Regulating the Sale of Products from Cows Treated with Recombinant Bovine Somatotropin

by Terence J. Centner and Kyle W. Lathrop

The Executive Office of the President claims that recombinant bovine somatotropin (rbST) is the most examined animal drug ever approved for use in the United States. More than 1,500 articles address issues concerning rbST and more than 20,000 animals have been used for rbST research. Although 10 February 1996 marked the second anniversary of commercial availability of rbST (Monsanto Company's Posilac®), a considerable number of farmers, consumers, and dairy marketing organizations continue to express reservations. Since federal approval of rbST, objections to this genetically engineered product have shifted to marketing strategies, administrative rules, and judicial challenges. In some areas, consumer reactions led retailers to market "rbST-free" milk and milk products. Thirteen states have adopted state-specific regulations concerning the labeling of dairy products. Conversely, some states prevent disclosure of any information regarding the use of rbST.

The federal government has also provided guidelines through its "Interim Guidance on the Voluntary Labeling of Milk and Milk Products from Cows that Have Not Been Treated with Recombinant Bovine Somatotropin." In this article we assess the Interim Guidance and then discuss our survey findings from states about rbST labeling. States' administrative rules governing the labeling of non-rbST-derived products show that some of the specific requirements by individual states may create problems for interstate marketing. Potential institutional developments are addressed in the final part.

Federal regulatory response

Since rbST is an animal drug rather than a food additive, the Food and Drug Administration (FDA) served as the lead agency in the federal approval process. Approval was based on scientific evidence that found rbST to be effective and safe for animals, milk and food products from treated animals to be safe for human consumption, and the manufacture of the drug to be safe for the environment. The FDA published its Interim Guidance regarding the use of rbST labeling to prevent false or misleading claims and supplement the primary enforcement activities of interested states.

Under section 403(a) of the Food, Drug and Cosmetic Act (FDCA), a food is misbranded if statements on its label or in its labeling are false or misleading. Misbranding also precludes information that without further details might be expected to mislead. Because all milk contains natural bST, truthful labels cannot claim that milk is "bST free." Labels can state that the milk comes "from cows not treated with rbST," but the FDA suggests that such a statement be used only if placed in a proper context with an accompanying notation that "No significant difference has been shown between milk derived from rbST-treated and non-rbST-treated cows."

In *Stauber v. Shalala*, consumers challenged the FDA's approval of Posilac and the agency's decision not to require labeling of rbST-derived products on two major grounds. The first argument alleged that the FDA's approval was arbitrary and capricious and in violation of federal administrative law, based on evidence that was not presented to the FDA during its review of the Posilac application, including higher levels of an insulin-like growth factor. Under established legal principles, the court found that the FDA had sufficient evidence for its decision.

The second argument advanced by the *Stauber* plaintiffs involved mandatory labeling of rbST-derived products based on the FDCA provisions cited in the Interim Guidance. The plaintiffs contended that rbST-derived milk differs in sufficiently significant ways from milk produced without rbST to constitute material facts warranting a label, the initial distinction being organoleptic traits. The court acknowledged that organoleptic differences in a food product could necessitate labeling, but the plaintiffs were unable to show that any discernable differences between rbST- and non-rbST-derived milk

exist. Thus, the court found no difference that warranted labeling.

State responses to rbST label information

With the adoption of the Interim Guidance, states have been advised to present the regulations to their respective dairy industries and offer further guidance to avoid violations of federal law. States have taken different approaches, and proposals addressing rbST labeling continue to be considered by state legislative committees. In the absence of a preemptive federal labeling law, producers must comply with labeling rules in the state where the milk is produced and sellers must comply with the requirements of the state where the milk product is sold. Products sold in more than a single state will need to meet the requirements of each state.

The response of a majority of states has been to simply follow federal law as set forth in the FDA's Interim Guidance (Alabama, Arkansas, Colorado, Delaware, Florida, Georgia, Hawaii, Idaho, Iowa, Kansas, Kentucky, Louisiana, Maryland, Mississippi, Montana, Nebraska, New Hampshire, New Jersey, New York, New Mexico, North Dakota, Oklahoma, Oregon, Rhode Island, South Carolina, South Dakota, Tennessee, Virginia, Washington, and West Virginia).

Through informal agency action, three states preclude dairy products sold within their jurisdictions from being labeled with information concerning rbST. The Nevada State Health Division concluded that "any labeling of milk, milk products, or frozen desserts will *not* be allowed." Illinois and Texas adopted policy statements concluding that state misbranding law precludes label claims regarding milk and milk products from non-rbST-treated cows.

Nine states have issued additional guidelines regarding the advisory guidance on labeling. Wisconsin and Minnesota passed state laws that provide for the development of rules for voluntary rbST labeling of dairy products, and Vermont enacted mandatory labeling regulations. State agencies in North Carolina, Michigan, Missouri, Ohio, Pennsylvania, and Utah prescribed mandatory rules or directives on voluntary labeling. Three general requirements of these state labeling requirements may be expected to affect milk producers and dealers. First, labels generally must be submitted to the requisite state agency for review prior to use. Second, the agency requirements preclude false or misleading advertising as defined by state law. Third, if labeling is used, reasonable substantiation that milk is from cows not treated with rbST may be required to avoid deceptive labeling.

Simply comparing the different labeling requirements of Minnesota and Wisconsin, two similarly situated states, reveals a potential problem of state-specific regulation. Dairy products from untreated cows labeled pursuant to the minimal requirements of Minnesota could not be sold in Wisconsin because the label would not carry the appropriate qualifying statement that there is no significant difference between milk derived from rbST treated cows and non-rbST-treated cows. Moreover, the Wisconsin labeling law permits the sale of rbST-free dairy products from other states only if the other state has a comparable law to Wisconsin's labeling law. Because Minnesota's law does not require the same contextual information concerning rbST, a court could deem that it was not comparable.

Vermont's mandatory labeling

Vermont is the only state at this time that has passed a statute that mandates the labeling of milk and milk products from rbST-treated cows. The rules apply only to milk, cream, cheese, ice cream, yogurt, sour cream, half and half, ice milk, and butter. Mandatory labeling legislation has been proposed in several other states, and the enactment of such legislation remains a goal of a significant number of consumers, farmers, and farm organizations.

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Wording of the Vermont statute commands that if a processor cannot prove that rbST has not been used to produce milk in dairy products being sold, then the product must be labeled. Under the implementing regulations, processors and distributors have three options for labeling milk and milk products in Vermont: labeling the package or container, shelf labels and a blue sticker on the product, or display-case labels.

The Vermont mandatory labeling statute has been challenged in the International Dairy Foods Association (IDFA) case by several trade associations seeking injunctive relief due to a violation of either of two independent constitutional provisions. The first challenge involves the infringement of commercial speech in violation of the First Amendment's free speech protections. The IDFA plaintiffs argue that, by requiring labels on milk and milk products derived from milk from rbST-treated cows, the statute disparages the product

without serving an adequate state interest. The second constitutional challenge involves violation of the Commerce Clause by the Vermont regulations. The IDFA plaintiffs contend that the regulations discriminate against interstate commerce and have the effect of favoring in-state economic interests.

In ordering the appropriate injunction, the Second Circuit Court of Appeals found irreparable harm caused by the Vermont statute due to infringement on the dairy manufacturers' constitutional right not to speak. The circuit court also found insufficient state interests to justify compromising protected constitutional rights. Therefore, the case has been remanded for an injunction. However, absent a trial on the merits, these constitutional issues may still be scrutinized by the judiciary.

Substantiation of rbST claims

The FDA addressed the issue of substantiating claims that milk and milk products are derived from untreated cows in the Interim Guidance. The only means of guaranteeing claims that milk comes from untreated cows is through recordkeeping and affidavits by dairy farmers and milk processors. With the exception of Pennsylvania, states with specific labeling provisions require the verification of the physical separation of all milk from cows treated with rbST from the farm to the package. In Michigan, North Carolina, and Utah, a third-party certification program is required. A potential problem with a certification process is the additional cost it may add to non-rbST-derived milk and milk products. The costs of paying for a certification program together with lower yields from foregoing the use of rbST means that milk and milk products derived from untreated cows are expected to be more expensive. Conversely, labels with rbST information provide firms with opportunities to develop niche marketing strategies.

Potential institutional developments

Governments in the United States have long regulated the sale of milk and milk products, with strict standards for human safety and well-being. Although the major response to the approval of Posilac in some areas has been market-driven segmentation of rbST-derived and non-rbST-derived milk and milk products, subsequent state regulations are creating new angles for this contentious issue. The IDFA lawsuit, filed just seven days after issuance of proposed state labeling rules in Vermont, discloses an industry readiness and willingness to resist state regulation of rbST labeling. The diverse state-by-state regulatory approach raises major considerations about potential legal challenges.

If the Vermont mandatory labeling statute survives the constitutional challenge, will other states decide to legislate mandatory labeling? Such legislation is attractive to politicians who desire to be seen as favoring family farms and may garner support of some special interest groups. Moreover, voters may see such legislation as beneficial to in-state producers.

Given the circuit court's decision based on the First Amendment in the IDFA case, how safe from legal challenge are other objectionable state rbST-labeling provisions? The finding that Vermont's mandatory labeling probably violates the free speech protections afforded by the First Amendment suggests that a state regulation precluding labeling could suffer the same infirmity.

Moreover, it is still possible that the Vermont mandatory labeling legislation or a state substantiation requirement accompanying voluntary labeling may offend the Commerce Clause. The major issue is whether a state with a third-party certification system can exclude out-of-state milk labeled as being derived from untreated cows when verification was simply based on affidavits. For example, North Carolina requires rbST-label claims to be supported by affidavits from individual farmers and processors through a third-party certification program. Can milk and milk products labeled as being derived from untreated cows from a neighboring state, certified only by producer affidavits, be excluded from North Carolina markets because they do not meet the third-party certification requirement? If North Carolina decides to exclude products that do not meet this requirement, so that out-of-state producers cannot market rbST-labeled products in North Carolina that were produced under less stringent certification requirements, does it constitute sufficient interference with interstate commerce to justify judicial relief for the excluded vendor? ◘

■ For more information

Centner, T.J. "State Regulation of Products from Cows Treated with Recombinant Bovine Somatotropin." *Agricultural Law Update*, July 1995, pp. 4–6.

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Thompson, P.B. "Food Labels and the Ethics of Consent." *Choices*, First Quarter 1996, pp. 11–13.

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