

UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF OHIO  
(EASTERN DIVISION)

INTERNATIONAL DAIRY FOODS ASSOCIATION	)	
	)	
Plaintiff,	)	
	)	CASE NO. _____
v.	)	
	)	
ROBERT J. BOGGS (solely in his official capacity as Ohio Director of Agriculture)	)	Honorable Judge _____, U.S.D.J.
	)	
Defendant.	)	ORAL ARGUMENT REQUESTED
	)	

**MOTION FOR PRELIMINARY INJUNCTION**

Plaintiff, by and through counsel, hereby moves on the Complaint and the annexed declarations of Mike Krueger (Shamrock Foods Company), Diane Manganaro (HP Hood LLC), Bill Riley (Dean Foods Company), Bob Michalek (Ben and Jerry’s Homemade Ice Cream), William Luth (Tillamook County Creamery Association), Rhonda L. Jordan (Kraft Foods, Inc.), Steve Schmid (Smith Dairy) and Joseph Mendelson (Center for Food Safety), for a preliminary injunction pursuant to 28 U.S.C. §§ 2201 and 2202 enjoining the Defendant until a hearing and decision can be held on the issuance of a permanent injunction from attempting to enforce section 901:11-8-01 of the Ohio Administrative Code concerning dairy product labeling.

As set forth in more detail in the accompanying Memorandum in Support which is incorporated herein by reference, section 901:11-8-01 of the Ohio Administrative Code, adopted May 22, 2008 and effective to all dairy product labeling beginning September 19, 2008, violates Plaintiff’s rights under the First and Fourteenth Amendments to the United States Constitution

and impermissibly burdens interstate commerce. Plaintiff and its members will suffer irreparable harm for which Plaintiffs have no adequate remedy at law if the regulation is enforced by the Defendant.

**WHEREFORE**, the Plaintiff respectfully requests that this Court issue a preliminary injunction enjoining the Defendant from enforcing section 901:11-8-01 of the Ohio Administrative Code.

Respectfully submitted,

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The commercial nature of speech does not remove it from the protections of the First Amendment or give the government unbridled authority to determine what can or cannot be said in the marketplace. *Edenfield v. Fane*, 507 U.S. 761, 767 (1993). Courts evaluate the constitutionality of government regulations of commercial speech pursuant to the framework set forth in *Central Hudson Gas & Elec. Corp. v. Pub. Serv. Comm’n of New York*, 447 U.S. 557 (1980). The government may impose restrictions on truthful, non-misleading speech only if it can affirmatively demonstrate: 1) that the restriction on commercial speech achieves a substantial government interest; 2) that the restriction on commercial speech directly and materially advances that interest; and 3) that the restriction is not more extensive than is necessary to serve that interest. *Central Hudson*, 447 U.S. at 564. The government bears the burden of establishing all of these criteria, and the failure to establish any one element is fatal to the regulation as a violation of the speaker’s First Amendment rights. *Edenfield*, 507 U.S. at 770. In this case, the Director cannot meet his burden as to the Ohio Rule because not only is there no evidence that the claims about rbGH on the labels of dairy processors, manufacturers and retailers are false or misleading, but also the labeling restrictions imposed by the Ohio Rule cannot pass any *Central Hudson* factor.

**1. The Ohio Rule Bans Protected Speech**..... **11**

In adopting the Ohio Rule, the Director concluded that an rbGH (recombinant bovine growth hormone) claim on the dairy label is inherently misleading if it contains certain government-prohibited words such as “rbGH Free” or “No rbGH” even when those words are accompanied by a production claim description along the lines of “our cows are not treated with the growth hormone rbGH”. The Ohio Rule’s ban is based on an assumption that consumers are no more discerning than children and are misled by a claim such as “rbST Free,” “rbGH Free” or “No rbGH” under every circumstance. The Ohio Rule impermissibly bans commercial speech without any evidence of actual deception by the existing labeling practices. *Peel v. Attorney Registration & Disciplinary Comm’n*, 496 U.S. 91, 105 (1990).

**2. The Ohio Rule Unlawfully Regulates Speech under Central Hudson.....13**

The Director has also concluded that in addition to the banned speech, certain dairy labels are potentially misleading even if they contain the Ohio-approved speech for the non-use of rbGH claim, if there is not a contiguous disclaimer conforming to the regulation’s strict requirements as to acceptable wording, placement, font, style, case, size and even color. These restrictions are only permissible if the Director can affirmatively demonstrate that the Ohio Rule satisfies all of the criteria articulated in *Central Hudson*. *Central Hudson*, 447 U.S. at 564. The Director, however, has not, and cannot, overcome these hurdles necessary to justify the Ohio Rule’s infringement on truthful, non-misleading commercial speech.

**a. *The Ohio Rule Does Not Further a Substantial Government Interest* ..... 14**

*Central Hudson* requires the Director to demonstrate first that the Ohio Rule serves a “substantial governmental interest.” *Central Hudson*, 447 U.S. at 564. While the interest in ensuring the accuracy of commercial information may be “substantial” under *Central Hudson* (*Edenfield*, 507 U.S. at 769), the Ohio Rule goes far beyond what is necessary to prevent false or misleading labels. The Director has not articulated a legitimate state interest that would justify: 1) requiring a contiguous contextual statement in the face of an FDA contrary conclusion regarding the use and readability of text using asterisks; and 2) imposing specific font, style, case, color and size requirements of that contiguous contextual statement. Rather than serving the interests of consumers, the evidence is that the stated reasons are pretext for nothing more than protectionism on behalf of Ohio dairy farmers through excessive labeling restrictions.

**b. *The Director Has Not Established That The Harm Is Real Or That The Restriction Will Alleviate The Harm in a Material Way*..... 20**

In order to carry the burden of proving the harms it recites are real and that its restriction will in fact alleviate them to a material degree, the Director may not rest on “mere speculation and conjecture” or “unsupported assertions.” *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 555 (2001); *Ibanez v. Florida Dep’t of Bus. & Prof’l Reg.*, 512 U.S. 136, 143 (1994). Assuming the Ohio Rule is intended to prevent consumer confusion, the Director has merely made the statement that all rbGH claims are deceptive and confuse consumers without producing any “real” or “concrete” evidence to support that conclusion.

**c. *The Ohio Rule Is More Extensive than Necessary.* ..... 21**

The Court must determine that there is a “reasonable fit” between Ohio’s goals and the means chosen to accomplish it – a means that is “narrowly tailored” to achieve the desired objective. *Lorillard Tobacco*, 533 U.S. at 556. The existence of numerous less-burdensome alternatives is a relevant consideration in determining whether the ‘fit’ between ends and means is reasonable. *Florida Bar v. Went for It, Inc.*, 515 U.S. 618, 632 (1995). Here, the Ohio Rule is unconstitutional because there are less-burdensome alternatives to the Ohio Rule’s strict requirements ranging from words that can and cannot be used, to the appropriate

use of asterisks linking any necessary statements, to the font, style, case, size and even color of the words that can be used.

**B. The Ohio Rule Violates the Dormant Commerce Clause of the U.S. Constitution.....23**

The Ohio Rule violates the principles of the dormant commerce clause for four reasons. First, it directly regulates and prevents, unless its terms are satisfied, interstate shipments of dairy products – thus endowing the Ohio Rule with the practical effect of having direct extraterritorial impacts on interstate commerce occurring outside Ohio. *Shafer v. Farmers Grain Co.*, 268 U.S. 189, 199 (1925). Second, the Ohio Rule imposes inconsistent regulatory burdens on interstate commerce. *Granholtz v. Heald*, 544 U.S. 460 (2005). Third, the history of non-use claims and Ohio’s recent entry into this regulatory arena effectively discriminates against dairy industry (including dairy farmers from out-of-state) out-of-state interests in order to protect Ohio dairy farmers. *Id.* Fourth, even if the impacts on interstate commerce are found to be merely incidental, the burden the Ohio Rule imposes on interstate commerce is excessive in light of the local interests the Ohio Rule purports to advance. *Pike v. Bruce Church, Inc.*, 397 U.S. 137, 142 (1970).

**1. The Ohio Rule Impermissibly Directly Regulates Interstate Commerce with Extraterritorial Impacts .....25**

The Ohio Rule has the practical effect of regulating interstate commerce (and speech) that takes place wholly outside Ohio’s borders. A non-Ohio processor selling its otherwise lawfully labeled product nationally or in surrounding states, is forced by the known commercial limitations inherent in the distribution of dairy and other food products to change its lawful labels in other states in order to comply with the Ohio Rule if it also sells any product in Ohio. Thus, the Ohio Rule in practical effect and result has an impermissible extra-territorial reach in that once a dairy product processor or manufacturer chooses to sell product in Ohio, it not only must label in accordance with the Ohio label, but it is commercially necessary to simultaneously use identical labels in other states even if those states do not restrict the commercial speech or even permit terms declared unlawful by Ohio (e.g. “rbGH Free – our farmers pledge”). *United States Brewers Ass’n., Inc., v. Healy*, 692 F.2d 275 (2<sup>nd</sup> Cir. 1982) *summarily aff’d* 464 U.S. 909 (1983) (*Healy I*); *Brown-Forman Distillers Corp. v. New York State Liquor Authority*, 471 U.S. 573 (1986); *Healy v. Beer Institute, Inc.*, 491 U.S. 324 (1989) (*Healy II*).

**2. The Ohio Rule Greatly Multiplies the Likelihood that Dairy Product Processors and Manufacturers will be Subject to Inconsistent Obligations.....30**

The practical effect of the Ohio Rule must be evaluated not only considering the consequences of the regulation itself, but also by considering how the challenged regulation may interact with the legitimate regulatory regimes of other States and what effect would arise if not one, but many or every, State adopted similar (but not identical) regulations. *Healy II*, 491 U.S. at 336. The Ohio Rule is contrary to existing provisions on the same subject in numerous other states and greatly multiplies the likelihood that dairy product

processors and manufacturers will be (and are) subject to inconsistent rights and obligations. *Healy II*, 491 U.S. at 334.

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The Ohio Rule also “unjustifiably operates to isolate” Ohio’s economy “from the national common market.” *C & A Carbone, Inc. v. Town of Clarkstown, N.Y.*, 511 U.S. 383, 406 (1994) (J. O’Connor concurring). The provision has the practical effect of both burdening interstate commerce and discriminating against out-of-state dairy interests because the rule takes away a labeling opportunity that created a competitive advantage for out-of-state dairy farmers seeking to capitalize on their non-use of rbGH. *Hunt v. Washington State Apple Advertising Comm’n*, 432 U.S. 333 (1977).

**4. Even if the Ohio Rule does not directly regulate or result in inconsistent regulation of interstate commerce, the Ohio Rule is unlawful as the burden imposed on commerce is clearly excessive to the local benefits. .....36**

Even if this Court were to conclude that the Ohio Rule imposes only incidental as opposed to direct burdens on interstate commerce, it must nonetheless be declared invalid as the burden imposed on commerce is clearly excessive relative to the putative local benefits. *Pike v. Bruce Church, Inc.*, 397 U.S. 137, 142 (1970). One of the principal questions to be asked in this context is whether the local interest could be promoted as well with a lesser impact on interstate activities. The Director in adopting requirements regarding font style, size, location and even color while also outright banning terms expressly permitted in other states has gone far past any rule reasonably necessary to promote the local interest.

**II. PLAINTIFFS WILL SUFFER IRREPARABLE HARM .....38**

The loss of First Amendment freedoms, for even minimal periods of time, unquestionably constitutes irreparable injury. *Elrod v. Burns*, 437 U.S. 347, 373 (1976). Violations of the dormant commerce clause also constitute irreparable injury because Plaintiff’s members will be required to make substantial changes to their label designs at significant cost that cannot be recovered from the State under the 11<sup>th</sup> Amendment. *Edelman v. Jordan*, 415 U.S. 651, 663 (1974); *see Basiccomputer v. Scott*, 973 F.2d 507, 511-12 (6<sup>th</sup> Cir. 1992).

**III. PRELIMINARILY ENJOINING THE OHIO RULE WILL CAUSE OHIO NO HARM .....39**

In the context of challenges to the constitutionality of laws, the Sixth Circuit has noted that “if the plaintiff shows a substantial likelihood that the challenged law is unconstitutional, no substantial harm to others can be said to inhere in its enjoinder.” *Déjà vu of Nashville, Inc. v. Metro. Gov’t of Nashville and Davidson County, Tenn.*, 274 F.3d 377, 400 (6<sup>th</sup> Cir. 2001).

**IV. PRELIMINARILY ENJOINING THE OHIO RULE WILL SERVE  
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**MEMORANDUM IN SUPPORT OF MOTION**  
**FOR PRELIMINARY INJUNCTION**

**INTRODUCTION**

In a misguided effort to support Ohio dairy farmers seeking to protect their chosen production methodology (e.g., using artificial growth hormone to increase milk production) from the pressures of the national marketplace, the Director of the Ohio Department of Agriculture (“Director”) has abandoned Ohio’s past practice of deferring to the federal labeling regulations and has singled out dairy products for special, highly restrictive and unprecedented labeling prohibitions and restrictions. The labeling regulation is directed at dairy processors and others who wish to advertise their dairy products as being from cows that have not been treated with the artificial growth hormone known as rbGH (recombinant bovine growth hormone) or rbST (recombinant bovine somatotropin). In short, the regulation found at section 901:11-8-01 of the Ohio Administrative Code (hereafter “Ohio Rule”) prescribes what message is permissible and how it may be conveyed by prohibiting the use of words that effectively communicate with the consumer, such as “No rbGH – our farmers pledge;” mandating the use of particular language to accompany the claim; and mandating the usage of particular placement, font, style, case, size and color.

The Ohio Rule, however, violates the First Amendment of the U.S. Constitution, which protects commercial speech such as labeling. International Dairy Foods Association (“IDFA”) thus brings this action to restrain the Director from enforcing a labeling regulation that prohibits its member processing companies from using terms and labeling methods that have been commonly used for approximately 14 years by the industry, and which have not been found to be inaccurate or inherently misleading by the Food and Drug Administration or the Federal Trade

Commission after reviews of the issue. The Ohio Rule on its face acknowledges that it is banning accurate claims – “Except as otherwise provided in this rule, accurate production claims will not be deemed false or misleading.” See App. 0106, ¶ D. That is “accurate” will be deemed “false” if Ohio says so.

The Ohio Rule also violates the dormant Commerce Clause because it will have an impermissible extra-territorial effect, will create the risk of inconsistent regulation among states that will frustrate the flow of interstate commerce and will discriminate against out-of-state dairy farmers by taking away a labeling opportunity that created a competitive advantage for out-of-state dairy farmers seeking to capitalize on their non-use of rbGH. Additionally, even if the Ohio Rule were considered to have an incidental affect on interstate commerce, it would still run afoul of the dormant Commerce Clause because any putative local benefit achieved by the Ohio Rule could be promoted as well with a lesser impact on interstate activities.

Since the Ohio Rule, absent action from this Court, will become fully effective September 19, and new labels nationwide will have to be developed and used by that date, IDFA members need immediate relief from the illegal mandates of the Ohio Rule. As a result of the impacts the Ohio Rule will have on protected speech and interstate commerce, a preliminary injunction is necessary to prevent irreparable harm and protect the rights of IDFA’s dairy processor members to engage in free speech under the First Amendment protection granted to commercial speech and to engage in interstate commerce without direct regulation or unlawful discrimination under the Commerce Clause of the U.S. Constitution.

### **SUMMARY OF FACTS**

IDFA is a trade association consisting of dairy processors and manufacturers ranging from single plant companies to multi-national organizations. Together they represent more than

85% of the milk, cultured products, cheese and frozen desserts produced and marketed in the United States. IDFA's members market many of the dairy products sold in Ohio. Many of these products (e.g. fluid milk, yogurt, cheese) are produced from milk received from farmers who pledge not to treat their cows with recombinant bovine growth hormone ("rbGH") also known as recombinant bovine somatotropin ("rbST"), a genetically engineered hormone administered to lactating dairy cows to increase their milk production. (Complaint ¶ 3.)

### **FDA APPROVES USE OF rbGH**

Lactating dairy cows naturally produce their own supply of bovine growth hormone, but when these cows are given injections of rbGH, the synthetic hormone combines with the naturally occurring bGH to permit an increase in the cows' milk production by up to ten percent. (Compl. ¶ 11.) Following a study by the Animal Sciences Division of Monsanto, on November 5, 1993, FDA approved its animal drug application for rbGH (POSILAC®). Relying on Monsanto's study, FDA approved rbGH for use because that study concluded that rbGH would be safe and effective for dairy cows, that milk from rbGH-treated cows would be safe for human consumption, and that production and use of rbGH would not have a significant impact on the environment. (Compl. ¶ 13.)

Many consumers today oppose the use of this genetically engineered hormone. Some are concerned with human health implications. Others believe that administering supplemental amounts of growth hormones to lactating dairy cows amounts to poor animal husbandry or are just opposed to the use of genetic engineering in the production of food. (Compl. ¶ 17.)

As a result of consumer demand, many of Plaintiff's members have individually decided that they will not accept milk from their suppliers that comes from cows that have been treated with rbGH. These members have entered into agreements with their suppliers to ensure that the milk they receive does not come from treated cows. Some IDFA members have agreed to pay

farmers a monetary premium to compensate them for participating in these agreements. (Compl. ¶ 21.) Additionally, IDFA members voluntarily label their products with messages to indicate that the farmers that supply that member with milk and cream have pledged not to treat their dairy cows with rbGH. (Compl. ¶ 22.)

### **FDA ISSUES GUIDANCE FOR VOLUNTARILY LABELING**

In response to state, industry and consumer requests, FDA in February 1994 issued interim guidance on the voluntary labeling of milk and milk products derived from cows not treated with rbGH to ensure that the statements made were not false or misleading. In its interim guidelines, later qualified in a July 27, 1994 letter, FDA asserted that labeling statements to the effect that products were from cows not treated with rbGH could satisfy the requirements of being truthful and not misleading. However, the agency stated, any implication that milk derived from cows not treated with rbGH is safer or of higher quality “could best be avoided by the use of accompanying information that puts the statement in proper context.” As one example of how such context could be achieved, the FDA suggested that labels employ the following contextual language: “No significant difference has been shown between milk derived from rbST-treated and non-rbST-treated cows” (“FDA Guidance”). 59 Fed. Reg. 6279, 6280, c.2 (Feb. 10, 1994). App. 0002. Moreover, FDA asserted that the term “rbST free” only *may* be misleading and could be formulated as “from cows not treated with rbST.” However, FDA has expressly stated that the proposed contextual language or even any contextual language is not necessary or mandatory. App. 0003-04.

Since 1994, Monsanto has requested that FDA or the Federal Trade Commission (“FTC”) limit the use of rbGH labels or to find that labels in the marketplace are misleading. With very limited exceptions, neither FDA nor FTC has found rbGH labels in the marketplace to be misleading. App. 0005-96. Having no success at FDA and FTC, Monsanto has more recently

turned to the states supported by dairy farmers using rbGH to obtain label restriction decisions that FDA and FTC have refused to make. (Compl. ¶ 29.) Ohio is the latest target.

## **OHIO ADOPTS NEW LABELING REGULATIONS**

Dairy products have been sold in Ohio with non-rbGH use labels since the 1990's. Ohio took no action against these labels until February 2008 when dairy farmers raised concerns about their customers' requirements for milk from cows not treated with rbGH. On February 7, 2008, the Director issued an Emergency Rule regarding dairy product labeling that for the first time in Ohio, and notwithstanding existing, unused authority to enforce truthful and non-misleading labeling, singled out rbGH for specific rules and restrictions that go beyond the FDA Guidance by preventing certain milk labels, requiring the FDA disclaimer language and imposing rules on placement, size and location of the FDA disclaimer language. App. 0099-104 ("Emergency Rule").

After industry reaction and hearings, the Defendant in his official capacity adopted May 22, effective September 19, 2008, the Ohio Rule solely regarding dairy labeling that, among other things: 1) prohibits certain truthful claims expressly permitted in other states (e.g. "rbGH Free") even when accompanied by a production claim along the lines of "our cows are not treated with rbST;" 2) requires the FDA "No significant difference . . ." language; 3) imposes size, style and location restrictions regarding the FDA language that are not consistent with other states; and 4) imposes a heretofore new requirement regarding verification of the non-use of rbGH claim beyond dairy farmer affidavits. App. 0105-06.

Specifically, the Ohio Rule requires that the FDA context language be in the same font, style and even color as the "permitted claim" ("this milk is from cows not supplemented with rbST" or substantially equivalent claim). The Ohio Rule prescribes a specific minimum size of print for the required FDA disclaimer language and requires that the FDA language be at least

half the size of the rbGH claim. The Ohio Rule proscribes existing claims in the marketplace (e.g. “rbGH Free”) even when such claims are accompanied by explanatory language such as “our farmers pledge no use of rbGH”. (Compl. ¶ 45.) The Ohio Rule prohibits the common use of an asterisk to link the “permitted claim” to the FDA context language. FDA says that the use of asterisks is commonly understood by consumers. App. 0097-98. Further, under the Ohio Rule, one is allowed to say “No Artificial Growth Hormone – our farmers pledge,” but not permitted to say “No rbST – our cows are not treated with rbST.” (Compl. ¶ 45.)

The Ohio Rule is the most restrictive, presently effective regulation. Other states with rbGH labeling regulations have adopted a less restrictive approach, including Minnesota, Wisconsin, Vermont, Maine and Alaska, which expressly permit terms banned in Ohio. App. 0381-96. In so doing, those states have, for now, avoided imposing their regulations on products produced outside their borders in conformance with another state’s rules and regulations or guidance.

### **THE OHIO RULE ADVERSELY IMPACTS IDFA’S MEMBERS**

It is important that Plaintiff’s dairy processor members, as national and regional distributors of milk and other dairy products, be able to label the products they sell in a consistent, uniform manner as they see fit. Requiring that one label be used in the State of Ohio, when another is used in virtually every other part of the country, imposes unjustifiable and impermissible burdens and costs on the Plaintiff’s members, and severely restricts the extent to which they can include truthful information about rbGH on the labels of their products sold in these other parts of the country in competition with regional companies expressly permitted to make claims prohibited or substantially limited by the Ohio Rule. (Compl. ¶ 63.)

The Ohio Rule by its terms and on its face would require most, if not all, existing labels for sale of dairy products in Ohio (and as a practical effect throughout the United States) to be

significantly modified to conform with the regimented Ohio Rule even though they are perfectly legal in other jurisdictions. The Director concluded that the cost of such compliance would be minimal (\$250 - \$300 per label) (App. 0109, ¶ 15) in the face of industry statements that costs for complying with Ohio Rule alone would be at least in the tens or even hundreds of thousands of dollars. App. 0103, 0135-36, 0323-34; App. 0420-72.

### **ARGUMENT**

Under Federal Rule of Civil Procedure 65, “[a] party seeking a preliminary injunction must show: (1) a likelihood of success on the merits; (2) that it will suffer irreparable harm if the injunction is denied; (3) that granting preliminary relief will not result in even greater harm to the nonmoving party; and (4) that the public interest favors such relief.” *See Hamilton’s Bogarts, Inc. v. Michigan*, 501 F.3d 644 (6th Cir. 2007). Plaintiff meets each of these four requirements which the court should consider and balance. *Performance Unlimited, Inc. v. Questar Publishers, Inc.*, 52 F.3d 1373, 1378 (6th Cir. 1995).

#### **I. PLAINTIFF HAS A STRONG LIKELIHOOD OF PREVAILING ON THE MERITS**

“To show a likelihood of prevailing on the merits, the [party seeking the injunction] must show the likely existence of a constitutional violation causally related to the result sought to be enjoined.” *Schenck v. City of Hudson*, 114 F.3d 590, 593 (6th Cir. 1997) (citations omitted) (alterations in original). As demonstrated below, Plaintiff will likely succeed as its Complaint and the declarations accompanying this memorandum raise serious and substantial questions regarding the constitutionality of the Ohio Rule. Indeed, as the Supreme Court has explained, “[i]f the First Amendment means anything, it means that regulating speech must be a last -- not first -- resort.” *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 373 (2002).

**A. The Ohio Rule Bans Protected Speech and Imposes An Unconstitutional Restriction On Truthful, Non-Misleading Commercial Speech**

The statements and claims on food labels are considered commercial speech. The importance of commercial speech to the economic interests of not only the speaker and the intended recipient (and an efficient overall economy) means that the First Amendment of the U.S. Constitution protects the freedom to convey messages in a commercial setting much like political speech. *Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council*, 425 U.S. 748, 762-63 (1976) (equating commercial speech to political speech about the merits of a labor dispute because both have economic repercussions). The commercial nature of the speech does not remove it from the protections of the First Amendment or give the government unbridled authority to determine what can or cannot be said in the marketplace:

The commercial marketplace, like other spheres of our social and cultural life, provides a forum where ideas and information flourish. Some of the ideas and information are vital, some of slight worth. But the general rule is that the speaker and the audience, not the government, assess the value of the information presented. *Thus, even a communication that does no more than propose a commercial transaction is entitled to coverage of the First Amendment.*

*Edenfield v. Fane*, 507 U.S. 761, 767 (1993) (emphasis added) (overturning law governing advertising by CPA on grounds it impermissibly restricted access to commercial information). IDFA brings this case to protect its members' rights to make truthful, non-misleading claims in the manner they choose.

The Ohio Rule violates the First Amendment rights of dairy processors and retailers because it prevents them from being able to convey their message in the manner they choose.<sup>1</sup> First, the Ohio Rule prohibits the use of certain words on the dairy label such as “rbST Free,” “rbGH Free” or “No rbGH” even when accompanied with production claim description language

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<sup>1</sup> The First Amendment of the U.S. Constitution applies to the States through the Due Process Clause of the Fourteenth Amendment. *Va. State Bd. of Pharmacy*, 425 U.S. at 749 n.1.

and even though those terms together with such production claims have become over the past 14 years terms of art accepted in other states. The Ohio Rule mandates that the only permissible claim dairy processors and manufacturers can make on their labels concerning rbGH is that: “this milk is from cows not supplemented with rbST.”<sup>2</sup> Furthermore, the Ohio Rule unduly restricts speech because a dairy processor or manufacturer that elects to claim that “this milk is from cows not supplemented with rbST” on its label must also include a contiguous disclaimer in the identical font, style, case and even color that, “[t]he FDA has determined that no significant difference has been shown between milk derived from rbST-supplemented and non-rbST-supplemented cows.” These restrictions do not pass muster under the First Amendment because they impermissibly restrict truthful, non-misleading commercial speech.

Courts evaluate the constitutionality of government regulations of commercial speech pursuant to the framework set forth in *Central Hudson Gas & Elec. Corp. v. Pub. Serv. Comm’n of N.Y.*, 447 U.S. 557 (1980) (holding unconstitutional a regulation completely banning an electric utility from advertising to promote the use of electricity). The first step in the analysis requires an evaluation of whether the regulation concerns speech that is inherently misleading or related to an unlawful activity. *Fla. Bar v. Went for It, Inc.*, 515 U.S. 618, 624 (1995) (analyzing the constitutionality of an advertising regulation after an initial finding that the advertising at issue did not concern unlawful activity and was not *per se* misleading); *see also In re R.M.J.*, 455 U.S. 191, 205 (1982) (finding an attorney advertisement that listed areas of practice was “not misleading on its face”). Only speech regarding an unlawful activity or that is inherently misleading is not afforded any First Amendment protection, and the government may prohibit such speech entirely. The issue of whether a statement is inherently misleading and beyond the

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<sup>2</sup> The ability to use a “substantially equivalent” phrase under the Ohio Rule leaves little room for dairy processors and manufacturers to convey truthful, non-misleading messages about rbGH in the manner they choose – a right protected by the First Amendment. (Declaration of Mike Krueger), App. 0423, ¶ I.3.

protection of the First Amendment is a question of law over which courts exercise *de novo* review. *Peel v. Attorney Registration & Disciplinary Comm'n*, 496 U.S. 91, 108 (1990) (determining that although a state court is in a position to review actions of its own State Bar, the regulation is not insulated from the Supreme Court's review of its constitutional infirmity).

If the commercial speech is truthful and not inherently misleading, the Supreme Court has long recognized that it is entitled to First Amendment protection. In this context, the government may impose restrictions on truthful, non-misleading speech only if it can affirmatively demonstrate: 1) that the restriction on commercial speech achieves a substantial government interest; 2) that the restriction on commercial speech directly and materially advances that interest; and 3) that the restriction is not more extensive than is necessary to serve that interest. *Central Hudson*, 447 U.S. at 564. The government bears the burden of establishing all of these criteria, and the failure to establish any one element is fatal to the regulation as a violation of the speaker's First Amendment rights. *Edenfield*, 507 U.S. at 770 (*quoting Bolger v. Youngs Drug Prods. Corp.*, 463 U.S. 60, 71, n.20 (1983)).

IDFA's members are entitled to deliver their accurate and not inherently misleading messages in the manner they see fit as speakers entitled to First Amendment protections because "speakers, not the government, know best both what they want to say and how to say it." *Riley v. Nat'l Fed'n of the Blind of N.C.*, 487 U.S. 781, 790-91 (1988). The First Amendment prevents "public authority from assuming a guardianship of the public mind through regulating the press, speech, and religion' [and] [t]o this end, the government, even with the purest of motives, may not substitute its judgment as to how best to speak for that of speakers and listeners...." *Id.* at 791-92 (citation omitted). It is for this reason that IDFA successfully sued Vermont in 1994 after Vermont adopted a statute requiring labeling of milk that came from cows treated with

rbGH. *International Dairy Foods Ass’n v. Amestoy*, 92 F.3d 67 (2nd Cir. 1996) (consumers “should exercise the power of their purses by buying products from manufacturers who voluntarily reveal [non-use of rbGH]”). The Ohio Rule, while the mirror image, flatly prohibits the disclosures the Second Circuit suggested in *Amestoy* could be voluntarily made to consumers.

In this case, the Director cannot possibly meet its burden as to the Ohio Rule because not only is there no evidence that the claims about rbGH on the labels of dairy processors and retailers are false or misleading, but also the labeling restrictions on commercial speech imposed by the Ohio Rule cannot pass any *Central Hudson* factor. The Director does not know what IDFA members want to say or how they want to say it. And, the Director cannot substitute his judgment with respect to this protected speech.

**1. The Ohio Rule Bans Protected Speech.**

In adopting the Ohio Rule, the Director concluded that an rbGH claim on the dairy label is inherently misleading if it contains certain government-prohibited words such as “rbGH Free” or “No rbGH” even if such words are accompanied with production claim language such as “our farmers pledge.” App. 0107-10 . These terms, and their like, are prohibited with no right to provide any context. The Director, however, adopted this prohibition on speech without any credible evidence to support the conclusion that the existing dairy labels, especially those that put the banned speech in context, actually mislead consumers about the safety and quality of milk from cows not treated with rbGH versus milk from cows treated with rbGH.

The Ohio Rule – although unique in its requirements – is not the first attempt by a government to weigh in on acceptable practices for labeling about rbGH to avoid misleading consumers. The FDA Guidance issued in 1994 addresses appropriate labeling statements that it would not consider false or misleading. App. 0001-02. In doing so, the FDA created a “Safe Harbor” for dairy processors and manufacturers. FDA has reaffirmed the appropriateness of the

Safe Harbor several times since its initial adoption, and as recently as June 2007, declined Monsanto's request to revisit the 1994 guidance. App. 0093. Additionally, in August 2007, the Federal Trade Commission declined Monsanto's request to undertake a formal enforcement action for misleading advertising relating to rbGH on the basis that except for a few instances, the advertisements were consistent with FDA guidance and not deceptive. App. 0094-96.

The FDA Guidance remains the industry standard that dairy companies use as a starting point for designing their label because they know if the label conforms with this guidance at a minimum, they can be certain that they are communicating the message to consumers in an accurate and truthful way. (Declaration of Diane Manganaro), App. 0430, ¶ 10. In adopting the guidance, FDA's key concern was avoiding the potentially misleading implication that milk derived from cows not treated with rbGH is safer or of higher quality than milk from cows treated with rbGH. App. 0001-02. However, from the outset, FDA also recognized that use of rbGH raised sufficient controversy that some consumers would want additional information and may want milk from cows not treated with rbGH. Unlike Ohio, FDA has never stated that concise statements, such as "rbGH Free" or "No rbGH," are inherently misleading and can never be used. FDA stated simply that such phrases "may be potentially misleading," and thus, a production claim descriptor such as "our cows are not treated with rbGH" and a contextual statement may help dispel any misleading implications. App. 0002. FDA explained that any misleading implications associated with a non-use of rbGH claim could be addressed by putting the claim in proper context for consumers using a statement like "No significant difference has been shown between milk derived from rbST-treated and non-rbST-treated cows."<sup>3</sup> App. 0002.

Unlike FDA, the Ohio Rule considers concise statements, such as "rbGH Free" or "No

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<sup>3</sup> IDFA recommends that its members adopt the FDA Guidance Safe Harbor. However, IDFA does not take a position on how each member should implement the Safe Harbor.

rbGH” inherently misleading and prohibits their use entirely even if accompanied by a production claim description. FDA stated that such phrases may be potentially misleading, and thus, a contextual statement is the means to best avoid any misleading implications.<sup>4</sup> The Ohio Rule’s ban is based on an assumption that consumers are no more discerning than children and are misled by a claim such as “rbST Free,” “rbGH Free” or “No rbGH” under every circumstance.<sup>5</sup>

The Supreme Court decision in *Peel* is determinative here. *Peel*, 496 U.S. at 91. In that case, the Supreme Court found that the state impermissibly restricted commercial speech on the grounds that there was no “evidence of deception,” and the state’s actions to limit commercial speech were based on “the paternalistic assumption that the recipients of petitioner’s letterhead are no more discriminating than the audience for children’s television.” *Id.* at 105. The Ohio Rule with its outright prohibitions on specific speech suffers from the precise defect identified in *Peel* and other cases.<sup>6</sup> As in *Peel*, the Ohio Rule impermissibly bans commercial speech without any evidence of actual deception by the existing labeling practices.

## **2. The Ohio Rule Unlawfully Regulates Speech under Central Hudson.**

The Director has also concluded that in addition to the banned speech, certain dairy labels are potentially misleading even if they contain the Ohio-approved speech for the non-use of rbGH claim, if there is not a contiguous disclaimer conforming to the regulation’s strict

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<sup>4</sup> Alaska, Maine, Minnesota, Vermont and Wisconsin have adopted specific regulations concerning dairy labels. None determined that an outright ban on these particular phrases was necessary.

<sup>5</sup> Ohio has not barred labels stating the synonymous “Our Farmers Pledge no Use of Artificial Growth Hormones.” App. 0438-41, Exs. A and B. Thus, Ohio is choosing which synonymous language is permissible.

<sup>6</sup> See, e.g., *Ibanez v. Fla. Dep’t of Bus. & Prof’l Regulation*, 512 U.S. 136, 137 (1994) (rejecting argument that attorney’s advertising reference to Certified Financial Planner credential inherently misleads public into believing that state approval exists); *In re R.M.J.*, 455 U.S. at 205; *Allstate Ins. Co. v. Abbott*, 495 F.3d 151, 166 (5th Cir. 2007) (insurance company’s recommendation of a tied body shop “does not involve an inherently false or misleading representation” that it is “the best available auto body repair service”); *Biogonic Safety Brands, Inc. v. Ament*, 174 F. Supp. 2d 1181, 1182 (D. Colo. 2001) (finding “implausible” the belief that “consumers exposed to the ‘Safe for Kids’ claim [in a pesticide label] would believe that ShooBug is safe for all kids”).

requirements as to acceptable wording, placement, font, style, case, size and even color. App. 0105-06. These restrictions are only permissible if the Director can affirmatively demonstrate that the Ohio Rule satisfies all of the criteria articulated in *Central Hudson*. The Director, however, has not, and cannot, overcome these hurdles necessary to justify the Ohio Rule's infringement on truthful, non-misleading commercial speech.

***a. The Ohio Rule Does Not Further a Substantial Government Interest***

*Central Hudson* requires the Director to demonstrate first that the Ohio Rule serves a "substantial interest" of the state. *Central Hudson*, 447 U.S. at 564; *In re R.M.J.*, 455 U.S. at 203. While the interest in ensuring the accuracy of commercial information may be "substantial" under *Central Hudson* (*Edenfield*, 507 U.S. at 769), the Ohio Rule goes far beyond the FDA Guidance and what is necessary to prevent false or misleading labels.

For instance, FDA has never indicated that the placement, font, style, case, color or size of any contextual statement the dairy processor or manufacturer elects to use would affect whether the dairy label is misleading to consumers. FDA subsequent to issuing the FDA Guidance told the New York Department of Agriculture that a contextual statement is not even required to prevent the label from being misleading: "in many instances a statement like 'from cows not treated with rbST' would not be misleading, and *in no instance is the specific statement 'No significant difference . . . ' required by FDA.*" App. 0003-04 (emphasis added).

The Director presents no evidence to support the conclusion of the Ohio Rule that in all circumstances a contextual statement that meets precise requirements for placement, font, style, case, color and size must be used to prevent the dairy label from being misleading. To the contrary, for example, one of the standard practices in food industry labeling, including non-use of rbGH claims, is to use asterisks to link one statement to another. The Ohio Rule in requiring a

contiguous contextual statement inherently rejects the use of asterisks and footnotes. Since the Director has not explained why the common use of asterisks is precluded here, one must presume that he concluded that such use is potentially or actually misleading. But, this is contrary to the findings of FDA. In an internal memorandum published as a reference to FDA rule-making for dietary supplements and required disclaimer language, the Acting Director, Division of Market Studies of the Department of Health & Human Services concluded, based upon its actual consumer surveys:

The use of asterisks or other symbols to link one statement to another, such as a footnote, is a very common format device that communicates effectively under many circumstances. . . . It is a technique to shorten copy and thereby improve readability. The concern that consumers may fail to recognize the link between the asterisked statement and the disclaimer should be minimal because this particular device is used in many different contexts and virtually all consumers will be familiar with its use.

Based on the agency's experience . . . , consumers have few problems with this kind of format device.

App. 0097-98; *see* 62 Fed. Reg. 49859, 49864 (Sept. 23, 1997). Further, with respect to the size of any statement, the memo concludes, "setting any minimum type size always involves tradeoffs between the scarcity of available label space and readability." App. 0098. While a specific size type was not endorsed, the memo recognized that a minimum size of 1/16 inch is common and reasonable standard. *Id.* This Court should find the FDA statement highly relevant and persuasive. Thus, while we are left to guess where the Director got his information that only a contiguous disclaimer in the same style of font, subject to a minimum font height (not necessarily related to 1/16 inch) and only in the same color as the claim will work, FDA has clearly concluded otherwise.

The Director has also at least twice described the purpose of the Ohio Rule in terms that reveal additional flaws under the First Amendment. In a press release that accompanied issuance

of the Ohio Rule, the Director described the purpose as ensuring accurate and “balanced information” regarding dairy products. App. 0105. Moreover, in at least one letter to an out-of-state milk processor concluding that that processor’s label is disallowed under the Ohio Rule (because the disclaimer is not contiguous with the non-use claim), the Director described the purpose as ensuring “only the most accurate information” and “that the public has the information necessary to make an informed decision.” (Decl. of Bill Riley, Ex. B.), App. 0438.

While the Director has the power under the First Amendment to regulate labels demonstrated to be potentially misleading, the Director’s own stated purpose goes way beyond those limited powers. The requirement of “balanced information” is not part of the Director’s powers. By its own terms, “balanced information” means a neutral point of view as defined by Ohio. Commercial free speech limitations do not include the limitation that information be “balanced.” Moreover, the immediate trouble with the term “balanced information” is that in this case, the State is defining what is balanced and what is not. *See Riley*, 487 U.S. at 790.

The requirement that “the public has the information necessary to make an informed decision about the dairy products they purchase” followed by the requirement that information not only be accurate, but “only the most accurate” also crosses the line. Where does the Director in commercial free speech doctrine have the power to require “information necessary to make an informed decision?” Why is it necessary to go beyond “accurate” and require “only the most accurate information?” The limiting terms “only” and “most” modifying accurate are again terms that cannot be justified under commercial free speech analysis.

Other than the statements made in the press releases and letters, the Director has not proffered any other justification or state interests that would be served by the Ohio Rule. When articulating a legitimate state interest served by the rule, the state cannot pass the first hurdle

under the *Central Hudson* test by relying solely on the prevention of misleading commercial speech as the interest to be served by regulation when the commercial speech at issue is not even potentially misleading. *Zauderer v. Office of Disciplinary Counsel of the Sup. Ct. of Ohio*, 471 U.S. 626, 640-41 (1985) (finding that the state failed to justify its restriction on truthful, non-misleading speech when the only state interest identified was prohibiting inherently misleading advertising); *In re R.M.J.*, 455 U.S. at 205 (holding restriction on commercial speech invalid because speech was not shown to be inherently misleading and the state suggested no other state interest served by the restriction).

The bottom line, therefore, is that the Director has not articulated a legitimate state interest that would justify: 1) requiring a contiguous contextual statement; and 2) imposing specific font, style, case, color and size requirements of that contiguous contextual statement. Rather than serving the interests of consumers, who were virtually unanimous in their opposition to the Ohio Rule during the rulemaking process, see App. 0111-380, the evidence is that the stated reasons are pretext for nothing more than protectionism on behalf of Ohio dairy farmers who believe they can stem the demand for milk produced without the use of rbGH by making the marketing of such products more difficult through excessive labeling restrictions. As one dairy farmer stated:

ODA's ruling will benefit the dairy industry in Ohio by creating a level playing field for producers. Currently, dairy producers are not protected from having their product disparaged through labeling, and because the FDA unfortunately chose to leave labeling decisions up to each state, it is vital that ODA step in to protect Ohio's dairy producers.

App. 0253. This is not a legitimate, substantial state interest for purposes of First Amendment analysis.

If ensuring accurate commercial information was in fact the government interest intended to be served, the Director did not even need to adopt a new regulation because until the adoption of the Ohio Rule, the federal guidance for dairy products were used for more than a decade in Ohio without any meaningful history of consumer complaints. Indeed, IDFA is unaware of any enforcement action taken by the Director regarding non-use of rbGH claims using the FDA Guidance as a framework before the Director decided to adopt a specific regulation on this issue. The non-use of existing authority and the absence of any meaningful history of consumer confusion or complaints concerning rbGH claims is a further indication that the Director did not implement the Ohio Rule to serve the government interest of ensuring the accuracy of commercial information.<sup>7</sup> See *Edenfield*, 507 U.S. at 770-71; *Pagan v. Fruchey*, 492 F.3d 766, 771 (6th Cir. 2007). Without evidence that rbGH claims on current labels are misleading consumers, the Director can hardly posit that he was prompted to adopt the regulation to serve that interest.

The Director's timing is especially telling because most Ohio processors requested that, effective February 1, 2008 dairy farmers supply them only with milk from cows not treated with rbGH. The Director issued the emergency rule applicable to dairy product labeling just six days later on February 7, 2008 even though Ben & Jerry's, for instance, has been selling non-rbGH labeled product in Ohio since 1997.<sup>8</sup> (Decl. of Bob Michalek), App. 0443, ¶ 4.1.

Since the approval of the use of rbGH in 1993, dairy processors and retailers have increasingly insisted that the products they produce and sell are made only with milk from cows not treated with rbGH in response to the growing demand from consumers. App. 0421, ¶ C. The

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<sup>7</sup> Ohio's regulations require the Director to use generally recognized federal standards for labeling. Ohio Admin. Code 901:3-1-11. Thus, Ohio has apparently determined its interest in ensuring the accuracy of commercial information can be achieved using the federal standards.

<sup>8</sup> The emergency rule was ultimately adopted with some slight modification as the Ohio Rule in May 2008.

overwhelming majority of comments they receive from consumers express concern about rbGH, and that they want to know whether their products are made from milk from cows not treated with rbGH. App. 0443, ¶ 4.3. Their own market research supported the conclusion that whether a product was made from milk from non-treated cows was an important consideration to consumers when making their purchasing decisions. App. 0421, ¶ C. As a result of this increased consumer demand for products made with milk from cows not treated with rbGH, dairy processors and retailers began displaying this information on their labels so that consumers could readily see that the product does not contain milk from cows treated with rbGH. (Decl. of Rhonda L. Jordan), App. 0461, ¶ 4. As a result, many processors have requested that their suppliers pledge not to use rbGH.

A key component of staying competitive is a label that readily conveys an easily recognized and understood message to consumers. App. 0462, ¶ 6. Products made with milk from cows not treated with rbGH have a competitive advantage with consumers in the current market, but that advantage all but disappears if processors, manufacturers and retailers are restricted in their ability to inform consumers using a message on the label that is not only truthful and accurate but also concise and easily recognized and understood by the consumer. App. 0462, ¶ 6. The Director's restrictions on labeling is a means to reverse market forces and improve the competitiveness of products made with milk from cows treated with rbGH, and in turn, bolster the waning sales for Ohio dairy farmers who want to continue to use rbGH.

The Ohio Rule thwarts the ability of processors, manufacturers and retailers to convey their message to consumers because the basic message gets obscured by the fact that any concise references to "rbGH Free" or "No rbGH" that a consumer might easily recognize are prohibited. On smaller containers in particular, dairy companies may be forced to remove their claim

regarding non-use of rbGH entirely due to space limitations.<sup>9</sup> The implications of a change in the label or removal of the claim entirely could be devastating to a company’s sales because consumers may be misled into thinking that there has been a change in policy and the product is now made with milk from rbGH-treated cows. App. 0463, ¶ 13. Not surprisingly, the few people voicing support for the Ohio Rule during the rulemaking process were not consumer groups.

***b. The Director Has Not Established That The Harm Is Real Or That The Restriction Will Alleviate The Harm in a Material Way.***

The Ohio Rule fails the next *Central Hudson* factor because the Director cannot “demonstrate that the harms it recites are real and that its restriction will in fact alleviate them to a material degree.” *Edenfield*, 507 U.S. at 770-771. In order to carry the burden of proving this factor, the Director may not rest on “mere speculation or conjecture,” *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 555 (2001) (citation omitted), or “unsupported assertions,” *Ibanez v. Fla. Dep’t of Bus. & Prof’l Reg.*, 512 U.S. 136, 143 (1994) (citation omitted). This is a “critical” factor because “otherwise, ‘a State could with ease restrict commercial speech in the service of other objections that could not themselves justify a burden on commercial expression.’” *Rubin v. Coors Brewing Co.*, 514 U.S. 476, 487 (1995) (quoting *Edenfield*, 507 U.S. at 771) (holding that a regulation prohibiting beer labels from displaying alcohol content violated the First Amendment).

Moreover, the Director “must come forward with some quantum of evidence, beyond his own belief in the necessity for regulation, that the harms it seeks to remedy are concrete and that its regulatory regime advances the stated goals.” *Pagan*, 492 F.3d at 771 (citing *Edenfield*, 507

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<sup>9</sup> FDA’s regulation of dietary supplements and the use of asterisks in that regulation is applicable here. According to FDA, consumers understand asterisks and the size of containers should be considered when regulating speech about specific health claims. App. 0097-98.

U.S. at 770-72) (holding that an ordinance prohibiting persons from parking vehicles with advertising on public roads unconstitutionally restricted free speech). As the Supreme Court summarized in *Ibanez*, “[i]f the protections afforded commercial speech are to retain their force, we cannot allow rote invocation of the words ‘potentially misleading’ to supplant the Board’s burden to ‘demonstrate that the harms it recites are real and that its restriction will in fact alleviate them to a material degree.’” 512 U.S. at 146 (citation omitted).<sup>10</sup>

The Director does not and cannot satisfy this “critical” requirement. Assuming the Ohio Rule is intended to prevent consumer confusion, the Director has merely made the statement that many rbGH claims are deceptive and confuse consumers without producing any “real” or “concrete” evidence to support that conclusion. A review of the record compiled by the Director during the rulemaking process provides no indicia of consumer deception. While there are a handful of comments in support of the rule – primarily from dairy farmers or their family members – the vast majority of the comments are from industry trade groups and actual consumers, who are not also farmers, opposing the Ohio Rule. App. 111-380, 466-69.

***c. The Ohio Rule Is More Extensive than Necessary.***

Finally, even if it could prevail on the other *Central Hudson* factors, the Ohio Rule would still be unconstitutional because it regulates far more “extensive[ly] than is necessary to serve” a legitimate state interest. *Central Hudson*, 447 U.S. at 566. This final prong of the *Central Hudson* factors requires the Court to determine whether there exists a “reasonable fit” between the government’s goals and the means chosen to accomplish it – a means that is “narrowly tailored” to achieve the desired objective. *Lorillard Tobacco*, 533 U.S. at 556; *Fla. Bar*, 515 U.S. at 632; *Chambers v. Stengel*, 256 F.3d 397, 404-05 (6th Cir. 2001). The tailoring

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<sup>10</sup> The Organic Dairy Association (“OTA”) simultaneously filed a separate action in this Court to invalidate the same Ohio Rule. OTA’s argument that the Director’s actions are void for vagueness are applicable here if the Director maintains that paragraph (B) of the rule is merely permissive and not mandatory.

requirement for commercial speech requires the Director to use a means that achieves the state's interest without restricting speech or that restricts less speech. *Thompson*, 535 U.S. at 371 (affirming the Court of Appeals' judgment that certain FDA regulations relating to advertising are unconstitutional). Moreover, "the existence of 'numerous and obvious less-burdensome alternatives is certainly a relevant consideration in determining whether the 'fit' between ends and means is reasonable.'" *Fla. Bar*, 515 U.S. at 632 (quoting *City of Cincinnati v. Discovery Network, Inc.*, 507 U.S. 410, 418 n.13 (1993)) (finding unconstitutional a regulation that banned news racks containing "commercial handbills" because the ban was not a reasonable fit to the city's legitimate interest in safety and aesthetics).

In this case, there are less-burdensome alternatives to the Ohio Rule's strict requirements ranging from words that can and cannot be used, to the appropriate use of asterisks linking any necessary statements, to the font, style, case, size and even color of the words that can be used. There are methods of conveying the message about non-use of rbGH on the dairy label that are not false or misleading but that would fall well short of complying with the Ohio Rule and its rigid requirements. In fact, the Director would have to look no further than labels consistent with FDA Guidance to find examples.<sup>11</sup> And the Director, in lieu of adopting new restrictive rules, could have relied on existing authority and enforced existing regulations. He failed to do so.

A key characteristic of the FDA Guidance under *Central Hudson* is its flexibility in that it does not impose precise mandates on what is or is not an acceptable labeling practice. Rather, it gives a dairy company the freedom to design its message using a menu of options to design the

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<sup>11</sup> The Ohio Rule is also more extensive than permitted by First Amendment jurisprudence in that it appears to place the burden of establishing the truthfulness of the advertising on dairy processors by imposing a verification process beyond that FDA and other states have not seen fit to impose on processors using voluntary labeling. The Ohio Rule appears to require more than Declarations for verifying a claim "our farmers pledge." Under the First Amendment, the burden of proving the truth or lack thereof of commercial speech is on the government in the first instance, not the messenger. *Edenfield*, 507 U.S. at 770 (quoting *Bolger v. Youngs Drug Prods. Corp.*, 463 U.S. 60, 71, n.20 (1983)).

label in the manner it would like with the only constraint that the statements be truthful and not misleading. Using this approach, FDA achieves its objective but does not infringe on First Amendment rights by restricting speech more than necessary because the dairy companies are free to design their labels in a number of different ways and can chose to convey the truthful, non-misleading message in the manner that they see fit. The Director has not followed FDA's example and has taken the other extreme and adopted a rule that dictates every aspect of the label and forces dairy companies to convey their message based not on their choices to meet their commercial needs and First Amendment rights, but based on government mandates and limits on commercial speech. See App. 0441, Ex. B.

Moreover, the Ohio Rule is a one-size-fits-all-rule that does not account for the reality that milk and dairy products are sold in containers of varying sizes. The same rigid requirements apply uniformly regardless of whether the dairy product is a single serving container of yogurt, a package of cheese, or a half-pint or gallon of milk. The Ohio Rule has the practical effect of precluding commercial speech about rbGH, particularly on smaller containers. (Decl. of Steve Schmid), App. 0471, ¶ 9.

In sum, the Ohio Rule's imposition of requirements on acceptable wording, placement, font, style, case, size and color impermissibly restricts truthful, non-misleading commercial speech. Under the rationale of the Ohio Rule, compliance with every single one of the regulations' requirements – down to the font color – is necessary to prevent the label from being misleading. Clearly, the Ohio Rule goes too far and does not represent a reasonable fit between the means and ends and is not narrowly tailored to achieve the desired objective – notably, an objective that is already achieved by existing practice.

**B. The Ohio Rule Violates the Dormant Commerce Clause of the U.S. Constitution**

The Commerce Clause provides that “Congress shall have the Power . . . [t]o regulate commerce . . . among the several states.” U.S. Const. Art. I, § 8, cl. 3. The Supreme Court “long has recognized that this affirmative grant of authority to Congress also encompasses an implicit or ‘dormant’ limitation on the authority of the States to enact legislation affecting interstate commerce.” *Healy v. Beer Institute, Inc.*, 491 U.S. 324, 326 n.1 (1989) (citations omitted) (“*Healy II*”). Thus, the so-called dormant commerce clause acts “even without implementing legislation by Congress” as a restraint against state action. *Great Atlantic & Pacific Tea Co. v. Cottrell*, 424 U.S. 366, 370-71 (1976) (citations omitted).

Under one prong of dormant commerce clause analysis, direct regulation of interstate commerce (subjecting interstate commerce to extraterritorial impacts or to the risk of inconsistent regulation by multiple jurisdictions) is prohibited by the States regardless of the purpose for which regulation is enacted. *Shafer v. Farmers Grain Co.*, 268 U.S. 189, 199 (1925). A regulation is also unconstitutional if it discriminates in purpose or effect against interstate commerce. *Granholm v. Heald*, 544 U.S. 460 (2005). As a final consideration, if necessary, while incidental regulation of interstate commerce may be permitted, such incidental regulation is prohibited if 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).

The Ohio Rule violates these principles for four reasons. First, it directly regulates and prevents, unless its terms are satisfied, interstate shipments of dairy products – thus endowing the Ohio Rule with the practical effect of having direct extraterritorial impacts on interstate commerce occurring outside Ohio. Second, the Ohio Rule imposes inconsistent regulatory burdens on interstate commerce. Third, the history of non-use claims and Ohio’s recent entry into this regulatory arena effectively discriminates against dairy industry (including dairy

farmers from out-of-state) out-of-state interests in order to protect Ohio dairy farmers. Fourth, even if the impacts on interstate commerce are found to be merely incidental, the burden the Ohio Rule imposes on interstate commerce is excessive in light of the local interests the Ohio Rule purports to advance.

1. **The Ohio Rule Impermissibly Directly Regulates Interstate Commerce with Extraterritorial Impacts**

As demonstrated in the Declarations and in the testimony before the Director, dairy products are not simply produced in Ohio and sold in Ohio. Instead dairy products subject to the Ohio Rule are, or were until issuance of the Ohio Rule, produced in Ohio and Arizona, New England, Pennsylvania, Indiana, Minnesota and many other states. (Decl. of William Luth), App. 0451-60; App. 420-50, 461-71. The same products, carrying the same labels are sold in all 50 states or at least in states surrounding Ohio even if produced in Ohio. There can be no doubt that Ohio dairy products are sold in interstate commerce and that many dairy products sold in Ohio come from out-of-state. Moreover, the Ohio Rule affects interstate commerce directly, and not just incidentally, and the Director knew or should have known about such direct regulation when he promulgated the Ohio Rule because a number of industry witnesses testified about the direct and unequivocal impacts of the Emergency Rule on their ability to compete in interstate commerce. *See* App. 0123-38, 0191-93, 0243-50, 0266-78, 0286-89, 0320-36.

Yet, the Ohio Rule has the practical effect of regulating interstate commerce (and speech) that takes place wholly outside Ohio's borders. A non-Ohio processor selling its otherwise lawfully labeled product nationally or in surrounding states, is forced by the known commercial limitations inherent in the distribution of dairy and other food products to change its lawful labels in other states in order to comply with the Ohio Rule if it also sells any product in Ohio. In complying with the Ohio Rule and giving up lawful labels outside Ohio, dairy product

processors and manufacturers will surrender any competitive advantage such labels provide in- or out-of-state along with their otherwise lawful commercial speech. Thus, the Ohio Rule is in practical effect and result no different as to its extra-territorial reach from the “price affirmation” statutes found unlawful in a trio of cases decided in the 1980’s. *United States Brewers Ass’n, Inc. v. Healy*, 692 F.2d 275 (2d Cir. 1982) (“*Healy I*”) *summarily aff’d* by 464 U.S. 909 (1983); *Brown-Forman Distillers Corp. v. N.Y. State Liquor Auth.*, 471 U.S. 573 (1986); *Healy II*, 491 U.S. at 324.

In the price affirmation cases, Connecticut and New York sought to protect in-state consumers from high beer and liquor prices by requiring monthly posted prices that could be no higher than prices offered out-of-state. However, the required price calculations had the practical effect of projecting pricing out-of-state thus imposing the Hobson’s choice on sellers between complying with the New York and Connecticut laws or freely setting prices in other states. *Brown-Forman*, 476 U.S. 579-82. Relying on *Baldwin v. G.A.F. Seelig, Inc.*, 294 U.S. 511 (1935) (New York statute illegally set minimum prices for milk by banning sale of milk in New York that had been purchased for lower price out-of-state) and citing *Healy I* with approval, the *Brown-Forman* Court refused to permit New York to protect its consumers while at the same time requiring that out-of-state economic interests “surrender whatever competitive advantages they may possess.” *Brown-Forman*, 476 U.S. at 580. Notwithstanding the laudable goal of protecting New York consumers from higher prices, the price affirmation statute was unlawful because of its inevitable extra-territorial effects.

These price affirmation statutes were illegal because the Commerce Clause “precludes the application of a state statute to commerce that takes place wholly outside of the State’s borders, whether or not the commerce has effects within the State.” *Healy II*, 491 U.S. at 326-

27, 335-37 (quoting with approval *Edgar v. MITE Corp.*, 457 U.S. 624, 642-43 (1982) (plurality opinion)). The Court in *Healy II* went further, expounding that lack of intent to reach out-of-state is irrelevant: “a statute that directly controls commerce occurring wholly outside the boundaries of a State exceeds the inherent limits of the enacting State’s authority and is invalid regardless of whether... the practical effect of the regulation is to control conduct beyond the boundaries of the State.” *Healy II*, 491 U.S. at 336 (citing *Brown-Forman*, 476 U.S. at 579).

The Ohio Rule not only prevents Ohio-produced dairy products from being sold lawfully in surrounding states unless they comply with Ohio’s requirements, but also imposes requirements on those having little or no connection with Ohio save the sale of dairy products there. Indeed, the Ohio Rule applies to non-Ohio companies selling dairy products in Ohio even if they are based in Arizona, have applied for and received approval for their dairy product label in Arizona and sell their dairy products nationally in a complex warehouse distribution system that prevents distribution variances for products sold in individual states. App. 0420, ¶ B. Thus, the Ohio Rule if permitted to operate will have the practical effect of regulating transactions that occur in the other 49 states. Given the structure of the distribution system employed by national customers, Kraft, Tillamook, Hood, Ben & Jerry’s, Shamrock and others do not control where particular product will be distributed once delivered to designated distribution points and thus cannot ensure that product with particular labeling is sent to particular geographic areas. *See* App. 420-72. Moreover, that warehouse distribution system depends for its success on limiting the product alternatives available and moving product at both a high volume and velocity. Thus, all of these companies will be prohibited by the commercial realities of the distribution of their nationally branded dairy products from selling their products through that necessary distribution system without first changing all of their labels to suit Ohio.

It is therefore apparent that the Ohio Rule is a direct restraint on interstate commerce and that it has a sweeping extraterritorial effect. Furthermore, if Ohio may impose such regulations, so may other States; and interstate commerce in dairy products would be thoroughly stifled. *MITE Corp.*, 457 U.S. at 642. In *MITE Corp.*, the Illinois Business Takeover act imposed notification and administrative review requirements on corporate tender offers even those with arguably incidental contacts to Illinois. The plurality opinion (cited with approval in *Brown-Forman* and *Healy II*), noted that sufficient Illinois contacts gave Illinois unlawful authority over out-of-state shareholders. The Takeover Act was thus found unlawful because of its out-of-state effects. So, too, will the Ohio Rule result in the stifling of sale of dairy products within these United States because processors now face differing rules in different states. Once direct interference or burdens on interstate commerce are established, the Ohio Rule is subjected to heightened scrutiny and “is a prohibited regulation and invalid, regardless of the purpose with which it is enacted.” *Id.* (quoting *Shafer*, 268 U.S. at 199) (citing *Hughes v. Alexandria Scrap Corp.* 426 U.S. 794, 806 (1976)).<sup>12</sup>

*MITE Corp.* also commands “[t]he Commerce Clause also precludes the application of a state statute to commerce that takes place wholly outside of the State’s borders, whether or not the commerce has effects within the State.” 457 U.S. at 642-43. While Ohio waited more than 14 years to join this debate about non-use claims, a number of labels regarding non-rbGH use have come into use in Ohio and elsewhere in compliance with the FDA Guidance and other state laws, regulations and guidance. This is especially true on nationally branded products such as Ben & Jerry’s Ice Cream (1997). *See* App. 0442-50. Indeed even as other states have adopted

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<sup>12</sup> Except for the case upholding Maine’s ban on imports of baitfish because Maine had no other way to prevent the spread of parasites and the alteration of native species (*Maine v. Taylor*, 477 U.S. 131 (1986)), every “virtually per se invalid” discriminatory regulation that has reached the Supreme Court has been found invalid. *Or. Waste Sys., Inc. v. Dep’t of Env’tl. Quality of Or.*, 511 U.S. 93, 99-101 (1994).

regulations (some expressly permitting terms found to be inherently misleading by Ohio – e.g. “No rbGH”), industry has adapted to those regulations because, until now, no state statute, regulation or guidance has on its face or as applied insisted on its rule in lieu of other approved labels from other states.

Illinois was an early adopter of a Technical Bulletin with which industry has conformed (subject to significant variance discussed below) after some members of commercial industry sued Illinois over its non-use label ban. *See Ben & Jerry’s Homemade v. Lumpkin*, No. 96-C-2748, 1996 W.L. 495554 (N.D. Ill. 1996). The federal lawsuit, alleging many of the same legal infirmities found in the Ohio Rule, settled. The resulting Technical Bulletin, as amended, is not as strict as the Ohio Rule. App. 105-06. Moreover, unlike the Ohio Rule, Illinois has not strictly imposed its rule so as to interfere with labels expressly approved by other states.

Notwithstanding the Technical Bulletin’s position that “rbST Free” claims will not be permitted, Illinois permits Shamrock’s “No rbST – our cows are not treated with the growth hormone rbST” label. App. 0421, ¶ F. Illinois thus far has avoided interfering with interstate commerce.

Similarly, another recent state to act in this arena, Pennsylvania, issued guidance (not a regulation) that expressly provides on its face for the opportunity to seek approval of a dairy product label that has been expressly approved by another state jurisdiction even if the label does not otherwise comply with Pennsylvania’s guidance. App. 0413-18. The Shamrock label has been submitted for approval pursuant to that provision. App. 0422, ¶ G.

Unlike the Illinois provisions as applied and the Pennsylvania guidance as facially written, the Ohio Rule on its face has the practical effect of controlling conduct beyond the boundaries of the state. App. 420-72. In particular, the Director publicly stated “anyone with sales out of Ohio would not need to worry about different label regulation so long as they

complied with Ohio’s strictest rule.” App. 0472, ¶ 15. As with the price affirmation statutes found unconstitutional in *Healy I*, *Brown-Forman* and *Healy II*, dairy product processors and manufacturers because of the Ohio Rule are faced with the very real Hobson’s choice (in this case three bad alternatives) of adopting the Ohio Rule for all labeling across the United States thus giving up their lawful and competitive right to speak in other jurisdictions discontinuing sales in Ohio or discontinuing their lawful First Amendment speech altogether. *Healy II*, 491 U.S. at 332 (citing *Brown-Forman*, 476 U.S. at 579-82).

As in *Healy I*, *Brown-Forman* and *Healy II*, applying these principles, the Ohio Rule has the impermissible extraterritorial effect: once a dairy product processor or manufacturer chooses to sell product in Ohio, it not only must label in accordance with the Ohio label, but it is commercially necessary to simultaneously use identical labels in other states even if those states do not restrict the commercial speech or even permit terms declared unlawful by Ohio (e.g. “rbGH Free”). *Healy II*, 491 U.S. at 334. In short, the Ohio Rule violates the central tenet of our Constitution, “that the peoples of the several states must sink or swim together, and that in the long run prosperity and salvation are in union and not division.” *Seelig, Inc.*, 294 U.S. at 523. Ohio has exceeded its state power by enacting regulations that directly assert jurisdiction over persons or property in other states. *MITE Corp.*, 457 U.S. at 643 (citing *Shaffer v. Heitner*, 433 U.S. 186, 197 (1977)).

2. **The Ohio Rule Greatly Multiplies the Likelihood that Dairy Product Processors and Manufacturers will be Subject to Inconsistent Obligations.**

The practical effect of the Ohio Rule also cannot be reviewed in a historical or geographical vacuum. With approval of rbGH by FDA and the issuance of the FDA Guidance, labeling of products as being not from cows treated with rbGH began almost immediately. *Healy II* also concluded that “the practical effect of the statute must be evaluated not only by

considering the consequences of the statute itself, but also by considering how the challenged statute may interact with the legitimate regulatory regimes of other States and what effect would arise if not one, but many or every, State adopted similar [but not identical] legislation.” *Healy II*, 491 U.S. at 336. In addition to protecting against inconsistent state regulation, the Commerce Clause specifically “dictates that no State may force an out-of-state merchant to seek regulatory approval in one State before undertaking a transaction in another.” *Healy II*, 491 U.S. at 337 (citing *Brown-Forman*, 476 U.S. at 582). Of course, that is what is now necessary -- approval of dairy product labels in Ohio has the practical effect of impacting approved labels outside Ohio. Thus, in order to sell dairy products in Indiana and Kentucky, a dairy product processor or manufacturer doing business in Ohio must first get approval of Ohio for its dairy product label.

Having waited this long to get involved with non-use of rBGH claims that have been on labels available for sale at retail for years, Ohio should not be permitted to interfere with interstate commerce as it has developed in the interim especially since other states expressly permit terms banned in Ohio. *See* App. 0381-96. Moreover, as detailed in the Shamrock Declaration, the state of Arizona worked with Shamrock to develop its label and also expressly participated in employing the use of the term “No rBST – our cows are not treated with the growth hormone rBST.” App. 0421, ¶ E. The Ohio Rule flies in the face of these existing provisions and greatly multiplies the likelihood that dairy product processors and manufacturers will be (and are) subject to inconsistent rights and obligations. *Healy II*, 491 U.S. at 334.

In addition to the very real world problem discussed above that sellers in Ohio will need to change their labels for all other states, the risk of inconsistent regulation is clear. A seller such as Hood or Shamrock who complies with the Ohio Rule nonetheless competes with milk sellers selling product in a more local area. In order to comply with the Ohio Rule, Hood must give up

its competitive right and advantage on national branded products to say what others are expressly permitted to say. This places Hood, in interstate commerce, in a competitive disadvantageous position in selling its dairy products outside Ohio. For instance, Exhibit 17 (App. 0419), is a milk label for Oakhurst dairy products sold in northern New England. The label is perfectly lawful (and not misleading) in the states in which it is offered (e.g. Maine, New Hampshire, Massachusetts).<sup>13</sup> The label, however, does not comply with the Ohio Rule because the FDA contextual language, while present, is not contiguous and is not in the same color as the non-use claim. However, Hood, because it sells in Ohio, cannot on its national brands match the Oakhurst label even for its sales of the same national brand in New England because it is commercially impossible to have different labels merely for Ohio. App. 0429, ¶ 16.

Moreover, with states like Minnesota and Wisconsin openly permitting a claim such as “rBGH Free,” but Ohio prohibiting such a claim, Hood has chosen to discontinue selling at least one product in Ohio (produced in Minnesota in accordance with that statute) in order to retain its competitive position in those markets where Ohio’s banned language is expressly permitted. The only reason Hood was able to make this particular decision though was because it had available an alternative non-use claim product that could be sold in Ohio. App. 0427-30, ¶ 7 & 20. This option does not exist for others (e.g. Tillamook or Shamrock) or for other Hood products for which there is no easy substitute. In that event, sales of branded products in Ohio that are also sold in competition with products lawfully produced and sold in Minnesota and Wisconsin are subjected to differential treatment solely because the Ohio Rule has extraterritorial effect. In

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<sup>13</sup> In 2003, Monsanto sued Oakhurst Dairy in federal district court in Massachusetts alleging that Oakhurst’s labels were misleading and disparaged Posilac. Ex. 15. Oakhurst made the claim “Our Farmers Pledge: No Artificial Growth Hormone.” That case was later settled on private terms, although today Oakhurst’s label continues to make a non-use claim with the added word “used” after “Hormone.” Exhibit 17 (App. 0419) contains the FDA Guidance Safe Harbor language although it is not contiguous to the non-use claim as required under the Ohio Rule, but rather appears in smaller print at the bottom of the label. The Oakhurst label would be banned in Ohio.

adopting the Ohio Rule, the Director has ignored the mountain of evidence of adverse interstate commerce impacts and direct regulation of interstate commerce, *see* App. 0123-38, 0191-93, 0243-50, 0266-78, 0286-89, 0320-36, in favor of professed concerns by the manufacturer of Posilac and the dairy farmers wishing to use Posilac. *See* App. 0119-22, 138-43, 149-71, 0232-43, 0250-54, 0280-86, 0293-99, 0311-18, 0357-64; *see also* App. 0402-12.

The Pennsylvania Guidance permits labels which Ohio prohibits and allows for labels that can be considered for special circumstances under commercial business standards that differ from the hard-line Ohio Rule. App. 0413-18. Unlike Ohio's absolute ban on phrases such as "No rbGH," Pennsylvania permits such claims if accompanied by the "our farmers pledge no use of" language. Ohio prohibits this approach. App. 0105-06; App. 0424. Pennsylvania does not dictate the color of the contextual language. The result is that Ohio has banned terms as being misleading even though those terms are expressly permitted in other jurisdictions. This is truly forbidding, closing existing interstate commerce in numerous ways. For dormant commerce clause purposes, the important point is that dairy products sold along the Ohio and Pennsylvania borders will be treated differently, interrupting the free flow of commerce either by forcing the Ohio Rule on Pennsylvanians or by preventing product declared to be perfectly legal for sale in Pennsylvania to be sold in Ohio. App. 0434, ¶ 7.

Given the commercial realities that govern dairy product distribution, the only way to comply with the Ohio Rule is to give up the competitive right to speak in other jurisdictions. The tone and tenor of non-use claim regulation was first set by FDA and then long before Ohio by states that set up suggested modes of communicating the message while still permitting truthful statements along the lines of "No rbST – our cows have not been treated with the growth hormone rbGH." The Ohio Rule is diametrically opposed to other states and is economic

protectionism of the worst kind because it results “in the type of balkanization the [Commerce] Clause is primarily intended to prevent.” *C & A Carbone, Inc. v. Town of Clarkstown, N.Y.*, 511 U.S. 383, 406 (1994) (O’Connor, J., concurring).

**3. The Ohio Rule Discriminates Against Established Interstate Commerce.**

The Ohio Rule also “unjustifiably operates to isolate” Ohio’s economy “from the national common market.” *Carbone, Inc.*, 511 U.S. at 423 (O’Conner, J., concurring) and has the practical effect of discriminating against interstate commerce. The history of non-use claims including the FDA Guidance, other state regulation expressly permitting terms prohibited by the Ohio Rule, market developments primarily out-of-state, and the timing of the Ohio Rule coinciding with Ohio processors deciding to join the non-use claim market all must be considered by this Court. *Hunt v. Wash. State Apple Advertising Comm’n*, 432 U.S. 333, 350 (1977) (this court is “confronted with the task of effecting an accommodation of the competing national and local interests”). The Ohio Rule cannot survive this scrutiny.

In *Washington State Apple*, Washington apple growers (like Oregon dairy farmers who own Tillamook) developed a special grade for Washington grown apples that exceeded any existing federal or state grade of apples. North Carolina adopted a regulation that required that apples sold in North Carolina “bear no grade other than the applicable U.S. grade or standard.” *Id.* at 335 (*quoting* N.C. Gen. Stat. § 106-189.1 (1973)). The effect of the North Carolina regulation was that Washington apple growers would have been forced to comply with the North Carolina rule not only in North Carolina, but throughout the United States. Similar to dairy industry distribution practices, apples are sold throughout the United States in a distribution system using preprinted cartons that created the following Hobson’s choice for Washington Apple growers: (1) after the fact, obliterate special grade for sale of apples only in North

Carolina; (2) repack apples destined for North Carolina in special containers; or (3) discontinue the preprinted containers entirely.

Notwithstanding North Carolina's defense that its regulation protected North Carolina consumers against fraud and deception, a unanimous Supreme Court concluded that the provision was unconstitutional. First, the provision had the practical effect of both burdening interstate commerce and discriminating against out-of-state growers. Since Washington apple growers had an established grading process and North Carolina did not, Washington apples bore a greater burden than those grown in North Carolina. Similarly here, Ohio dairy farmers have not until now been asked to provide non-use Declarations by their processors. Yet, Ben & Jerry's, Tillamook and Shamrock among others have been selling product in Ohio with non-use claims for many years.

Second, the North Carolina statute had the practical effect of stripping away Washington's competitive advantage "it has earned for itself." *Washington State Apple*, 432 U.S. at 351. Third, the prohibition on Washington graded apples "has a leveling effect which insidiously operates to the advantage of local apple producers." *Id.* So too Oregon dairy farmers as competitors of Ohio dairy farmers for sale of manufactured dairy products will not only have increased costs imposed on them regarding any change in labels, dairy farmers in Oregon (Tillamook), Vermont (Ben & Jerry's) and Arizona (Shamrock) are also being asked to give up the competitive and economic advantages they have earned through non-use claims. This, too, has a leveling effect protecting Ohio dairy farmers from out-of-state competition from states that have expressly permitted terms prohibited by Ohio or have not acted in the non-use claim arena beyond the FDA Guidance.

Despite the Ohio Rule’s facial neutrality, this Court should conclude that the burdens fall more heavily on out-of-state dairy interests including dairy farmers from out-of-state producing directly, or through dairy processors to whom they sell, milk with non-use claims. As in *Washington State Apple*, there are ready and available tried and true means short of outright bans on certain speech and unduly restrictive requirements regarding location, size and color. See App. 0381-96. Having found no proof of confusion in the North Carolina market regarding Washington apple graded apples, the final sentences of the Supreme Court’s decision in *Washington State Apple* governs here: “Concededly, even in this latter instance, some potential for ‘confusion’ might persist. However, it is the type of ‘confusion’ that the national interest in the free flow of goods between the States demands be tolerated.” *Washington State Apple*, 432 U.S. at 354. The Ohio Rule does not tolerate or permit the free flow of goods in the national interest.

4. **Even if the Ohio Rule does not directly regulate or result in inconsistent regulation of interstate commerce, the Ohio Rule is unlawful as the burden imposed on commerce is clearly excessive to the local benefits.**

Even if this Court were to conclude that the Ohio Rule imposes only incidental as opposed to direct burdens on interstate commerce, it must nonetheless be declared invalid as the burden imposed on commerce is clearly excessive relative to the putative local benefits. *Pike*, 397 U.S. at 141. Thus, regulations can regulate even-handedly and may have incidental, as opposed to direct, impacts on interstate commerce and be found unlawful. At a minimum, the Ohio Rule falls into this category of regulation and should be struck down.

One of the principal questions to be asked in this context is whether the local interest could be promoted as well with a lesser impact on interstate activities. The answer here is a resounding “yes.” Ohio is not acting in a vacuum, but rather after fourteen years of developed

regulation and guidance on this subject with which it is inconsistent. The fact that no other state has found it necessary to impose this level of restriction, the fact that FDA in an explanation of its guidance has stated that the contextual language is not even always necessary, the fact that other states expressly permit “No rbGH” style claims even if accompanied by claim descriptor language “our farmers pledge no-use of”, all leaves no room for doubt that whatever the Ohio interest, “it could be promoted as well with a lesser impact on interstate activities.” *Pike*, 397 U.S. at 141.

This Court correctly concluded in an earlier case that this type of restriction found in the Ohio Rule is not lawful. *Lever Bros. Co. v. Maurer*, 712 F. Supp. 645 (S.D. Ohio 1989). In *Lever Brothers* a predecessor of the current Director barred the sale of a product called “DAIRYBROOK” which included the phrase “reduced calorie butter product” in smaller type. Butter was used on other descriptive labeling on the package and in advertising. Concluding that labeling the product as “butter” was misleading, that Director proposed barring the product.

This Court found that the Director’s actions unlawfully interfered with interstate commerce under *Pike*. While Dairybrook repeatedly used the term butter, it was in fact not 100% butter. Consumers were not misled said this Court by using the term butter. Ostensibly, the Court believed that consumers could be trusted to understand that the comparison to regular butter revealed that the product was not actually butter. The Court clearly concluded that Ohio consumers were more sophisticated than today’s Director finds. This Court cited many of the same concerns concerning impacts in interstate commerce as being burdens on interstate commerce and found that the rule there would deprive consumers of important information concerning the nature of Dairybrook. *Id.* at 653-54 (citing *Dean Foods Co. v. Wisc. Dep’t of Agric., Trade and Consumer Prot.*, 478 F. Supp. 224, 232 (W.D. Wis. 1979) (holding that

Wisconsin’s treatment of a labeled non-dairy beverage – banning it -- because it purported to be a substitute for milk was an unlawful interference with interstate commerce)). The Dean Foods Court’s discussion of the result and alternative is especially instructive here:

This can be described only as the most burdensome, gross, and radical of the alternative means available. The least burdensome is to permit the sale of Choco-Riffic, subject to those **minimal** requirements as to labeling, packaging, display or advertising reasonably necessary to assure that purchasers of average intelligence and prudence will be provided the opportunity to make a knowing choice.

*Dean Foods*, 478 F. Supp. at 232 (emphasis added).

The Director in the Ohio Rule in adopting requirements regarding font style, size, location and even color while also outright banning terms (outright ban is not minimal regulation) expressly permitted in other states has gone far past any rule reasonably necessary. The *Dean Foods* court provided a highly relevant concluding observation in criticism of the regulation struck down there: “defendants consider clear labeling an effective guide to purchasers’ choices, so long as the content of the label is forbidding enough to suit their purpose.” So, too, is the Ohio Rule forbidding and illegal.

## **II. PLAINTIFFS WILL SUFFER IRREPARABLE HARM**

“The loss of First Amendment freedoms, for even minimal periods of time, unquestionably constitutes irreparable injury.” *Tucker v. City of Fairfield*, 398 F.3d 457, 464 (6th Cir. 2005) (quoting *Elrod v. Burns*, 437 U.S. 347, 373 (1976)). Violations of the dormant commerce clause also constitute irreparable injury especially as demonstrated by the attached declarations since Plaintiff’s members will be required to make substantial changes to their label designs at significant cost (App. 0420-72) that cannot be recovered from the State under the 11<sup>th</sup> Amendment. *Edelman v. Jordan*, 415 U.S. 651, 663 (1974); see *Basicomputer v. Scott*, 973 F.2d

507, 511-12 (6th Cir. 1992) (as with Plaintiffs' members here loss of "customer goodwill and loss of fair competition (competitive losses) amounts to irreparable injury").

**III. PRELIMINARILY ENJOINING THE OHIO RULE WILL CAUSE OHIO NO HARM**

In the context of challenges to the constitutionality of laws, the Sixth Circuit has noted that "if the plaintiff shows a substantial likelihood that the challenged law is unconstitutional, no substantial harm to others can be said to inhere in its enjoinder." *Déjà vu of Nashville, Inc. v. Metro. Gov't of Nashville & Davidson County, Tenn.*, 274 F.3d 377, 400 (6th Cir. 2001).

**IV. PRELIMINARILY ENJOINING THE OHIO RULE WILL SERVE THE PUBLIC INTEREST**

Preventing ongoing violations of Constitutional rights is always in the public interest. *See, e.g. Chabad of S. Ohio & Congregation Lubavitch v. City of Cincinnati*, 363 F.3d 427, 436 (6th Cir. 2004).

**CONCLUSION**

In light of the foregoing, Plaintiff respectfully requests that this Court grant Plaintiff's motion for a preliminary injunction, or, in the alternative, set this matter down for an early hearing on the preliminary injunction, ordering that any discovery occur on an expedited basis, and for such other and further relief as to this Court may seem just, proper and equitable.

Respectfully submitted,

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