

reasons set forth below, the Renewed Motion for a Preliminary Injunction is DENIED.

II. Background

A.

The record before the Court includes testimony presented at the hearing conducted on July 31 and August 1, 1995, as well as a vast amount of evidence presented in the form of affidavits and exhibits. Upon review of the present record and the testimony presented, the Court makes the following findings. See Fed. R. Civ. P. 65(a)(2) ("[A]ny evidence received upon an application for a preliminary injunction which would be admissible upon the trial on the merits becomes part of the record on the trial and need not be repeated upon the trial.")

The plaintiffs, International Dairy Foods Association, Milk Industry Foundation, International Ice Cream Association, National Cheese Institute, Grocery Manufacturers of America, Inc. and the National Food Processors Association, are trade associations whose

¹(...continued)

would not pursue their claims under the Supremacy Clause for the purpose of seeking preliminary injunctive relief. Accordingly, in the instant ruling, the Court renders no opinion on the merits of any claim the plaintiffs may pursue under the Commerce Clause. See, e.g., Toy Manufacturers of America v. Blumenthal, 986 F.2d 615 (2d Cir. 1992); Grocery Manufacturers of America, Inc. v. Gerace, 755 F.2d 993, 999-1003 (2d Cir.), aff'd mem., 474 U.S. 801 (1985); Lever Brothers Co. v. Maurer, 712 F.Supp. 645, 647-52 (S.D. Ohio 1989); Animal Legal Defense Fund Boston, Inc. v. Provimi Veal Corp., 626 F.Supp. 278 (D. Mass.), aff'd mem., 802 F.2d 440 (1st Cir. 1986); Cosmetic, Toiletry and Fragrance Association, Inc. v. State of Minnesota, 440 F.Supp. 1216 (D. Minn. 1977), aff'd, 575 F.2d 1256 (8th Cir. 1978).

members process, manufacture, market and distribute dairy products in Vermont.

The defendants, Vermont Attorney General Jeffrey L. Amestoy and Vermont Commissioner of Agriculture, Food and Markets Leon Graves, are responsible for administration and enforcement of 6 V.S.A. § 2754.

Bovine somatotropin (hereinafter "BST") is a naturally occurring hormone in dairy cows. BST is a metabolic hormone that is released from the pituitary gland and which influences the amount of milk produced.

Recombinant bovine somatotropin ("rBST") is a version of BST produced in laboratories through recombinant DNA technology. rBST is injected into the bloodstream of a cow to supplement the amount of BST naturally produced. It stimulates lactation and boosts milk production in treated cows by increasing the efficiency with which supplemented cows convert feed into milk.

Before any animal drug can be distributed for commercial use in the United States, the drug sponsor must receive approval from the Food and Drug Administration (hereinafter "FDA"). See 21 U.S.C. § 360b. After extensive study, the FDA concluded that rBST has no appreciable effect on the composition of milk produced by treated cows, and that there are no human safety or health concerns associated with food products derived from cows treated with rBST. Moreover, rBST is orally inactive in cows and is biologically inactive in humans. Accordingly, there appears to be widespread

agreement that the use of rBST presents no increased health risk to consumers.

In fact, because there are no BST receptors in the mammary glands which facilitate the transfer of BST from the blood into milk, only trace levels of BST appear in milk, whether or not animals are administered rBST. Therefore, no difference in the level of BST produced by treated or untreated cows can be detected using current technology.

On November 5, 1993, the FDA approved the commercial use of rBST by farmers. In addition, the FDA determined that it would not mandate the labeling of food products derived from cows injected with rBST. Nevertheless, recognizing consumer interest in having information about rBST, the FDA determined that it would permit voluntary labeling of what may eventually prove to be a smaller number of products derived from untreated cows.

In describing "Appropriate Labeling Statements," the FDA interim guidelines explain:

Because of the presence of natural bST in milk, no milk is "bST-free," and a "bST-free" labeling statement would be false. Also, FDA is concerned that the term "rbST free" may imply a compositional difference between milk from treated and untreated cows rather than a difference in the way the milk is produced. Instead, the concept would better be formulated as "from cows not treated with rbST" or in some other similar ways. However, even such a statement, which asserts that rbST has not been used in the production of the subject milk, has the potential to be misunderstood by consumers. Without proper context, such statements could be misleading. Such unqualified statements may imply that milk from untreated cows is safer or of higher quality than milk from treated cows. Such an implication would be false and misleading.

FDA believes such misleading implications could best be avoided by the use of accompanying information that

puts the statement in proper context. Proper context could be achieved in a number of different ways. For example, accompanying the statement "from cows not treated with rbST" with the statement that "No significant difference has been shown between milk derived from rbST-treated and non-rbST-treated cows" would put the claim in proper context.

59 Fed. Reg. at 6280.

The defendants assert that the FDA approved the use of rbST, even though the Agency recognized a slight increase in the incidence of mastitis in injected cows. In addition, the defendants have demonstrated the existence of consumer concern about the use of rbST. However, the defendants admit that "[c]onsumers cannot distinguish rbST-derived milk from traditionally-produced milk" because "[t]here is no sensory difference between the two products." Defendants' Proposed Findings of Fact (paper 63) at para. 67. Moreover, they admit that "[m]ilk from cows injected with rbST does not taste better or stay fresher longer; it is neither more nutritious nor, under current market conditions, less expensive." Id. at para. 68.

On April 13, 1994, Vermont Governor Howard Dean signed into law 6 V.S.A. § 2754. Section 2754 requires the labeling of milk and milk products offered for retail sale in Vermont and made with milk from cows treated with rbST. In pertinent part, §2754(c) provides: "If rbST has been used in the production of milk or a milk product for retail sale in this state, the retail milk or milk product shall be labeled as such."

The State does not claim that health or safety concerns prompted the passage of the Vermont Labeling Law. Instead, it

bases its justification for mandatory labeling not otherwise required by the FDA on strong consumer interest and the public's "right to know" whether a particular dairy product contains milk produced by cows given rBST.

Section 2754(d) authorizes Vermont's Commissioner of Agriculture to adopt rules to implement the labeling law. On June 14, 1995, the Commissioner of Agriculture filed implementation rules. The labeling requirement takes effect on September 12, 1995, with certain disclosure requirements effective on August 12, 1995. The law is currently due to sunset on June 30, 1997, so that the legislature can reexamine and evaluate the labeling scheme.

The rules allow for shelf-labeling of milk derived from rBST-treated cows through the use of blue shelf labels, blue stickers, or explanatory signs placed in retail establishments. It is anticipated that larger supermarkets will use a combination of shelf labels and blue stickers. The shelf labels are transparent blue overlays designed to snap into place over the existing unit price information. The blue stickers are round blue dots which may be placed directly on items that are physically difficult to locate or are sold in the deli department. These labels and sticker contain no text; however, they refer to a sign which the State will provide at no cost to retailers.

The sign, which will be placed at each appropriate dairy or freezer case, explains:

rBST INFORMATION

THE PRODUCTS IN THIS CASE THAT CONTAIN OR MAY CONTAIN MILK FROM rBST-TREATED COWS EITHER (1) STATE ON THE

PACKAGE THAT rBST HAS BEEN OR MAY HAVE BEEN USED, OR (2)
 ARE IDENTIFIED BY A BLUE SHELF LABEL LIKE THIS
 [sample label]

OR (3) A BLUE STICKER ON THE PACKAGE LIKE THIS.
 [sample dot]

The United States Food and Drug Administration has determined that there is no significant difference between milk from treated and untreated cows. It is the law of Vermont that products made from the milk of rBST-treated cows be labeled to help consumers make informed shopping decisions. (6 V.S.A. Section 2754) [emphasis in original].

Plaintiff's Exhibit 9.

Thus, while tracking some of the FDA's suggested language, the Vermont label is actually the converse of the labeling suggested by the FDA in its interim guidelines: It provides notification that a product is derived from a rBST-treated cow. The State anticipates that most smaller retailers, convenience stores and gifts shops which sell few dairy products will use explanatory signs. These signs contain the same language as the "rBST INFORMATION" signs, except that they provide space to list products.

Therefore, Vermont's labeling law does not require any manufacturer to change any product container to comply. The State believes that this labeling system will communicate accurate product information to consumers and reduce uncertainty regarding the use and effect of rBST. On the other hand, the plaintiffs contend that, in effect, the label constitutes a warning because it serves to disseminate information which the FDA has not required.²

² Because it is not dispositive of any issue presently under consideration, the Court makes no finding on the issue of whether Vermont's label constitutes a "warning."

Vermont's regulations also make it the manufacturer's responsibility to ensure proper labeling of their milk and milk products. The plaintiffs estimate the cost of routine inspection of retail establishments may exceed \$750,000. The defendants expert testified that this expense could be substantially reduced in a number of ways, including contracting with the retailers themselves to perform inspections. Under present conditions, it appears that any additional cost to manufacturers which results from participation in Vermont's mandatory labeling scheme could be recouped by a minimal increase in the cost of milk.

B.

The parties do not dispute that the use of rBST in the production of milk has resulted in a great deal of consumer interest. They have presented a plethora of survey information and testimony in which experts speculate as to the effect of the use of rBST and of the Vermont Labeling Law on Vermont consumers.

The State's surveys show that Vermont consumers have a high awareness of issues surrounding the use of rBST and are in favor of the type of labeling required by the Vermont Labeling Statute. Apparently, a majority of Vermonters do not want to purchase milk products derived from rBST-treated cows. Their reasons for not wanting to purchase such products include: (1) They consider the use of a genetically-engineered hormone in the production unnatural; (2) they believe that use of the hormone will result in increased milk production and lower milk prices, thereby hurting

small dairy farmers; (3) they believe that use of rBST is harmful to cows and potentially harmful to humans; and, (4) they feel that there is a lack of knowledge regarding the long-term effects of rBST.

By contrast, the plaintiffs' surveys suggest that the statement required under the Vermont Labeling Law acts as a warning by raising consumer concerns about the safety and wholesomeness of milk. According to plaintiffs' data, 73% of consumers prefer to purchase unlabeled milk and milk products. Significantly, none of the parties' survey information takes into account the impact that differences in price may have on consumers' preference of unlabeled over labeled items.

III. Discussion

A. Irreparable Harm

A party seeking injunctive relief ordinarily must show: (a) It will suffer irreparable harm in the absence of an injunction; and (b) either (i) a likelihood of success on the merits or (ii) sufficiently serious questions going to the merits to make them a fair ground for litigation and a balance of hardships tipping decidedly in the movant's favor. See, e.g., Polymer Technology Corp. v. Mimran, 37 F.3d 74, 77-78 (2d Cir. 1994); Jackson Dairy, Inc. v. H.P. Hood & Sons, Inc., 596 F.2d 70, 72 (1979) (per curiam). The plaintiffs have pursued their claim for injunctive relief solely by attempting to demonstrate irreparable harm and a likelihood of success on the merits.

A showing of irreparable harm is a prerequisite to the granting of an injunction. See, e.g., Grand Light and Supply Co., Inc. v. Honeywell, Inc., 80 F.R.D. 699, 702 (D. Conn. 1978).

"Irreparable harm is an injury that is not remote or speculative but actual and imminent, and for which a monetary award cannot be adequate compensation." Tom Doherty Associates, Inc. d/b/a Tor Books v. Saban Entertainment, Inc., Docket No. 94-9310, slip op. at 5573 (2d Cir. July 12, 1995) (citation and quotation omitted); Here, the plaintiffs have not demonstrated they will suffer irreparable harm as a result of compliance with the Vermont Labeling Law and accompanying regulations.

Based on the evidence presently before the Court, it is speculative as to whether any of the plaintiffs will suffer a loss as a result of Vermont's Labeling Law. While some consumers may be less inclined to purchase "labeled" products, others may be more inclined to buy milk from cows treated with rBST after reading the label's explanation of the FDA's position.

Moreover, the Court is unconvinced that the plaintiffs will be unable to recoup additional expenses connected with compliance. The evidence suggests the use of rBST will result in lower milk prices; this fact may offset additional costs the plaintiffs may incur as a result of labeling. In any event, at least one expert testified the cost of labeling and inspection of retailers can be recouped by a less than one cent per gallon increase in the price of a gallon of milk.

The plaintiffs also argue they will suffer irreparable harm because the Eleventh Amendment bars retrospective monetary relief against the State. "[T]he Eleventh Amendment bar simply indicates irreparability, but does not, in itself, establish harm." Kansas Health Care Association, Inc. v. Kansas Department of Social and Rehabilitation Services, 31 F.3d 1536, 1543 (10th Cir. 1994).

Moreover,

[w]ithout intending to disparage the importance of such an injury, we observe that all that is lost is profits. Any time a corporation complies with a government regulation that requires corporation action, it spends money and loses profits; yet it could hardly be contended that proof of such an injury, alone, would satisfy the requisite for a preliminary injunction.

A.O. Smith Corp. v. FTC, 530 F.2d 515, 527 (3d Cir. 1976).

The plaintiffs do not contend that any of their members will be put out of business, or will suffer an egregious loss of business and goodwill. Plaintiffs have asserted the possibility that their members may withdraw from selling their products in Vermont. Admittedly, Vermont is a very small market for most of the plaintiffs. Whether any manufacturers would withdraw from Vermont is questionable and, in any event, would be the result of a unilateral decision to leave rather than comply with the labeling statute. In short, even assuming they have shown irreparability, the defendants have not demonstrated a probability of actual and imminent harm as a result of compliance. See Jackson Dairy, 596 F.2d at 72.

Finally, the plaintiffs argue that any loss of First Amendment freedoms, even for a minimal period of time, constitutes

irreparable injury. See, e.g., Paulsen v. County of Nassau, 925 F.2d 65, 68 (2d Cir. 1991). However, "the assertion of First Amendment rights does not automatically require a finding of irreparable injury, thus entitling a plaintiff to a preliminary injunction if he shows a likelihood of success on the merits." Hohe v. Casey, 868 F.2d 69, 72-73 (3d Cir.), cert. denied, 493 U.S. 848 (1989).

Ordinarily, it is the purposeful suppression of speech which constitutes irreparable harm. See Goldie's Bookstore, Inc. v. Superior Court, 739 F.2d 446, 472 (9th Cir. 1984). Compliance with the Vermont Labeling Law does not prohibit the plaintiffs from disseminating a message. Instead, it requires the plaintiffs to truthfully disclose the method used in producing their product. Under these circumstances, the Court does not find that the plaintiffs' assertion of a First Amendment violation leads ineluctably to the conclusion that they will suffer irreparable harm.

B. Likelihood of Success on the Merits

1. Commerce Clause

Even assuming the plaintiffs could demonstrate potential irreparable harm, they have not demonstrated a likelihood of success on the merits. The Commerce Clause grants to Congress the power "[t]o regulate Commerce . . . among the several States." U.S. Const., Art. 1, § 8. It also limits the power of states to erect barriers against interstate trade. See Lewis v. B.T.

Investment Managers, Inc., 447 U.S. 27, 35 (1980). However, "[i]n the absence of conflicting federal legislation, the States retain authority under their general police powers to regulate matters of 'legitimate local concern,' even though interstate commerce may be affected." Id. at 236. As the Supreme Court has explained:

Where the statute regulates evenhandedly to effectuate a legitimate local public interest, and its effects on interstate commerce are only incidental, it will be upheld unless the burden imposed on such commerce is clearly excessive in relation to the putative local benefits If a legitimate local purpose is found, then the question becomes one of degree. And the extent of the burden that will be tolerated will of course depend on the nature of the local interest involved, and on whether it could be promoted as well with a lesser impact on interstate activities.

Pike v. Bruce Church, Inc., 397 U.S. 137, 142 (1970) (citation omitted); accord Lever Brothers v. Maurer, 712 F.Supp. at 653.

The Vermont Labelling Law applies to both in-state and out-of-state producers. Contrary to the plaintiffs' assertions, the cost of compliance seems minimal. The law does not prohibit the use of rBST. It does not require any manufacturer to change its method of milk collection. Rather, it simply requires manufacturers to disclose whether their milk sources may have used rBST.

The local interest which the Vermont statute is designed to protect is a legitimate one. "States have traditionally acted to protect consumers by regulating foods produced and/or marketed within their borders." Grocery Manufacturers v. Gerace, 755 F.2d at 1003. The instant law is specifically designed to provide the type of information in which Vermont consumers have demonstrated an overwhelming interest. Cf. Hunt v. Washington Apple Advertising

Commission, 432 U.S. 333, 353 (1977) (Statute invalidated where it did "little to protect consumers against the problems it was designed to eliminate.")

Vermont takes no position on whether rBST is beneficial or detrimental. However, Vermont has determined that its consumers want to know whether rBST has been used in the production of their milk and milk products. The Vermont label is designed to give consumers that information. In addition, given the doubts some consumers have regarding the safety of rBST, the label may serve to allay some fears. Furthermore, the record shows, aside from health concerns, some disagree on the effects of the use of rBST on cows and farmers. Vermont has determined that its citizens are entitled to have information which assists them in making purchases consistent with their beliefs on the appropriateness of rBST use. Cf. FDA's Interim Guidance on Voluntary Labeling (Plaintiff's Exhibit 8), 59 Fed. Reg. at 6280 ("Proper context could also be achieved by conveying the firm's reasons (other than safety or quality) for choosing not to use milk from cows treated with rBST")

Even if a statute does not patently regulate or discriminate against interstate commerce, it still may violate the Commerce Clause if its effect is to favor in-state economic interests over out-of-state interests. See, e.g., Brown-Forman Distillers Corp. v. New York State Liquor Authority, 476 U.S. 573, 579 (1986). The instant record does not support the plaintiffs' speculation that nearly all in-state producers will benefit from the labeling law

and all out-of-state producers will be harmed. Cf. Dixie Dairy Co. v. City of Chicago, 538 F.2d 1303, 1310 (7th Cir. 1976), cert. denied, 429 U.S. 1001 (1976) (Under city inspection ordinance, almost no out-of-state milk processors obtained permits.) Both in-state and out-of-state producers have chosen to refrain from using rBST. Depending on which statistics one accepts, nationwide only about one-third of lactating cows presently are being treated with rBST. The evidence demonstrates no clear distinction between an in-state manufacturer's ability to secure milk or sell dairy products which are not derived from rBST-treated cows and that of an out-of-state manufacturer. The record also contains no persuasive support for plaintiffs' assumption that the Vermont Labeling Law only benefits local dairies. The plaintiffs seem to believe that most Vermont farmers will choose not to use rBST. However, the Court finds no reason to conclude that the percentage of Vermont farmers using rBST does not or will not eventually reflect national statistics.

In compiling their statistics, all parties assume the price of labeled milk will be the same as unlabeled milk. However, it is just as probable that farms which use rBST will produce more milk, thereby driving down the cost of labeled milk and making that lower priced milk more desirable to consumers. Nevertheless, plaintiffs conclude that, given the choice, consumers will always choose to purchase unlabeled milk. At this time, one can only speculate as to whether any in-state producer, whether it uses rBST or not, will derive a benefit over a similarly-situated out-of state producer.

In short, the plaintiffs have not carried their burden of demonstrating the Vermont's Labeling Law impermissibly favors in-state economic interests. Cf. City of Philadelphia v. New Jersey, 437 U.S. 617 (1978) (invalidating statute prohibiting importation of waste collected outside the state).

2. First Amendment

The Supreme Court has recognized a "common sense" distinction between speech relating to a commercial transaction, which is subject to government regulation, and other types of speech. See Bolger v. Youngs Drug Products Corp., 463 U.S. 60, 64 (1983). Because the use of rBST is currently the subject of public debate, the plaintiffs assert that this case does not involve the type of commercial speech which is subject to less protection than other constitutionally-safeguarded forms of expression. See Zauderer v. Office of Disciplinary Counsel, 471 U.S. 626, 637 (1985) ("There is no longer any room to doubt that what has come to be known as 'commercial speech' is entitled to protection of the First Amendment, albeit to protection somewhat less extensive than that afforded 'noncommercial speech'.")

The Court rejects this argument and finds that, despite the current public debate, the labels required by 6 V.S.A. § 2754 relate to commercial transactions involving specific products and are therefore commercial speech. See Rubin v. Coors Brewing Co., ___ U.S. ___, 115 S.Ct. 1585 (1995); see also Central Hudson Gas & Electric v. Public Service Commission, 447 U.S. 557, 562-63 n. 5

(1980) (Mere fact that products may be tied to public concerns does not transform speech into noncommercial speech.)

The First Amendment protects both the freedom to speak and the freedom not to speak. See Harper & Row v. Nation Enterprises, 471 U.S. 539, 559 (1985). Nevertheless, "[t]he First Amendment . . . does not prohibit the State from insuring that the stream of commercial information flow cleanly as well as freely." Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, 425 U.S. 748, 771-72 (1976).

Generally, "[c]ommercial speech that is not false or deceptive and does not concern unlawful activities . . . may be restricted only in the service of a substantial governmental interest, and only through means that directly advance that interest." Zauderer, 471 U.S. at 638. Vermont has a substantial interest in informing consumers of the use of rBST in the production of milk and dairy products sold in the state. The Vermont labels disseminate truthful commercial information, and, contrary to the plaintiffs' assertions, do not necessarily disparage dairy products. See id. at 646.

By implementing labeling which does not require manufacturers to change their individual production methods or product packaging, the State has closely tailored the law to the interest it seeks to advance. The disclosures that Vermont requires are accurate and, when viewed in conjunction with the label itself, do not force manufacturers to endorse either the use or non-use of rBST. Finally, plaintiffs have not suggested any more limited way for the

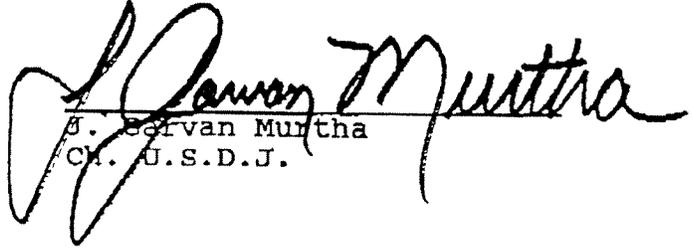
State to effectively inform consumers on whether rBST has been used in the production of products for sale. See Central Hudson, 447 U.S. at 566. Accordingly, the plaintiffs have not met their burden of demonstrating a likelihood of prevailing on their First Amendment claims. See generally Association of National Advertisers, Inc. v. Lungren, 44 F.3d 726 (9th Cir. 1994).

IV. Conclusion

The plaintiffs' Renewed Motion for Preliminary Injunction is DENIED.

SO ORDERED.

Dated at Brattleboro, Vermont, this 9TH day of August, 1995.


J. Servan Murtha
Ch. U.S.D.J.