

## **SITUATION ANALYSIS: FIRST YEAR OF BOVINE SOMATOTROPIN AVAILABILITY TO THE DAIRY PRODUCER - AN OPINION OF ONE**

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### **Introduction**

By a process unknown to me, I was invited by Barney Harris to give this presentation. As you know, I am from the "other company", one that so far has failed to achieve Food and Drug Administration-Center for Veterinary Medicine (CVM) approval to market bovine somatotropin in the US. I believe Barney was interested in having someone involved in bovine somatotropin research, but not from Monsanto, the marketing company, make this presentation.

Bovine somatotropin (BST) is a product of biotechnology; the BST gene was isolated from the bovine and cloned into *E. coli*. *E. coli* express BST in fermentation and the BST is then extracted and purified. The "BST companies" (Monsanto, Eli Lilly, American Cyanamid, and The Upjohn Company) interpreted in the early 1980s that BST approximated a "perfect product" for the dairy industry - natural, no residue, enhancement of the efficiency of milk production, no capital investment required, no dairy cow management system changes. We did not predict the ensuing controversy associated with a biotechnology product and "messing with milk." I believe that bovine somatotropin holds tremendous promise for enhancing efficiency of milk production in the 21st century. BST is simply another opportunity for the dairy cow manager to produce milk more efficiently. Additionally, I believe unequivocally in the food value and the contribution of dairy products to the diet of people worldwide.

### **Bovine Somatotropin Approved by FDA-CVM**

The first and only bovine somatotropin approved in the US is produced by Monsanto under the name Posilac. Posilac was approved by FDA-CVM on 5 November 1993. Posilac's generic name is Sometribove.

As part of the CVM approval of Posilac to increase milk yield of lactating dairy cows in the US, CVM concluded that there was no basis under the statute to require special labeling of dairy products derived from cows receiving Posilac. However, FDA identified that companies could voluntarily label their products provided the information was truthful and not misleading. On 6 and 7 May 1993, the FDA Veterinary Medicine Advisory Committee (VMAC) and Food Advisory Committee (FAC) held a public hearing on the question of whether or not dairy products derived from cows receiving BST needed a label. I was a testifier at that hearing along with Jeremy Rifkin, an aide to Senator Russell Feingold, Congressman Bernard Sanders, Congressman Charles Stenholm, Dr. Michael Hanson, and 44 additional individuals. The advisory committee members' statements at the time led me to interpret no label would be required. A

Federal Register Notice (Volume 59, No. 28, Thursday, February 10, 1994) identified guidelines for labelling ("Interim Guidance on the Voluntary Labeling of Milk in Milk Products from Cows that have not been treated with recombinant bovine somatotropin"). There is no milk safety or regulatory basis for a need for labels for dairy products derived from cows receiving Posilac.

As part of the Monsanto approval on 5 November 1993, CVM identified several restrictions:

1. A two-year tracking system of the milk production and residues in 21 top dairy states to periodically compare the amount of milk discarded after Posilac introduction with the amount discarded prior to approval;
2. A 12 month comparison of the proportion of milk discarded due to positive drug tests between Posilac and untreated herds;
3. A reporting system to monitor all Posilac use and follow-up on all compounds;
4. Monitoring of use of Posilac in 24 commercial dairy herds for mastitis, animal drug use, and the resulting loss of milk.

The CVM approval identified that adequate safeguards are in place to prevent unsafe levels of antibiotic residues from entering the milk supply. The CVM concluded that BST poses no risk to human health. The CVM concluded that there was virtually no difference in milk from cows receiving BST and cows not receiving BST. The presence of no negative post-approval action by CVM against Posilac in 1994 leads me to interpret that the post-approval data accumulated to date support Posilac as being safe and effective as approved by CVM.

In addition to the above restrictions on the approval of Posilac, Senator Feingold (Wisconsin) was successful in implementing into the 1993 Budget Reconciliation Bill a requirement for an economic analysis of the impact of Posilac; this activity required 90 days from the date of approval to market introduction. Therefore, Monsanto was not allowed to market Posilac until 3 February 1994. The White House Office of Management and Budget issued a report in January 1994 that stated: 1) there was no evidence that BST poses a health threat to humans or animals; 2) the National economic impact of BST usage was expected to be positive; 3) no significant reduction was expected for the demand for milk and dairy products; and 4) consumers would pay less for milk or that milk price would increase at a lower rate as a result of the use of BST. If I understand correctly, Monsanto initiated the marketing of Posilac on 4 February 1994.

### **Success of Posilac in the Marketplace**

The information herein is derived from public documents. I have no information gained directly from Monsanto. This synopsis is based on the first six months of

marketing Posilac in the US. There appears to be a consistent reporting of approximately 10,000 farms using Posilac, representing more than 800,000 of the 9.5 million dairy cow population, and a use of approximately 6.8 million doses. As I read various sources of literature, talk with dairy extension agents and talk with dairy scientists, I interpret there are at least 10-15% of the lactating dairy animals in the US receiving Posilac. With Lauderdale's simplistic arithmetic, I assure you that as a member of The Upjohn Company, I drool over the first year Posilac market penetration.

I interpret the success of Monsanto is predicated on two important factors: (1) BST increases milk yield in lactating dairy cows (IT WORKS!) and, for Posilac, this translates to an average of 10 lbs/per cow per day; (2) the effectiveness of Monsanto's marketing program. Monsanto markets Posilac directly to farmers. Within days of ordering Posilac the customer receives a telephone call from a Monsanto representative asking if the customer has any questions or concerns. Both telephone contacts and personal contacts continue with the customer on a regular basis. If a customer expresses concern, this concern is relayed to a field sales staff who visits the dairy and, if necessary, contacts a Monsanto technical services representative for follow-up. All customers receive follow-up telephone calls regardless of whether or not they have concerns. During the first six months of Posilac's use, Monsanto initiated 21,115 telephone calls and received 56,947 telephone calls.

An independent research firm reported that 90% of the producers using Posilac were satisfied with the product, that 97.3% of the producers recognized an increase in milk production on an average of 10 lbs of milk daily for each animal, and only 0.4% expressed concerns regarding animal health. The consistency of the published information indicating the excellence of the Monsanto marketing program sends a message to the Animal Health industry that a new and important player has set new standards of quality of service for the Animal Health industry.

Even in Wisconsin, a state with a strong recent history of anti-BST activities, over 3,000 dairy producers (about 10% of dairy herds in Wisconsin) were estimated to be using Posilac by May of 1994. "Rumors" from other states suggest that, in states where the dairy producers represent an older population, a higher percentage of producers are using Posilac on more cows in an attempt to increase production without increasing capital investment for facilities.

### **Efficacy and Safety**

The CVM approval of Posilac was based on a greater quantity and quality of data and the data were evaluated with greater intensity than for any Animal Health product approved in the US. The data support that Posilac increases milk yield, is not debilitating to cow health (in-so-far as the dairy manager feeds the cows to body condition and milk yield), and the milk is safe for human consumption. The dairy industry literature (Hoard's Dairymen, Extension Bulletins, Dairy Herd Management, and numerous other sources) have published numerous articles, interviews and editorials regarding the safety and effectiveness of BST in general and Posilac in particular. I

believe anyone managing cows can use BST (Posilac) to bring individual cow milk yield to the level of the best cows in that herd. In order to increase milk yield of the highest producing cows in the herd, the manager must be able to feed and manage to the higher milk production. The ability of the dairy cow manager to feed to the highest production of that herd establishes the upper limit of use of BST on that herd.

The views of the "small dairy", "large dairy", breeder, consumer, processor, marketer of dairy products, advocates for both positive and negative, political, legal, pharmaceutical, etc. have all been aired extensively in both the printed media and on radio and television. Review of this information can lead to conclusions that BST is more advantageous for the "small dairy", will drive "small dairies" out of business, is more advantageous to "large dairies", that BST is positive and negative for bull proof and bull selection. The controversy surrounding the effectiveness and safety of BST did not go away. The controversy continues to be dredged up, primarily, in my opinion, by the anti-biotechnology and anti-production enhancement groups in the US rather than the data on safety and effectiveness - BST (Posilac) is safe and effective for increasing milk yield of lactating dairy cows.

Strategy not size (or BST) will keep dairy producers competitive. Posilac (BST) can be rationally used to fit some but not all production strategies relative to the economic competitiveness of an individual dairy. BST can be evaluated just like other management practices to make a rational decision that BST does or does not make a significant positive contribution to the economics of milk production in that dairy herd.

### **Consumer Acceptance**

I find no data indicating US consumption of fluid milk and dairy products has decreased during 1994. In contrast, data suggest that consumption of dairy products continues to increase. Therefore, I interpret that Posilac has not had a negative impact on the consumption of dairy products, even though there has been extensive negative publicity through magazines, newspapers, television and radio. However, there are instances where there has been a "negative" impact. For example, Wisconsin Rapids (Wisconsin) began offering elementary children the option of juice instead of milk in school lunches in response to a petition by citizens to prevent their children from being exposed to milk that potentially could have come from cows receiving Posilac. The Chicago Public School Board addressed the possibility to force milk to be supplied to the Chicago schools as "farmer certified rBST free". Numerous state school lunch administrators were requested by various persons/groups to write 1994 dairy product specifications stipulating dairy products to be "free of rBST". In Minneapolis, Land-O-Lakes and Marigold Foods introduced brands of dairy products that were certified "to be from cows not receiving Posilac". Numerous niche dairy brands are available in the market; these niche brand dairy products have varying degrees of identification as being derived from cows not receiving BST and are having varying degrees of success. None have taken away the dairy food case of major markets.

A multiplicity of editorials/opinion pieces have been published in such diverse media as the journal *Science* (264:11, 1994), *Kalamazoo Gazette*, *Detroit Free Press*, *New York Times*, *Wall Street Journal*, *American Health*, *Feedstuffs*, *Hoards*, *The Dairyman*, *Newsweek*, etc. The perspectives presented ranged, as one would expect, from full support for rational evaluation and use of Posilac in the production of milk to a ban on the use of BST in lactating dairy cows in the US and a boycott of all dairy products derived from cows receiving BST. BST even made the television show "X-Files" in December 1994. The program centered on a Wisconsin farming community, showed bizarre behavior of local people, especially children; initially the investigators suggested that the use of BST was the cause of the bizarre behavior; however, the bizarre behavior was eventually "linked" to a series of government experiments by a local pediatrician who was injecting children with "DNA derived from aliens". This far-fetched story, in my opinion, suggests that BST has "arrived" and has taken its place in popular culture.

Although Posilac was approved by FDA-CVM in November 1993, state labeling legislation regarding dairy products derived from use of BST was debated during 1994 in at least 13 states. Minnesota and Wisconsin have voluntary labeling regulations, Vermont has a mandatory labeling regulation and Maine restricts the "Maine Quality Seal" to "rbst free dairy products". For 1995, I anticipate BST labeling discussions to be held in at least 17 states, including the four states that have labeling. As part of the discussions regarding labels, some states are attempting to implement a record keeping system that would identify every animal receiving BST. Additionally, debate continues on the national level (House of Representatives and the Senate) in an attempt to achieve some type of BST national labeling law and/or a ban on the use of BST in lactating dairy cows.

A Federal Register guideline, issued on 10 February 1994, gave guidance as to what would be acceptable for a voluntary labeling of dairy products derived from cows not receiving BST. Under those guidelines, FDA identified that milk or dairy products could not be labeled as free of BST because BST is a natural component of milk. Since a label statement "free of recombinant bst" could suggest such milk was different (better) than milk derived from cows receiving BST, FDA decided that such a statement has the potential to be misunderstood by the consumer and such a label could not be used. As a result of the FDA guidelines, Monsanto chose to initiate lawsuits against two companies that were labeling milk and dairy products outside of the FDA guidelines as interpreted by Monsanto.

Based on the extensiveness and negativity of the publicity and the attempted boycotts regarding the marketing of milk derived from cows receiving Posilac, I find encouraging that there has not been a negative impact on the consumption of dairy products. Numerous creameries, milk cooperatives, and food stores have aided the negative publicity by issuing public statements regarding their intent either to label dairy products from cows receiving (not receiving) BST or to refuse to market dairy products derived from cows receiving BST. In general, when such actions were taken by food stores, the actions were predicated on fear of consumer concern, fear of threatened boycotts, or a belief that milk derived from cows receiving BST is unsafe and unfit for consumers.



Whatever the perspective taken, the bases were always an allegation that there was something wrong with the milk derived from cows receiving BST. The worldwide data incontrovertibly supports an interpretation that milk derived from cows receiving BST (Posilac or any other BST product) is safe for human consumption because the milk is not different from milk derived from cows not receiving BST.

### **Status in Canada and the European Union (EU)**

In September 1994, both Monsanto and Lilly agreed to an 11 month delay on the sale of BST in Canada. A seven member industry-government-consumer panel was established in Canada to address the issues surrounding use of BST in lactating dairy cows. The seven member panel is to present a report prior to July 1995 that addresses the impact of BST on the dairy industry, on animal health, on the cattle breeding industry and on human health, as well as an evaluation of consumer reaction to BST use in the US. In my opinion, each of the "BST impact" topics to be addressed by the panel has been assessed thoroughly and competently in the US, in the EU and in Canada. The data support an interpretation that BST can have either a positive impact or a neutral impact on each of the BST impact topics. To date, marketing of Posilac in the US has not had a negative impact as measured by consumer reaction.

In the European Union, the Farm Council decision of 13 December 1994 extended the moratorium on the marketing of BST in the EU until 31 December 1999. The moratorium precludes the marketing for human consumption of dairy products derived from cows administered BST under research conditions. The EU believe additional testing of the safety of BST in lactating dairy cows in the EU would provide "valuable information" for use in future Farm Council debate regarding approval to market BST in the EU.

### **A Swirl of Related Activities**

The Government Accounting Office (GAO) was requested by members of the House of Representatives to investigate potential conflict of interest of three CVM employees regarding the approval of Posilac. The three CVM employees were investigated and cleared of any potential or actual conflict of interest. However, these accusations continue. Another public accusation was directed towards Monsanto for "pre-approval promotion" of Posilac, an activity that is forbidden in the US. This accusation appears to be predicated on seminars presented by Monsanto representatives to academia, to veterinary groups, and to representatives of the dairy industry. Monsanto has rebutted this accusation based on their interpretation that they were functioning within the regulations.

For veterinarians, the veterinary journals have published numerous papers, letters to the editor, position papers, and opinions during 1993 and 1994. The opinions/positions range from BST should be banned and BST is devastating to the health of cows to the perspective that BST can be utilized effectively and economically in cows to enhance milk production and increase the profitability of the dairy.

Proper statistical analyses of the data on BST effects on safety to cow health have been a topic of controversy. Academicians on both sides of the Atlantic have written letters to the editor and the topic has been addressed in such journals as Science (265:170, 1994), Nature (371:647, 1994), The Lancet (344:815, 1994), The Lancet (344:197, 1994) and Food Chemical News (31 October 1994, pg. 39). The controversy surrounds the "appropriate" statistical analyses of the data and the "completeness of the data set" for the Posilac cow health data. All data from all studies, whether the studies were completed or partially completed, must be submitted to CVM for evaluation to address the questions of efficacy, target animal safety, and human food safety. Regulatory decisions have been made in at least the European Union, US, Canada, and numerous other countries; based on review of the data, regulatory decisions all support Posilac to be safe for use in lactating dairy cows with respect to the safety of milk and the safety of cow health.

The Pure Food Campaign and The Humane Farming Association have attempted to ban/block use of BST in the US. The Federal courts have been used in an attempt to block BST use and/or approval. Food store boycotts have been attempted. Dr. Samuel Epstein, Professor of Occupation and Environmental Medicine at the University of Illinois, as recently as October 1994, stated that cow body fat contains carcinogens, that bovine growth hormone reduces the cow's body fat therefore increasing the likelihood that these carcinogens could be released into the milk, leading potentially to an increased risk of cancer in humans consuming such milk (Country Living, October 1994, p. 46, 56). Thus, even the challenges to human health of milk derived from cows receiving BST continue. The safety of milk has been addressed by worldwide regulatory agencies and by the National Institutes of Health - the milk is safe!

### Summary

Marketing of Posilac in the US was initiated on 4 February 1994. I interpret 10-15% of the lactating dairy cows in the US are receiving Posilac for at least some portion of their lactation. The preponderance of the dairy press has been supportive of the rational use of Posilac as an economically important management practice to increase milk yield. Negative publicity and actions continue for Posilac and BST in National and State Legislatures, in newsprint/radio/tv, and in the Federal courts. Milk and dairy product consumption have not been negatively affected. The niche marketing and labeling of milk and dairy products derived from cows not receiving BST have had limited success but have not eroded the milk market for milk and dairy products derived from cows receiving Posilac. The dairy industry appears to accept BST can be a positive adjunct to efficient production of milk. I believe the success of Posilac is predicated on the fact that an unprecedented quantity and quality of studies were completed worldwide to establish the safety and efficacy of BST as used in lactating dairy cows. The 1994 marketing success of Posilac has been beyond the expectations of the majority of us working in the BST research arena.