from south of 36<sup>th</sup> parallel to be held for 90 days prior to importation unless bill of health obtained from state veterinary board); Huron Cement Co. v. Detroit, 362 U.S. 440 (1960)(municipal ordinance limiting the amount of smoke that may be emitted by ships docked in the city’s harbor).

### B. Balancing of Local and National Interests

If it is determined that state legislation addresses a legitimate state concern, a court may nevertheless strike down the legislation if it finds the burden on interstate commerce outweighs the state interest in addressing the matter of local concern:

In the application of [commerce clause] principles some enactments may be found to be plainly within and others plainly without state power. But between these extremes lies the infinite variety of cases in which regulation of local matters may also operate as a regulation of commerce, in which reconciliation of the conflicting claims of state and national power is to be attained only by some appraisal and accommodation of the competing demands of the state and national interests involved.

Southern Pacific Co. v. Arizona, 325 U.S. 761, 768-69 (1945).

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In assessing the burden on interstate commerce, a court will be particularly suspicious of laws that treat out-of-state products differently than similar in-state products:

In determining whether a State has overstepped its role in regulating interstate commerce, this Court has distinguished between state statutes that burden interstate transactions only incidentally, and those that affirmatively discriminate against such transactions. While statutes in the first group violate the Commerce Clause only if the burdens they impose on interstate trade are ‘clearly excessive in relation to the putative local benefits,’ statutes in the second group are subject to more demanding scrutiny.

Maine, 477 U.S. at 138 (citation omitted). Examples of laws that affirmatively discriminate against interstate commerce are laws explicitly preventing the import of certain products from other states and laws placing additional taxes on materials imported from other states.

In this case, the proposed legislation would be applied evenhandedly to the labeling of all products sold in the state of Colorado, regardless of where they were manufactured, and there would therefore be no affirmative discrimination against out-of-state businesses. The statute would therefore be reviewed under the more liberal standard of whether the burdens are clearly excessive in relation to the local benefits. Other factors to be considered in performing this balancing test include the nature of the local interest involved, see Pike, 397 U.S. at 142, whether the local interest could be promoted as well with a lesser impact on interstate activities, id., the nature and extent of the burden on interstate commerce, see Southern Pacific, 325 U.S. at 770, whether the provision is in conflict with any policy or action of Congress, see Robertson, 328 U.S. at 449, whether the legislation is appropriately designed to address the issue to which it is directed, id., and whether the purported evil will go unregulated without local controls. Id.

In assessing the nature of the local interest involved here, it should be noted that the courts have repeatedly emphasized the importance of allowing states to protect their citizens from fraud and deception, particularly in the area of food products:

If there be any subject over which it would seem the states ought to have plenary control, and the power to legislate in respect to which, it ought not to be supposed, was intended to be surrendered to the general government, it is the protection of the people against fraud and deception in the sale of food products.

Plumley, 155 U.S. at 472. “A state enactment forbidding the sale of deceitful imitations of articles of food in general use among the people does not . . . interfere with the freedom of commerce among the several states,” but rather, is “legislation which ‘can be most advantageously exercised by the states themselves.’” Id. at 479.

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Of the cases that we have reviewed, the case with the facts most closely analogous to those at issue here is Savage v. Jones, 225 U.S. at 501. That case dealt with an Indiana statute regulating the sale in that state of “concentrated commercial feeding stuff,” or food for domestic animals. The state statute required that each package of feeding stuff sold in the state include a label listing the net weight of the product, the name and location of the manufacturer, the ingredients contained in the feeding stuff, and the minimum percentages of crude fat and crude protein. The statute also included provisions for the registration and inspection of feeding stuff sold in the state. Violations of the statute were subject to criminal penalties.

In determining that the Indiana statute did not violate the dormant commerce clause, the Supreme Court first noted that the “evident purpose of the statute is to prevent fraud and imposition in the sale of food for domestic animals, a matter of great importance to the people of the state.” Id. at 524. The court found that the statute’s requirements were directed to that end and were not unreasonable, emphasizing that the law was not aimed at interstate commerce but was applied without discrimination to all feeding stuff sold in the state. Although acknowledging that a state cannot unreasonably burden interstate commerce, the court stated that “when the local police regulation has real relation to the suitable protection of the people of the state, and is reasonable in its requirements, it is not invalid because it may incidentally affect interstate commerce . . . .” Id. at 525.

The court concluded that the state “was entitled, in the exercise of its police power, to require the disclosure of the ingredients contained in the feeding stuffs offered for sale in the state, and to provide for their inspection and analysis. The provisions for the filing of a certificate, for registration and for labels, were merely incidental to these requirements, and were appropriate means for accomplishing the legitimate purposes of the act.” Id. at 528. This case is significant because the law at issue required out-of-state manufacturers to adjust their labeling practices to conform to Indiana law in order to sell their goods in that state. Under this rule, there appears to be no reason why Colorado could not require out-of-state manufacturers wishing to sell goods in this state to conform to Colorado’s labeling requirements for genetically engineered foods, assuming that such requirements are found promote a legitimate state interest.

Under this balancing approach, a court would have to weigh Colorado’s interest in protecting its citizens from harm that may result from the consumption of genetically engineered foods, and its interest in allowing consumers to make informed choices with regards to the purchase of genetically engineered foods, against the indirect burden on interstate commerce that would result from requiring out-of-state companies shipping goods

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into a state to conform to Colorado's labeling requirements.<sup>3</sup> However, the mere fact that a company might have to incur some additional expense in order to comply with a law is not alone a sufficient burden to strike down a state law. See, e.g., Armour & Co. v. State of North Dakota, 240 U.S. 510 (1916)(state requirement for labeling of lard containers would "involve a change of packing by the company and the cost of that change, but this is a sacrifice the law can require" to protect the public from deception), Borden Co. v. Liddy, 200 F. Supp. 221, 223 (S.D. Iowa 1961)(upholding state law that could require additional costs of \$364,000 per year to plaintiff). A more compelling argument against the state law might arise, however, where a variety of differing state laws were in effect on the subject, requiring a manufacturer to create different labels for shipping the same product to different states. Therefore, it would be in Colorado's interest to look at other state laws on the same subject to ensure consistency of approach.

### III. FEDERAL PREEMPTION

Even if a particular state law regulating interstate commerce is permissible under the dormant commerce clause, it will be struck down if a court determines that it is pre-empted by federal law. There several ways in which federal preemption may be found. First, federal legislation may contain an express statement prohibiting states from enacting legislation on the same subject. Second, even without an express prohibition of state legislation, an intent to exclude state legislation may be found where the federal legislation is so extensive and pervasive that it is assumed that Congress intended to occupy the entire field that is the subject of the legislation. Finally, state legislation will be struck down if it is found to conflict with a federal law on the same subject. Such conflict may exist either directly, where it would be impossible to comply with both the federal and the state law, or indirectly, where individual state legislation would thwart the objectives of the federal law.

We here review the two statutes most likely to be cited as pre-empting state food labeling laws, the Fair Packaging and Labeling Act ("FPLA"), 15 U.S.C.A. §§ 1451 - 1461 (1998 & 2001 Supp.), and the Federal Food Drug and Cosmetic Act ("FDCA"), 21 U.S.C.A.

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<sup>3</sup> Examples of cases in which the burden on interstate commerce was found to outweigh the local interest can be found in Pike v. Bruce Church, Inc., 397 U.S.137 (1970)(state's interest in having high-quality Arizona cantaloupes identified as coming from Arizona did not justify an in-state packaging requirement which would require a grower to construct a new and unnecessary packaging plant at a cost of \$200,000), and in Southern Pacific Co. v. Arizona, 325 U.S. 761 (1945)(state's interest in promoting safety by limiting the length of trains does not justify burden of breaking up and reforming trains at Arizona border).

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§§ 301 - 397 (1998 & 2001 Supp.).<sup>4</sup> In reviewing these statutes, it should be emphasized that the Supreme Court has repeatedly expressed reluctance to find preemption of state statutes, particularly in areas such as health and safety that have traditionally been left to the states.

A. Fair Packaging and Labeling Act

The purpose of the FPLA is set forth in Section 1451's Congressional declaration of policy:

Informed consumers are essential to the fair and efficient functioning of a free market economy. Packages and their labels should enable consumers to obtain accurate information as to the quantity of the contents and should facilitate value comparisons. Therefore, it is hereby declared to be the policy of the Congress to assist consumers and manufacturers in reaching these goals in the marketing of consumer goods.

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<sup>4</sup> It is possible that preemption arguments could be made based on other federal laws; however, we have focused on the FPLA and the FDCA as the most likely candidates for a broad-based federal preemption argument. A more exhaustive review of potential preemption arguments might include federal laws relating to specific commodities such as meat, poultry, and dairy products. In this regard, it is important to note that the FPLA does not cover meat, poultry, or any commodity subject to the Federal Seed Act.

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To accomplish this purpose, the law prohibits the distribution of goods whose labels do not conform to the statute or its implementing regulations. In addition to net quantity, the statute requires that labels specify “the identity of the commodity and the name and place of business of the manufacturer, packer or distributor.” § 1453.

The FPLA authorizes the Secretary of Health and Human Services (the “Secretary”) to promulgate regulations to administer the requirements of the FPLA, and to promulgate additional regulations designed to “prevent the deception of consumers or to facilitate value comparisons as to any consumer commodity.” However, the scope of these additional regulations is limited to the following specific areas: (1) establishing and defining standards for characterization of the size of packages, (2) regulating statements relating to sale prices, (3) requiring the inclusion of common names of products and a list of ingredients, and (4) preventing the “nonfunctional-slack-fill” of packages. The Secretary is also authorized to request that manufacturers establish voluntary product standards when he or she determines that there is “undue proliferation” of measures of comparable products impairing the ability of consumers to make value comparisons.

### i. Express Prohibition of State Legislation

With regards to the first method of preemption described above, the FPLA does contain a statement expressly prohibiting states from regulating one aspect of food labeling:

It is hereby declared that it is the express intent of Congress to supersede any and all laws of the States or political subdivisions thereof insofar as they may now or hereafter provide *for the labeling of the net quantity of contents* of the package of any consumer commodity covered by this chapter which are less stringent than or require information different from the requirements of section 1453 of this title or regulations promulgated pursuant thereto.

15 U.S.C.A. § 1461 (emphasis added). The statute does not expressly prohibit state legislation of any other aspects of food labeling.

### ii. Implied Prohibition of State Legislation

Even where a federal statute does not expressly prohibit state legislation on a particular topic, an intent to prohibit such legislation may be found where the federal scheme is so extensive as to indicate an intent to “occupy the field.” However, the Supreme Court has stated that in areas of the law that are traditionally occupied by the states, it will “start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.” Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 230 (1947); see also Schwartz v. Texas, 344

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U.S. 199 (1952)(“It will not be presumed that a federal statute was intended to supersede the exercise of the power of the state unless there is a clear manifestation of intention to do so.”). The Supreme Court has specifically held that regulation of food labels is among the areas traditionally occupied by the states. See Jones, 430 U.S. at 525. In this case, we have found no indication of a clear and manifest purpose of Congress to supersede the states’ authority to regulate food labeling.

To the contrary, the fact that the FPLA expressly addresses state legislation of food labeling in the area of net quantities strongly supports an argument that no other aspect of food labeling was intended to be preempted by the statute. This interpretation of the FPLA was confirmed by the United States Supreme Court in Atlantic Ocean Products, Inc. v. Leth, 393 U.S. 127 (1968), which affirmed without opinion the ruling of the district court in Atlantic Ocean Products, Inc. v. Leth, 292 F. Supp. 615 (1968). This case involved a challenge to Oregon state legislation limiting the use of the word “Halibut” in the labeling of fish products. After citing the statutory language quoted above, the district court held that “[t]he Fair Packaging and Labeling Act only supersedes State ‘net contents’ regulations. Congress, by omitting an express limitation on the State’s power to regulate product names, did not intend to preempt this area of regulation.” Id. at 618 (citations omitted). Similarly, the FPLA omits an express limitation on the State’s power to regulate the labeling of genetically engineered foods, and therefore clearly did not intend to preempt this area of regulation.

Where Congress has intended to occupy the entire field of labeling of a particular product, it has explicitly stated as such. For example, the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C.A. 136 et seq. (“FIFRA”) includes a provision stating that states “shall not impose or continue in effect any requirements for labeling and packaging in addition to or different from those required under” FIFRA. Although FIFRA does occupy the field of labeling of these products, in Wisconsin Public Intervenor, 501 U.S. at 612, the Supreme Court held that FIFRA did not preempt a local permitting ordinance, in part because the express preemption language would have been “pure surplusage if Congress had intended to occupy the entire field of pesticide regulation.” The court further noted that although FIFRA contained a comprehensive regulatory scheme, it nevertheless left “substantial portions of the field vacant,” thereby leaving “ample room for States and localities to supplement federal efforts” to regulate pesticide use. Id. Similarly, the express limitation of net quantity labeling regulation in the FPLA would have been “pure surplusage” if Congress had intended to occupy the entire field of product labeling, and the FPLA leaves substantial portions of the field of product labeling vacant.

### iii. Conflict With Federal Law

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In this case, it is clear that there is no direct conflict between the FPLA and a state requirement that genetically engineered foods be labeled. The FPLA does not address the labeling of genetically engineered foods in any way, and it would be possible to comply with a state labeling requirement without violating any provision of the FPLA.

Because there is no direct conflict between the FPLA and state regulation of genetically engineered food labeling, the reviewing court will need to determine whether, “under the circumstances of this particular case, [the state] law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.” Hines v. Davidowitz, 312 U.S. 52, 67 (1941). This inquiry requires the court “to consider the relationship between state and federal laws as they are interpreted and applied, not merely as they are written.” Jones, 430 U.S. at 526.

As explained above, the purpose of the FPLA is to allow consumers to obtain accurate information regarding the quantity of a package’s contents in order to facilitate value comparisons. See § 1451. It seems obvious that this purpose would not be impacted in any way by the labeling of food products containing genetically engineered ingredients. If anything, this information might facilitate a value comparison by a consumer because many consumers consider non-genetically engineered foods to be more desirable and are willing to pay more for such products.

The United States Supreme Court has heard one challenge to state legislation based upon alleged preemption by the FPLA. In Jones v. Rath Packing Co., 430 U.S. at 519, the court reviewed a California statute requiring that the weight or measure of packaged foods be not less than that listed on the package. It was alleged that this statute was in conflict with the FPLA, which was interpreted to allow for reasonable variations in quantity based upon loss of gain or moisture during distribution. The court held that the ban on state laws requiring “different information” from the federal law was intended to apply only to labeling requirements that were inconsistent with the federal standard. Because manufacturers complying with the state law would also be in compliance with the federal law, the court found no inconsistency.

However, the court did find that the state law stood as an obstacle to the accomplishment of the Congressional objective of facilitating value comparisons. Because a product manufactured in compliance with the California standard might have a weight different to an identically labeled product manufactured elsewhere, the court determined that the state law undermined the express purpose of the legislation. The court therefore struck down the state law. The findings of this case do not appear to be applicable here, because the proposed legislation has no relation to the labeling of product weights, and could have no impact on the federal objective of facilitating value comparisons based upon weight.

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### A. Federal Food Drug and Cosmetic Act

The FDCA prohibits, among other things, the manufacture, delivery, or receipt of any food, drug, device or cosmetic that is “adulterated or misbranded.” 21 U.S.C.A. § 331. The meaning of the term “misbranded food” for purposes of the FDCA is set out in Section 343, and includes any food with a label that is “false or misleading in any particular.” More specific requirements for the labeling of foods are found both in this section and in regulations issued by the Secretary, *see* 21 C.F.R. § 101 et. seq., including requirements for the listing of ingredients and specified nutrition information. Significantly, neither the FDCA nor the Secretary’s labeling regulations address in any manner the labeling of genetically engineered foods or ingredients.

#### i. Express Prohibition of State Legislation

Although the FDCA does not expressly prohibit all state legislation in the area of food labeling, it does prohibit states from enacting requirements that are “not identical” to certain specified requirements of the FDCA. § 343-1. The following requirements of the FDCA are covered by this preemption provision:

Section 343(g): Requirement that foods for which the Secretary has established a definition and standard of identity conform to such definition and standard.

Section 343(c): Requirement that imitation foods be labeled as such.

Section 343(e): Requirement that packages bear labels containing name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of the contents.

Section 343(i)(2): Requirement that labels list the common or usual name of the product’s ingredients.

Section 343(b): Prohibition on selling food under the name of another food.

Section 343(d): Prohibition on misleading containers.

Section 343(f): Requirement that required information be prominently displayed on label.

Section 343(h): Requirement that foods comply with standards of quality and fill promulgated by Secretary.

Section 343(i)(1): Requirement that label bear the common or usual name of the food.

Section 343(k): Requirement that use of artificial flavoring, artificial coloring, or chemical preservatives be identified.

Section 343(q): Requirements relating to nutrition labeling.

Section 343(r)(1): Requirements relating to labeling of levels of nutrient and health-related claims.

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None of these requirements relate to the labeling of genetically engineered foods, and there is therefore no express preemption of state legislation in this field.

ii. Implied Prohibition of State Legislation

Although the preemption provision quoted above is far more extensive than that found in the FPLA, the fact that particular sections of the FDCA, rather than the entire act, were named as being preemptive of state law gives a strong indication that Congress did not intend to preempt the entire field of subjects covered by the FDCA (see discussion and citations in Section III(A)(ii) above). This interpretation finds explicit support in the enactment of the Nutrition Labeling and Education Act of 1990 (the “NLEA”), Pub.L. 101-535, Nov. 8, 1990, 104 Stat. 2353, which added the preemption provisions of Section 343-1 to the FDCA. Section 6(c) of Pub.L. 101-535, which is printed in the Historical and Statutory Notes under Section 343-1 of the annotated code, states that the NLEA “shall not be construed to preempt any provision of State law, unless such provision is expressly preempted under [Section 343-1] of the Federal Food, Drug, and Cosmetic Act.”

However, Section 6(c) of Pub.L. 101-535 later contains a somewhat contradictory statement that the enactment of Section 343-1 and its accompanying notes, including the note quoted in the previous paragraph, “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 Federal Food, Drug, and Cosmetic Act not amended by subsection (a), any other Federal law, or any Federal regulation, order, or other final agency action . . . .” It is not clear what Congress was trying to accomplish by this language, especially after expressly disavowing any intent to preempt any area not specifically named in Section 343-1. One possible explanation is that Congress wanted to make clear that in the event of a conflict between state and federal law in an area not expressly preempted, federal law would still control. Another possibility is that Congress was unable to agree on the scope of the intended preemption, and therefore decided to maintain the status quo with regards to preemption for any provision not expressly named in Section 343-1.<sup>1</sup> In light of this potential interpretation, the remainder of this section continues with the preemption analysis without regard for Section 343-1.

As discussed above, even where a federal statute does not expressly prohibit state legislation on a particular topic, an intent to prohibit such legislation may be found where the federal scheme is so extensive as to indicate an intent to “occupy the field.” Because the

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<sup>1</sup> The committee report for Pub. L. 101-535 did not discuss the meaning of these provisions. It may be advisable to perform further research on the legislative history of this enactment to determine if it might provide some insight into the congressional intent.

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provisions of the FDCA cover significantly more topics and contain significantly more requirements than the FPLA, there exists here at least a stronger argument that the federal scheme is pervasive enough to warrant an implication of federal preemption. However, the comprehensiveness of a federal law does not alone imply an intent to preempt state laws: “[M]erely because the federal provisions were sufficiently comprehensive to meet the need identified by Congress did not mean that States and localities were barred from identifying additional needs or imposing further requirements in the field.” Hillsborough County v. Automated Medical Labs, 471 U.S. 707, 717 (1985). See also New York Dept. of Social Services v. Dublino, 413 U.S. 405, 415 (1973)(“The subjects of modern social and regulatory legislation often by their very nature require intricate and complex responses from the Congress, but without Congress necessarily intending its enactment as the exclusive means of meeting the problem.”)

In addition to preemption based upon federal statutes, preemption can also be based upon federal regulations. See Hillsborough, 471 U.S. at 713. The Secretary has promulgated extensive regulations relating to food labeling under the authority of both the FDCA and the FLPA, and the extent of these regulations may provide support for an argument that the federal government intended to occupy this field. However, the Supreme Court has stated that it is “even more reluctant to infer pre-emption from the comprehensiveness of regulations than from the comprehensiveness of statutes,” id. at 717, for the following reasons:

As a result of their specialized functions, agencies normally deal with problems in far more detail than does Congress. To infer pre-emption whenever an agency deals with a problem comprehensively is virtually tantamount to saying that whenever a federal agency decides to step into a field, its regulations will be exclusive. Such a rule, of course, would be inconsistent with the federal-state balance embodied in our Supremacy Clause jurisprudence. Moreover, because agencies normally address problems in a detailed manner and can speak through a variety of means, including regulations, preambles, interpretive statements, and responses to comments, we can expect that they will make their intentions clear if they intend for their regulations to be exclusive. Thus, if an agency does not speak to the questions of pre-emption, we will pause before saying that the mere volume and complexity of its regulations indicate that the agency did in fact intent to pre-empt. Given the presumption that state and local regulation related to matters of health and safety can normally coexist with federal regulations, we will seldom infer, solely from the comprehensiveness of federal regulations, an intent to pre-empt in its entirety a field related to health and safety.

Id. at 717-718 (citation omitted).

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The Supreme Court has reviewed several challenges to state regulation of subjects covered by the FDCA and its implementing regulations.<sup>2</sup> For example, in Borden Co. v. Liddy, 200 F. Supp. 221 (S.D. Iowa 1961), the court upheld an Iowa statute requiring that all ice cream sold in the state contain at least 12% milk fat, despite the fact that federal regulations promulgated under the FDCA required only 10% milk fat. The court rejected the plaintiff's contention that the federal regulations preempted the state law, despite the fact that compliance with the state law would involve the construction of a new plant in the state as well as significant cost increases. Id. at 223.

Another example is found in the context of drug regulation under the FDCA. In Pharmaceutical Society, State of N.Y. v. Lefkowitz, 454 F. Supp. 1175 (S.D. N.Y. 1978), the plaintiffs sought to enjoin the operation of state laws relating to generic drugs, including a labeling requirement for drug containers. The plaintiffs asserted that the federal government's comprehensive system of drug regulation evidenced an intent to preempt state regulation in this field. The court rejected this challenge, finding that "Congress has not legislatively expressed an intent to preclude states from entering the area of drug regulation." Id. at 1179. With regards to the state's variation on the federal labeling requirements, the court determined that "states are not barred from regulating product labeling, they are only limited where the labels or warnings pertain to problems which have already been addressed by the federal government." We would argue that this rule should also be applied in the context of food labeling, and that because the federal government has not addressed the problem of labeling of genetically engineered foods, states are entitled to address this issue.

The Supreme Court has repeatedly emphasized that "the regulation of health and safety matters is primarily, and historically, a matter of local concern." Id. at 719. Therefore, any proponents of federal preemption in this area must first overcome the presumption that Congress did not intend to supercede the "historic police powers" of the states; such presumption will be overcome only if that was the "clear and manifest purpose of Congress." Rice, 331 U.S. at 230. The same presumption applies with regards to federal regulations. See Hillsborough, 471 U.S. at 718. Considering Congress' failure to expressly preempt the field of food labeling while preempting a portion of that field, the failure of the federal regulations to include any preemption provisions, the fact that the FDCA leaves

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<sup>2</sup> The Supreme Court has also upheld state laws against challenges based on the Food and Drugs Act of 1906, the predecessor to the FDCA. See, e.g., Corn Products Refining Co. v. Eddy, 249 U.S. 427 (1919)(upholding state law relating to the labeling of syrups), Standard Stock Food Co. v. Wright, 225 U.S. 540, 549 (1912)(upholding state law relating to labeling of stock food containers), Armour & Co. v. State of North Dakota, 240 U.S. 510 (1916)(upholding state law relating to labeling of lard containers).

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substantial portions of the field of food labeling vacant, and the fact that the Supreme Court has upheld state food labeling laws against claims of preemption based upon the FDCA and its predecessors, it does not appear that there is sufficient indication of a clear and manifest purpose of Congress to overcome the presumption that it did not intend to supercede the historic police powers of the state in the area of food labeling.

### iii. Conflict With Federal Law

Again in this case, it is clear that there is no direct conflict between the FDCA and a state requirement that genetically engineered foods be labeled. The FDCA does not address the labeling of genetically engineered foods in any way, and it would be possible to comply with a state labeling requirement without violating any provision of the FDCA. Because there is no direct conflict between the FDCA and a state requirement for the labeling of genetically engineered foods, the question will be whether the state law stands as an obstacle to the accomplishment of the Congressional purpose. Hines, 312 U.S. at 67.

The FDCA contains no explicit statement of its purpose, but its purpose can easily be derived from a review of its provisions and of the case law interpreting those provisions. The provisions of the FDCA show an intent to allow the public to make informed choices about the foods that they are purchasing and to protect the public from foods that are harmful. More generally, the Supreme Court has stated that the “overriding purpose” of the FDCA is to “protect the public health.” United States v. Bacto-Unidisk, 394 U.S. 784, 798 (1969); see also Retkwa v. Orentreich, 579 N.Y.S.2d 577, 579 (Sup. 1991)(FDCA designed “to protect consumers who are unable to protect themselves from dangerous drugs, devices, foods and cosmetics.”), United States v. 250 Jars, Etc., of U.S. Fancy Pure Honey, 218 F. Supp. 208, 212 (E.D. Mich. 1963)(FDCA passed “for the purpose of protecting unwary customers in vital matters of health . . .”), United States v. Omar, 91 F. Supp. 121, 122 (D. Neb. 1950)(one of purposes of FDCA to require “informative and truthful labeling.”).

Clearly, state requirements for the labeling of genetically engineered foods would not interfere with these purposes. To the contrary, the purpose of such laws would also be to protect consumers from products that have not been adequately tested to ensure their safety and to require informative and truthful labeling that would give consumers the ability to decide whether or not they wish to purchase such products. State requirements for the labeling of genetically engineered foods would therefore provide a vital supplement to the FDCA in an area that the federal government has not yet addressed.

The Supreme Court has stated that the basic principal to be derived from its preemption caselaw is that “federal regulation of a field of commerce should not be deemed preemptive of state regulatory power in the absence of persuasive reasons - either that the nature of the regulated subject matter permits no other conclusion, or that the Congress has

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unmistakably so ordained.” Florida Avocado Growers v. Paul, 373 U.S. 132, 142 (1963). There is a strong argument here that there are no such persuasive reasons for the preemption of state regulation of genetically engineered foods. The subject matter is one that is within the police powers of the state, and it is one that continues to be regulated by the states in conjunction with federal laws. Further, Congress has given no clear indication that it intended all state regulation of food labels to be superceded by the FDCA or its implementing regulations.

### IV. CONCLUSION

Although constitutional arguments may be raised against the implementation of state laws requiring the labeling of genetically engineered foods, the case law discussed above is generally positive and provides us with strong arguments, both that such legislation is authorized under the commerce clause, and that it is not preempted by the FPLA or the FDCA. Further research may be warranted to determine whether any other federal statutes could be cited in a preemption argument. Any state legislation introduced in Colorado should be checked against existing or proposed legislation from other states to ensure uniformity and avoid any conflicting requirements. Finally, all of these arguments could be avoided entirely if Congress could be persuaded to enact uniform federal legislation on this subject. However, the promulgation of legislation by a few individual states may provide the most effective impetus for the enactment federal legislation.