Use of Bovine Somatropin (BST) In the United States: Its potential Effects

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EXECUTIVE SUMMARY

On November 5, 1993, the U.S. Food and Drug Administration (FDA) approved the metabolic protein hormone, bovine somatotropin (BST), for commercial use in the U.S. BST is used to increase milk production in dairy cows. Since FDA's action, experts in various Federal agencies have reviewed the available scientific evidence and other data related to the impact of potential BST use. This report presents their findings on BST's implications for U.S. consumers, the dairy industry, and the economy. Key findings are:

Safety

There is no evidence that BST poses a health threat to humans or animals. It has been studied more than any other animal drug, and been found safe by FDA and many other scientific bodies in the U.S., Europe, and around the world. FDA also concludes there is no legal basis requiring the labeling of BST milk, since the milk is indistinguishable from non-BST milk. Voluntary labeling is permitted.

The Dairy Industry

Income for individual farmers who adopt BST is likely to increase. Productivity and profit per cow should rise for both small and large farms. BST favors good herd management rather than small or large farms. BST is likely to reinforce productivity changes that have been occurring for decades in the U.S. dairy industry. BST use will increase U.S. milk production by about one percent, through FY 1999. This production will likely lead to slightly lower prices for milk, averaging about two percent lower over the next six years. These lower prices are expected to result in declines in aggregate farm income from dairy farming of about one percent over this same period. Lower milk prices from BST use are also expected to contribute to higher Federal Government dairy price-support costs, but decreased Federal costs for nutrition programs like Food Stamps and the Special Supplemental Food Program for Women, Infants and Children (WIC). Federal dairy price-support program costs would increase by approximately $l50 million in the peak year, FY 1996, and decline in later years. This would represent a 1.8 percent increase in total projected Federal farm commodity subsidies for that peak year. Savings in the costs of Federal feeding programs would begin in FY 1997, and could completely offset the increased cumulative costs of the Federal dairy price-support program over 10 years. While there would be savings in the feeding programs before FY 1997, those savings would be used to either increase program participation rates or provide additional benefits to participants.

Consumption of Dairy Products

Consumers are expected to benefit over the next six years with BST use due to the availability of more milk at lower prices. Largely because of this increase, the net national economic impact of BST usage is expected to be positive. No significant reduction of demand for milk and dairy products is expected to result from BST use. While some surveys reveal strong consumer

resistance to BST, others indicate confidence in the U.S. milk supply, and no substantial intent to forego use of BST milk. There appears to be a need for nutrition Outreach on BST's effects.

The Environment

BST is expected to have a minor, but beneficial net impact on the environment. It should lead to a slightly smaller u.S. dairy herd, and therefore less pollution through decreased use of fertilizers for feed production, and less cow manure and methane production.

Exports

BST should have little, if any, effect on U.S. dairy exports. Nearly half of U.S. dairy export volume goes to countries that have approved the use of BST, and more countries are expected to do so. The European Uffion (EU), major dairy exporter, recently decided to extend its BST moratorium for one year, instead of the anticipated seven years. For countries to ban BST use, after the hormone has been scientifically found to be safe, would undermine efforts to eliminate unfair trade barriers to U.S. exports.

Biotechnoloqy Industries

U.S. leadership in biotechnology, as well as private-sector investment for research and development in the biotechnology industry, would be enhanced by proceeding with BST, and would be impeded if there were new Government obstacles to such bio-tech products following their approval for use by FDA and other regulatory agencies.

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CHAPTER I.

INTRODUCTION

For generations, food production increased with the help of new technologies, such as crop rotation, fertilizers, information management, and selective breeding of plants and livestock. Now, proponents of a new type of technology -- biotechnology -- claim that it will supply, as the next century begins, more food at less cost to meet growing demand at home and abroad in markets that will become more competitive. The first major agriculture related product of biotechnology research is bovine somatotropin (BST), or bovine growth hormone (BGH). Biotechnology has also been used widely for several years in the U.S. for cheese production, but attracted little attention.

BST is a natural protein hormone that controls the amount o produced by cows. It is a metabolic hormone, not a growth hormone like a steroid, that is released from the anterior pituitary gland of cattle and, until recent years, could be produced only by cows.

As early as the 1930s, Russian scientists reported that injecting dairy cows with bovine pituitary extracts increased milk yield. This increase in milk production was eventually attributed to BST. However, wide-spread commercial use of the extracts was never seriously pursued; only very small and impure amounts were obtainable from cows at slaughterhouses. With the advent of recombinant DNA biotechnology, it became possible to put the BST gene into bacteria and induce these bacteria to produce large quantities of the hormone. In the early 1980s, it was demonstrated that BST, derived by recombinant DNA processes in a laboratory and administered to cows, could enhance their milk production. This made it feasible to consider recombinant BST (rBST) for commercial use. (In this study, "BST" refers to recombinant BST unless specifically identified as naturally produced BST.)

In the U.S., a substance like BST must be thoroughly tested and studied, prior to its commercial availability or use, by the Food and Drug Administration (FDA), an agency of the U.S. Department of Health and Human Services (HHS). BST is a candidate for the most thoroughly examined drug ever in terms of its safety for humans, animals, and the environment. FDA investigations, as well as those conducted by scientific bodies in the U.S., Europe, and around the world, have affirmed BST's safety. These include the National Institutes of Health, the Congressional Office of Technology Assessment, and the drug regulatory agencies of Canada, the United Kingdom, and the European Union.

In addition, BST is being analyzed and discussed by the media, farm groups, consumers, and others. Many seek even further assurance about the safety of BST use. Others question the implications of BST use for economic and social life, for the dairy industry, and for the environment. Will it impair the livelihood of small farms? Will it encourage the development of large dairy farms that will increase erosion and pollution? Or will the use of BST improve the environment, and lower consumer and Government costs of milk and other dairy products -- a source of nutrition vital to lower-income people? These questions are important, and the concerns they represent must be addressed.

In the Omnibus Budget Reconciliation Act of 1993 (OBRA 1993), Congress enacted a moratorium on the sale of BST for 90 days following its approval by FDA. The stated purpose of the moratorium was to allow Congress time to consider the impact of BST in the U.S. As a courtesy, the Administration informally agreed to conduct a study to assist Congress in its deliberations on BST issues. FDA subsequently approved BST for U.S. sale and use on November 5, 1993.

1. **Purpose of the Study**

This study is designed to examine the use of BST in its broad economic context, including its social implications. The study seeks to inform policy-makers and the general public by investigating the claims and concerns raised about BST. It is objective and based on the best available science and other data, but sensitive to questions that may not have been addressed adequately up to now by medical researchers, environmental scientists, or economists.

The study provides information on the findings, claims, and fears about BST. It summarizes the latest evidence on the response of cows to BST, and gathers together the economic consequences

in ~ several areas of concern, from farm income to further development of new biotechnology products. Moreover, it presents in one document the available evidence on the broadly-defined economic and social implications of BST use, including the effect on the Federal Budget.

The Administration has heard from people from across the U.S. speaking in recent months on BST. They voiced apprehension and hope about BST, but also about the Federal Government's efforts to ensure the safety of their food and drugs, and about the appropriate role of science and technology in their future.

The confidence with which U.S. citizens can face a more competitive and complex future depends in no small measure on their trust in governmental institutions. The Administration believes that it has a responsibility in several broad areas of the BST debate: (1) health security in the form of the safety and purity of American food and medicines; (2) animal safety; (3) environmental safety; and (4) economic productivity as enhanced by advances in science and technology, including biotechnology. All are key elements in the debate surrounding BST. It is, therefore, appropriate and timely that the Administration study an emerging technology of potential importance to American life. It is not the purpose of this study to endorse or oppose BST, or otherwise imply a statement of Administration policy on BST beyond the statements of Executive Branch agencies included in the study, which does not make policy recommendations.

2. Approach and Organization of the Study

BST is the most studied animal drug ever approved by the FDA. It has also been examined by many other organizations around the world. More than 1,500 studies, books, professional papers, and surveys have examined BST and its implications for human safety, animal health and well-being, economic change, ethics, farm structure and incomes, the environment, investment in biotechnology, rural social life, and other issues.

This study does not attempt another technical BST assessment, duplicating previous efforts. Rather, it provides a summary of the most reliable professional analysis and judgment on major topics associated with BST's use, including its economic implications. In the course of the study, it became clear from surveying work already conducted that the discussion of BST at this point is less in need of additional technical analysis, and more in need of broad dissemination of information on what is already known about BST.

The study's research and preparation was undertaken by a team of about 40 specialists representing eighteen offices in seven , Federal agencies assembled specifically for this purpose and coordinated by the Executive Office of the President. Study participants were chosen for their expertise on various topics. They reviewed the professional literature and popular discussion of BST issues. They participated in the design of the study and its collaborative approach. They drafted sections and were encouraged to review each others' work, contributing insights across agency and disciplinary lines. Individual chapters are the products of several agencies. The study was then reviewed in draft by non-governmental experts in professional societies, universities, and policy-analysis organizations.

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CHAPTER II.

THE SAFETY OF BST

BST is the most examined animal drug ever approved for use in the U.S. (see the Appendix for a chronology of major BST studies and events). In November 1993, BST was found safe by the Food and Drug Administration (FDA), the U.S. government's testing agency. FDA's finding was based on hundreds of formal scientific studies and tests conducted over many years around the world. FDA verified the reported data of over 120 studies and also held hearings on safety-related issues. BST has been declared safe by other respected scientific and professional organizations, including the American Dietetic Association, the National Institutes of Health, the Congressional Office of Technology Assessment, and the HHS Office of the Inspector General. Moreover, BST has been examined, found safe, and approved for use by numerous foreign government regulatory agencies. In fact, no professionally-recognized scientific group has concluded, on the basis of current knowledge, that there is doubt about the safety of BST in milk production.

Nevertheless, doubts remain for some people about the safety of BST used in milk production. Will BST lead to unforeseen medical problems overlooked by scientists? Will it cause allergic reactions by some individuals? Will it lead to antibiotic residues in milk or meat as drugs are used to combat mastitis (an infection in the udder, which is associated with increased milk production in cows)?

In 1992, the U.S. General Accounting Office (GAO) investigated allegations that FDA should look more carefully at the indirect health risks of BST. What did the GAO conclude?

Doubts about FDA's decision to approve BST are not altogether surprising, since the general public rarely hears about FDA's process used to investigate new drugs. Because of the normally proprietary nature of both drug development and the review of drugs by FDA, the public is usually unfamiliar with the agency's review process, especially for drugs for food-producing animals. Some people wonder how thoroughly FDA investigated BST, or why FDA did not require that "BST milk" be labeled.

The first section of this chapter seeks to present the conclusions of the scientific community on specific issues of concern about BST. It explains the basic nature of BST, and also examines the concerns about insulin-like growth factors and antibiotics. The second section describes FDA's process of investigating BST. The third section examines the scientific basis for FDA's conclusion why the labeling of milk produced by cows receiving BST injections would not be required, but would be permitted.

1. **Human Food Safety**

a. **General Features of BST**

A number of factors were included in FDA's decision that milk and meat from cows treated with BST were safe for consumption. First, BST is a protein hormone. Unlike the steroid hormones that have caused public concern in the past, protein hormones are degraded enzymatically when ingested, like all proteins found in food. This is the reason that BST must be injected into cows, rather than fed, to be effective. A similar example is the treatment of diabetes with insulin. Since insulin is a protein hormone, it must also be injected to be effective. In order to eliminate the human food safety concern for drug residues, each BST sponsor must demonstrate the oral inactivity of their BST compound in animals.

Natural BST exists as four biologically active variants of 190 or 191 amino acids. For many years, it was erroneously believed that BST only acted to promote general body growth; hence the name commonly used -- bovine growth hormone. However, it is now known that BST is an important metabolic hormone and plays an important role in regulating the metabolism of proteins, fats, and carbohydrates. Like all protein hormones, BST elicits a biological response by binding with high affinity to specific receptors on the cell membrane of target cells.

In addition, pituitary BST has no biological activity in humans, even if injected. Its molecular structure is substantially different from that of human somatotropin due to at least a 35 percent difference in amino acid sequence. The binding of BST to the human somatotropin receptor is several orders of magnitude ' lower than that of human somatotropin and too low to elicit a biological response. In the 1950s, clinical trials were conducted by injecting large quantities of farm animal pituitary preparations into children and adults for several weeks or months. These pituitary preparations did not stimulate growth or cause consistent metabolic effects.

Another consideration is that humans are normally exposed to trace levels of BST in beef, milk, and other dairy products at levels similar to those in cows supplemented with BST. Also, heating, such as with cooking and pasteurization, inactivates BST that may be present in milk or meat products.

The overall nutritional composition of milk is not altered due to BST treatment of cows. Therefore, the nutritive and processing qualities of milk are not changed.

b. **Insulin-like Growth Factors (IGF)**

In the 1980s, evidence was growing in the scientific community that indicated many actions of somatotropins are mediated by insulin-like growth factors, especially IGF-l. Administration of somatotropins usually increased levels of circulating IGF-l, and it was learned that the structure of bovine IGF-l was identical to human IGF-l. The role of dietary IGF-l on the gastrointestinal tract has been evaluated in several studies that showed that IGF-l is present in human saliva and digestive juices, and it is not active in the upper gastrointestinal tract. IGF-l is also a protein with a structure very similar to insulin, and so presumably it would not be orally active. Nevertheless, because of limited data on the effects of BST-treated cows on IGF-l milk content, FDA requested additional information from the BST sponsors.

Through this research, it was learned that the IGF-l content of milk varies widely between cows and herds. Milk IGF-l concentration also varies over the lactation cycle and is especially high

during the first few weeks of lactation, an interval that should be prior to the period of BST use. The IGF-l content of milk of individual BST-treated cows increases slightly; however, the values remain within the normal range of concentrations for IGF-l in milk of untreated cows. Human milk also contains IGF-l and at concentrations similar to that of milk of treated and untreated cows. It was also determined that IGF-l is orally inactive, similar to insulin and BST itself. The amount of IGF-l consumed from milk would be much less than that reaching the stomach from saliva and digestive secretions. Furthermore, the levels of IGF-l in milk from both controlled and treated cows are 100 to 1,000 times lower than endogenous blood levels in humans. Thus, even if IGF-1 were ingested and not destroyed in the digestive tract but absorbed intact, the dilution of a few nanograms of the undigested IGF-1 into the large endogenous plasma pool in humans would be physiologically insignificant. Therefore, milk IGF-1 levels are safe for all consumers, including infants.

On the basis of this and other information, FDA concluded that there are no human safety aspects with food products derived from dairy cows treated with BST. Because of public interest in the human food safety of BST, FDA's Center for Veterinary Medicine (CVM) took the unprecedented step of authoring a paper published in the August 24, 1990, issue of Science covering in detail the decision to authorize food derived from BST-treated cows to be consumed by humans (Juskevich, J.C. and Guyer, C.G. 1990. Bovine Growth Hormone: Human Food Safety Evaluation. 249: 875-884). FDA scientists summarized more than 12 studies that examined the safety of milk and meat from dairy cows treated with BST. These studies led FDA to conclude that the use of BST presents "no increased health risk to consumers".

FDA's position has been affirmed by external review groups including: (1) a December 1990 National Institutes of Health Technology Assessment Conference on BST; (2) the Congressional Office of Technology Assessment in a 1991 report; (3) the 38th Joint Expert Committee on Food Additives of the World Health Organization and the Food and Agricultural Organization of the United Nations (Veterinary Drug Residues: Bovine Somatotropins, 1992); (4) an extensive audit of FDA's review process conducted by the Office of the Inspector General, HHS, issued February 21, 1992; (5) drug regulatory bodies of the European Union (Final Scientific Report of the Committee for Veterinary Medicinal Products on the Application for Marketing of Somatech and Optiflex 640, January 1993); and (6) studies conducted by other countries, including Canada and the United Kingdom. These scientific experts reached the same conclusion as FDA -- that the food products from BST-treated cows are safe for human consumption.

Since BST is orally inactive and has no biological activity in humans, FDA has no human food safety concerns for BST residues in tissues or milk. Residue studies and a regulatory analytical method are not required for drug products for which there are no human food safety concerns. Specifically, FDA regulations [21 CFR 514.1(b)(7)] state that "...When data or other adequate information establish that it is not reasonable to expect the new animal drug to become a component of food at concentrations considered unsafe, a regulatory method is not required". Since a tolerance and regulatory method are not required by FDA for BST products, CVM has not requested the sponsoring firms to pursue the development of analytical methods.

c. **Mastitis and Antibiotics**

In a report released August 6, 1992, the General Accounting Office (GAO) agreed that BST did not represent a direct human food safety risk, but raised a concern about the potential for increased antibiotic residues in food products from cows treated for mastitis. Mastitis is the most common disease in dairy cows and occurs in other lactating mammals as well. Milk producers routinely use antibiotics to counter the disease's effects. FDA concluded that the risk of clinical mastitis was slightly higher in dairy cows treated with Monsanto's sometribove (BST) product. Other BST products must be reviewed on a "stand alone" basis for their risks of clinical mastitis.

FDA considered this potential effect on the human food safety of sometribove and concluded that the increase in clinical mastitis in sometribove-treated cows was not a public health concern with respect to antibiotic residues in milk. Although the incidence of clinical mastitis increased moderately in treated cows, there was no indication that these cases of mastitis were more difficult to treat, as reflected by similar average duration of cases between treated and controlled cows. When examined on a per-unit milk basis, the increase in the incidence of clinical mastitis due to sometribove (approximately 0.1 cases per cow per year) is about four to nine times less than the effects due to other sources of variation in the incidence of mastitis, such as season, stage of lactation, parity (the number of lactations for a given cow), and herd-to-herd variation. For example, on a per-unit milk basis, the increase in mastitis incidence from winter to summer is at least nine times greater than the increase due to sometribove treatment. Also, the increase in mastitis between early lactation (when sometribove would not be administered) compared to late lactation is at least seven times greater than the effect of sometribove. (See references by Smith et al. [1985, J. Dairy Science 68:1531]; Morse et al. [1988, J. Dairy Science 71:848]; and Hogan et al. [1989, J. Dairy Science 72:1547]).

Another important factor is that therapeutic drugs, such as antibiotics for the treatment of clinical mastitis, are to be used in food-producing animals only under approved conditions and with appropriate withdrawal periods (as established by FDA) to ensure that food products are safe for human consumption. State and Federal regulatory bodies currently monitor milk supplies for drug residues, and any milk that contains illegal residues is discarded. In addition, the dairy industry currently tests every tanker truck of milk for beta-lactam (penicillin-type) drugs prior to processing. The beta-lactams are the most commonly used drugs for the treatment of mastitis, so that even if an increase in use of these drugs -- and an increase in illegal residues -- occurred as a result of increased mastitis, residues would result in the rejection of the milk before it entered the marketplace. Moreover, dairy producers who experience an increased incidence of mastitis would likely reevaluate their use of BST.

An indication of the magnitude of the public health concern for violative antibiotic residues in food can be assessed from data on penicillin. Three to ten percent of the human population is allergic to penicillin. Allergic reactions are the most common side effect of the beta-lactam antibiotics, the predominant therapeutic treatment for clinical mastitis. Penicillin allergies develop following long-term (weeks) exposure to therapeutic large doses. Once an individual is allergic to penicillin, smaller doses can cause allergic reactions. Typically, these reactions consist of a skin rash and are not considered to be significant health risks. In the last 25 years, there have been less than 10 cases of allergic reactions worldwide following the consumption of penicillin residues in milk (Dewdney et al., 1991, Food Chem. Toxicol. 21:477-483). All of these adverse reactions involved penicillin residues in the milk at levels well above FDA's current tolerance of

five parts per billion (ppb). Currently, the commonly used screening test for beta-lactam residues in milk is the Bacillus stearothemophilus disc assay, which detects penicillin residues at >3-5 ppb.

In view of the much larger variation in the number of clinical mastitis cases due to other factors, the monitoring of milk for illegal drug residues, and the minuscule public health concern for beta-lactam antibiotic residues in milk, FDA concluded that the use of sometribove was safe.

FDA's Veterinary Medicine Advisory Committee and expert consultants were convened for an open public hearing in March 1993 to discuss the issue of increased mastitis in sometribove-treated cows and a potential increase in the risk of antibiotic residues in milk. After hearing presentations from interested parties, and after considering the data presented to the Committee, the Committee concluded that, while sometribove treatment might cause an increase in mastitis, the increased risk to human health posed by mastitis and resultant use of antibiotics was insignificant.

2. **The FDA Investigation Process**

Prior to commercial distribution of any animal drug in the U.S., the drug sponsor must receive approval from FDA. Until approval is received for the specific proposed use of the drug, it cannot be legally sold in the U.S. for this purpose. The review of BST products by FDA has been unusual in part because it has been highly visible to the public. FDA is prohibited by regulations (21 CFR 514.11 and 21 CFR 514.12) from disclosing to the public data or information on animal drugs under review, because such data or information are considered confidential. An exception was made when each of the four BST sponsors authorized disclosure and publicly acknowledged that they were seeking approval of their products.

a. **The First Review Process**

FDA's CVM has the responsibility to review applications for animal drugs. To obtain drug approval, the drug sponsor must prove that the drug is effective and safe. Effectiveness means that it does what the sponsor claims (e.g., increases milk production). For food-producing animals, safety covers three areas: (1) safety to humans of the food products from animals receiving the drug; (2) safety to the target animal; and (3) safety of its manufacture and use to the environment. In addition to these requirements, firms must demonstrate to CVM that they can consistently manufacture the drug to a specific potency and purity. The environmental safety and manufacturing quality of BST products are the only areas of review in which the biotechnology aspects of these drugs are considered. All other areas of review are based upon the end product, the drug, not on the method of production.

Monsanto's BST application comprises over 500 volumes containing over 200,000 pages of data and reports concerning the safety and effectiveness of its BST product. CVM estimates that it spent over 30 person-years reviewing and evaluating this application. The quality and appropriateness of the FDA review process was carefully investigated by the HHS IG at the request of Congressman John D. Conyers, Jr. This investigation lasted over a year and a half. The HHS IG report dated February 21, 1992, concluded that its review could find no evidence

that Monsanto or FDA had engaged in manipulation or suppression of animal health data. The review process was also investigated by GAO at the request of several members of Congress. GAO's investigation took over two and a half years to complete, and a report was issued on August 6, 1992. GAO did not find any evidence of data suppression or manipulation (but did raise a concern about the potential for increased antibiotic residues). GAO concluded that all critical FDA research guidelines were followed in the investigational review of BST products. While it found that some guidelines were not addressed, GAO believed that these were not threats to the validity of the pivotal study conclusions.

Four pharmaceutical firms have been seeking FDA approval for their BST products. These products are identical or very similar to the natural BST variant containing 191 amino acids. The products differ in the amino acids that are substituted for the terminal alanine residue. The pending drug products also differ in dosing regimens; some are daily injectable products, while others are sustained release formulations. With respect to CVM's review, each product must stand alone; that is, a firm must demonstrate all aspects of safety, effectiveness, and manufacturing quality for a product before that specific product can be approved. Only Monsanto's product known as sometribove, or Posilac, has been approved by FDA to date.

Under the Federal Food, Drug, and Cosmetic Act (FFDCA), FDA cannot consider social and economic impacts of an animal drug in its review process. CVM's role with respect to approval of an animal drug is to determine whether the drug is safe and effective, to evaluate the consistency in the manufacturing quality of the drug, and to ensure that product labeling describes how to use the drug safely and effectively if it is approved. After approval, the marketplace determines the use of a production drug in the same manner as it does for any new production practice or technology.

b. **Marketing of Food from Test Animals**

A concern expressed by the public during the review of BST products has been that food products from test animals are allowed into the human food chain. At any point in the investigational stage of any drug for food-producing animals, drug sponsors may request authorization from FDA for use of food products from test animals for human consumption (21 CFR 511.1(b)(5)). To support this request, each sponsor must provide CVM with adequate scientific data to demonstrate that consumption of these food products will not be inconsistent with public health. CVM reviews this information and, on the basis of the available data, determines whether the food products can be marketed and under what circumstances. FDA's decision may be that the food products may not be marketed, may be marketed after a certain drug withdrawal period, or that no withdrawal period is required during the investigational studies. The agency's decision can be reevaluated when new data relating to human food safety become available.

Early in the investigational stages for BST products, milk and meat from treated cows had to be withheld from human consumption for at least 5 and 15 days, respectively, after the last day of BST exposure. Later, as sufficient data were submitted, FDA was able to determine that milk and meat from treated cows were safe for human consumption, and that no withdrawal period was required during the remainder of the investigational period.

c. **Review of Animal Effectiveness and Safety**

The effectiveness of an animal production drug must be demonstrated under expected use conditions at a minimum of three different geographical locations in the U.S. A major objective of effectiveness trials is to determine an effective dose of the drug. Therefore, at least three different dosage groups plus a placebo-treated control group are tested using the proposed treatment regimen. For example, with Monsanto's sometribove product, treatment of cows begins during the 9th week of lactation and continues to the end of the lactation period.

The evaluation of the effectiveness and animal safety of BST products is challenging because there were relatively few previous applications for dairy production drugs. Dairy cows are unique food animals in that they are not terminal in the same manner as beef animals or pigs, which have a relatively short standard growing period. Dairy cows typically remain in a herd up to four lactations, with each lactation lasting roughly a year. A lactation is initiated each time a cow has a calf. The length of each lactation varies considerably among cows and is dependent upon when they are rebred. Thus, there are many complicating factors that need to be considered to standardize the measurement of effectiveness. In addition, only salable milk is considered when evaluating effectiveness. If a cow's milk is withheld from sale due to mastitis or certain therapeutic treatments, the cow's milk production for that day is recorded as "zero". Thus, a dairy production drug must significantly increase the production of salable milk. Effects of the drug on milk composition are also evaluated.

The safety of production drugs to the dairy cow is critical, because the animal is expected to sustain a high level of production for several years, give birth to a healthy calf approximately once a year, and remain healthy during this time. A unique aspect of the review of dairy production drugs is that the effectiveness studies are used, in addition to the animal safety study, to obtain additional animal safety data. This is necessary to provide sufficient data to evaluate the result of treatment on low-incidence health effects. Effects of dairy production drugs such as BST on the following animal safety variables are evaluated: nutrient requirements, reproduction and offspring, mastitis and other clinical health conditions and the therapy necessary to treat such conditions, injection site reactions, hematology, blood chemistry, pathology, and histopathology. All effects (effectiveness and safety) are monitored separately for first lactation cows (i.e., heifers) and older cows because of their biological differences. Heifers are still growing -- persistency in their milk production over a lactation differs from older cows, and variation among animals is less.

Once all of the data on animal safety of a drug are properly analyzed and any adverse effects are identified, there are a number of ways FDA can rule on side effects. In the case of severe safety hazards, the drug would not be approved. Less severe problems might be overcome by approving a lower, but still effective, dose of the drug. Another important approach is the drug label and/or insert that may include precautionary statements and/or information on appropriate management practices to help minimize minor but repeatable health problems caused by the drug. It also informs the user of the risks that might be encountered in using the product. In the case of sometribove, FDA's approval included the requirement for Posilac labeling that described proper administration and effects of treatment on nutritional needs, reproduction, health, and other potential effects to the treated cow as well as recommended management of treated animals.

d. **Review of Environmental Safety**

The effects of both the production and use of an animal drug on the environment are considered by FDA as part of the review process. The agency's specific conclusions on the environmental safety of sometribove are addressed in Chapter V.

e. **Quality Control**

A manufacturing review is an integral part of FDA's evaluation for all pharmaceutical products, including animal drugs. The manufacturing information provided by the sponsor for FDA review must verify product quality, identity, purity, and potency. Furthermore, the sponsor must submit data demonstrating that it can consistently manufacture the product according to these quality standards following FDA's mandated Good Manufacturing Practices regulations. The commercial product must be the same as that used for the animal safety, animal effectiveness, and human food safety studies.

The quality controls and manufacturing process information for drug production are generally not published, since this is proprietary information. However, FDA has published several documents describing manufacturing controls considerations for both fermentation and recombinant products (e.g., "Points to Consider in the Production and Testing of New Drugs and Biologicals Produced by Recombinant DNA Technology").

The FFDCA requires that drug sponsors provide FDA data to determine the safety and effectiveness of their product. If these data are not otherwise available, the firm must fund research to generate this information. Due to the length of animal safety and effectiveness trials for BST products, over a million data points can be generated from these studies for each BST product. Because the accuracy of these data is critical to the review of animal drugs, FDA takes a number of steps to monitor the reliability of research results.

Pivotal efficacy and animal safety studies are well-controlled studies designed to evaluate the effectiveness and/or animal safety of the animal drug under expected conditions of use. Before a firm conducts its pivotal studies, it usually submits , study protocols to FDA, although this is not a requirement. In this way, FDA can comment on the adequacy of the studies and recommend any changes or additions that are necessary. Drug sponsors may also choose to conduct non-pivotal studies with the drug. Effects of the drug under different feeding or management conditions might be evaluated in these studies, or basic research might be conducted to understand the drug's metabolic actions. Non-pivotal studies are not necessarily conducted under proposed conditions for use of the animal drug, although all studies, pivotal and non-pivotal, must be conducted under FDA regulations provided for Investigational New Animal Drugs (21 CFR 511). Reports from all non-pivotal studies must be submitted with the application for the animal drug. If results of any of these studies are inconsistent with those of the pivotal studies for the drug, and/or they suggest significant adverse reactions not apparent in the pivotal studies, FDA may request additional information from these non-pivotal studies.

For Investigational New Animal Drugs, sponsors must submit to FDA drug shipment notices at the initiation of every study, indicating the location of the trial, expected time-frame, the number

and type of animals to be treated, the drug to be used, maximum dose, duration of treatment, and whether it is a pivotal study. Thus, FDA knows where trials with the drug are being conducted. With this information, a concerted effort is made to inspect pivotal trials under CVM's Bioresearch Monitoring Program and to have CVM scientists participate in the inspections to evaluate the conduct of these studies and data collection. Inspections are conducted under short notice over several days. Conduct of the study, adherence to the protocol, recording of data, and drug inventories are closely monitored. Results of the inspection are sent to FDA to aid review scientists in evaluating the adequacy of the trials used to test safety and effectiveness. Drug production plants are also inspected by FDA chemists and investigators.

Although the sponsors fund and monitor safety and effectiveness studies, the majority of the trials for dairy production drugs are conducted by independent scientists at universities or in commercial herds. All safety studies must be conducted in accordance with FDA's Good Laboratory Practices (GLP) regulations (21 CFR 58), which are intended to ensure the quality and integrity of safety data submitted to FDA.

Finally, in addition to descriptions of the studies and summaries of results, sponsors must submit to FDA the raw data from their pivotal trials, so that FDA can check the accuracy and completeness of the summary results derived by the sponsors and their statistical methods. Should significant problems in the conduct of a pivotal study be discovered, FDA will reject the study. If errors are found in the database of pivotal studies, FDA will require the firm to audit its database to correct errors.

f. **Post-Approval Monitoring**

Since BST has been a controversial product and the public continues to express concerns, Monsanto voluntarily developed a post-approval monitoring program, in consultation with FDA, for its BST product. The program comprises:

- An evaluation of the use of BST in 24 commercial dairy herds, representing small and large farms in all regions of the country. The health of treated cows will be monitored with specific focus on mastitis, animal drug use, and milk loss due to mastitis or drug treatment.
- Active and passive systems to provide an early alert on all complaints, including reports of adverse effects. All customers will be routinely contacted following their BST purchases to gain information on product acceptability and answer any questions. In addition, customers will be urged to report any problems they experience with the product through the system's toll-free line.
- A two-year tracking system of milk production and drug residues. Information will be collected from the 21 top dairy states representing at least 50 percent of the total milk production, and will compare discard rates for the six months after the sale of BST and a similar six-month period prior to BST sale.
- A 12-month evaluation of milk tanker trucks to examine and compare the percent of milk discarded due to positive drug tests between BST-treated and untreated herds. This evaluation will involve participation by the dairy industry, and will compare results with the National Milk Drug Residue Database system.

FDA believes this monitoring and the data it will provide about the incidence of mastitis in BST-treated cows under "real life" conditions are additional efforts necessary to assure the public that each and every question is being taken seriously -- even after BST approval. The information from this monitoring will be considered by an FDA advisory committee to ensure a full public airing of the data.

3. **Labeling of Milk from BST-Treated Cows**

FDA considered whether milk produced by BST-treated cows should be specially labeled. A joint meeting of the Veterinary Medicine and Food Advisory Committees was held on May 6 and 7, 1993, to address the labeling issue. After considering the issue with the assistance of these committees, FDA decided that it does not have a legal basis under the FFDCA that would justify requiring labeling for milk from cows treated with BST.

In the past, FDA has imposed food labeling requirements under the FFDCA's sections 201 and 403, which set forth when a food is considered to be misbranded:

Section 403(a) states that a food is misbranded if its labeling is false or misleading in any particular way. Section 201(n) explains that, in determining whether labeling is misleading, the agency needs to take into account not only representations made about the product, but also

"the extent to which the labeling ... fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article ....".

FDA has used the second part of section 201(n) -- "material with respect to consequences" -- to impose labeling requirements for safety reasons. For example, the agency has required patient labeling for oral contraceptives (21 CFR 310.501), hearing aids (21 CFR 801.420), and intrauterine contraceptive devices (21 CFR 801.427) to provide information about the risks involved in using these products. FDA has also required user labeling for tampons because of the risk of toxic shock syndrome (21 CFR 801.430). The agency was asked to require ingredient labeling for tampons because of consumer concerns about the safety of some ingredients (reproposed rule on labeling for menstrual tampons, 54 Fed. Reg. 25076, 25085 June 12, 1989). However, FDA was not aware of any data showing an association between any particular ingredient and any risk to health, including allergic reaction, sensitivity, or irritation. Absent information showing that disclosure of tampon ingredients was necessary for the safe or effective use of the product, the agency concluded that it did not have the legal authority to impose an ingredient labeling requirement (final rule on labeling for menstrual tampons, 54 Fed. Reg. 43766, 43769-70 Oct. 26, 1989).

In the food area, FDA has required a special warning statement to appear on the label of protein products intended for use in weight reduction (21 CFR 101.17(d)). Self-pressurized food containers must bear labels warning against spraying in the eyes, puncturing, or incinerating (21 CFR 101.17). The agency has expressed concern that a general policy of requiring warning statements on foods to announce the presence of specific ingredients would overexpose consumers to warnings and decrease their effectiveness, and it has, therefore, declined to require warning statements on food labels except in specific instances where there is scientifically-based

evidence of a potential health hazard (final rule, food labeling, declaration of ingredients, 58 Fed. Reg. 2850, 2872 Jan. 6, 1993; see also proposed rule, 56 Fed. Reg. 28592, 28615 June 21, 1991).

Most advisory committee members at the joint meeting in May 1993 concluded that no health consequences, or no consequences at all, would result from consumption of foods from BST-treated cows. Some committee members cited potential economic consequences, such as an impact on small dairy farms. Several committee members listed possible health consequences, such as exposure to antibiotic residues or decreased milk consumption, although some of these members discounted any health consequences as minimal or insignificant.

FDA is not aware of data showing that adverse human health consequences will result from BST's use. The agency has determined that current data indicate that any increased exposure to antibiotic residues in milk that may result from the use of BST will be insignificant, although post-approval monitoring (described above) will be conducted to verify this determination.

FDA believes that the extensive milk monitoring system that is in place ensures that milk consumed in the United States is safe, including that from cows treated with BST. FDA does not believe that the possible economic consequences of BST use present an appropriate basis for a labeling requirement under the FFDCA.

Pursuant to section 201(n), labeling also may be misleading if it fails to reveal facts that are material in the light of representations made about the article. FDA has also imposed labeling requirements under this part of section 201(n), including a requirement for finished foods that are irradiated. The agency reasoned that irradiation could cause changes in the organoleptic or storage properties of finished foods and that these changes could be significant in light of consumers' perception of the foods as unprocessed (final rule, denial of request for hearing, and response to objections on irradiation in the production, processing, and handling of food, 53 Fed. Reg. 53176, 53205 Dec. 30, 1988). In contrast, FDA did not require irradiated ingredients to be specially labeled, because it lacked evidence that irradiation of an ingredient would affect the characteristics of a multiple ingredient food in any significant way and because a food consisting of more than one ingredient has obviously been processed, and so consumers would not be misled (Id.; 51 Fed. Reg. 13376, 13389 April 18, 1986). Most comments on the rulemaking that supported a labeling requirement did so because of safety concerns about irradiation. However, because of FDA's determination that the irradiation of foods being permitted was safe, the agency did not rely on these arguments as a basis for the labeling requirement (51 Fed. Reg. at 13389).

The "representations" part of section 201(n) does not appear to apply to milk derived from cows treated with BST. FDA believes that there are no significant differences between this milk and that from untreated cows. Moreover, the agency is not aware of any representations about milk from cows treated with BST that would be misleading unless accompanied by the information that BST was used.

For these reasons, FDA does not believe that it can require special labeling for milk derived from cows treated with BST under the FFDCA's sections 403(a) and 201(n).

Section 403(i)(1) of the FFDCA states that a food is misbranded unless its label bears the common or usual name of the food, and section 403(i)(2) states that, if the food is fabricated from two or more ingredients, its label must bear the common or usual name of each ingredient. Under FDA regulations, the common or usual name must "accurately identify or describe, in as simple and direct terms as possible, the basic nature of the food or its characterizing properties or ingredients" (21 CFR 102.5(a)).

FDA recently required that the common or usual name of a protein hydrolysate include the identity of the food source from which the protein was derived (21 CFR 102.22). The agency determined that, because the source of a protein hydrolysate has a significant effect on the product's composition and function, it must be identified in the common or usual name to describe adequately the nature of the ingredient, as required by 21 CFR 102.5(a) (proposed rule, 56 Fed. Reg. at 28599; Final rule, 58 Fed. Reg. at 2867. For example, "hydrolyzed soy protein" is an acceptable name, but "hydrolyzed vegetable protein" is not. 21 CFR 102.22(a)). See Footnote.

[Footnote--The agency also recognized that, for religious or cultural reasons, consumers are interested in being able to identify the source of a protein hydrolysate, and it determined that for these consumers the protein source of a protein hydrolysate is a material fact. 56 Fed. Reg. at 28600; 58 Fed. Reg. at 2866. Cf. 49 Fed. Reg. 22769 (June 1, 1984) (establishing in 21 CFR 184.1259 the term "cocoa butter substitute primarily from palm oil" as common or usual name to alert consumers to possible animal origins of components of the product); 58 Fed. Reg. 2850, 2862 (Jan. 6, 1993) (establishing in 21 CFR 101.4(b)(22) terms for coatings on fresh produce to assist consumers in avoiding certain animal-based products for reasons of religious, cultural, or ethnic dietary restrictions). Avoidance of animal products is not a concern that is relevant to the present situation. Moreover, unlike hydrolyzed protein from various sources, milk from cows treated with BST is not inherently different from other milk, and the fact of BST supplementation is not necessary to describe the basic nature of the milk. See 58 Fed. Reg. at 2867.]

A food that is altered so that its original name does not describe its basic nature or characterizing properties may need a separate common or usual name to distinguish it from the original product. For example, FDA has established common or usual names for restructured foods, such as potato chips made from dried potatoes (see 21 CFR 102.41). Restructured foods are foods bearing the names of traditional foods, and often resembling those foods in appearance, but manufactured ~y new processes (proposed rule on common or usual names for restructured foods, 38 Fed. Reg. 20746 Aug. 2, 1973). FDA has stated that the common or usual name of a restructured product must describe not only the food's basic properties, but must also "identify differences from the traditional food that affect the basic integrity of the product". (final rule on common or usual name for onion rings made from diced onions, 40 Fed. Reg. 54536, 54537 Nov. 24, 1975; cf. 21 CFR 146.145(c) (specifying that orange juice from concentrate must be labeled as such).

When asked to address whether milk and other products from cows treated with BST are changed in any way, most advisory committee members stated that there would be no alteration, or that any alteration would be insignificant. Several members thought these products are altered by virtue of increased antibiotic residues or somatic cell counts.

FDA has concluded that if milk from BST-treated cows is different from other milk, any difference is insignificant, and it would not be appropriate to require a separate common or usual name under section 403(i) for this milk. "Milk" accurately describes both milk from treated cows and that from untreated cows. The agency does not view supplemental BST that may end up in milk as an "ingredient" of the milk, and so does not believe that section 403 (i) (2) applies in this situation.

Under the FFDCA, FDA has required certain information to appear on labels when its absence would mislead consumers or when, without the information, a food would be described inaccurately. The level of consumer interest in having particular information is important, and a high degree of interest has prompted the agency to impose some requirements. However, consumer interest alone is not enough. FDA has stated that:

"with respect to food labeling, the consumer's right to know has been defined by the Federal Food, Drug, and Cosmetic Act. The agency has no basis to impose additional requirements once a manufacturer has met the statutory obligation" (final rule, denial of request for hearing, and response to objections on irradiation in the production, processing, and handling of food, 53 Fed. Reg. 53176, 53205 n. 10 Dec. 30, 1988) .

Despite consumer interest in special labeling for milk derived from BST-treated cows, FDA has determined that there is not an , adequate factual basis for imposing a labeling requirement under the FFDCA's section 403. However, FDA has ruled that food companies may voluntarily label their products, provided the information is "truthful and not misleading" (HHS News, 11/5/93).

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CHAPTER III.

THE DAIRY INDUSTRY

The basic analytic issue concerning BST centers on the U.S. dairy industry. If BST did not increase milk production and make dairy farmers want to use it, there would be no product and no controversy. It is important, then, to specify BST's potential effect on the dairy industry. How much additional milk from BST-treated cows will be produced, by what type of cows, under what conditions, and receiving what type of herd management? With answers to those questions, the rate at which BST will be used by dairy farmers can be estimated. Will BST sweep across the land, eliminating small herds, forcing them either to expand or disappear? Will BST cause milk production and processing to shift from the Great Lakes region to the West and Southwest? How will BST affect farm income and profit margins for small farms? Will taxpayers pay the "social cost" of BST through increased Federal budget outlays under USDA's dairy price-support program?

For decades, the dairy industry has been experiencing often difficult structural change. Improvements in farming have made cows and farmers more productive and more efficient, and

lowered the prices consumers pay for milk and dairy products. Farms --most of which are family farms -- have become larger and more sophisticated in their dairy production methods. They use scientific breeding techniques, computers, veterinary medicines, and nutrition and feeding regimes, to name several advances welcomed by most farmers and consumers. Where does BST fit in with these advances? Will BST revolutionize dairy production, or reinforce established trends? This chapter seeks answers to these questions.

1. **Effects of BST on Milk Production Per Cow**

By 1993, scientists throughout the world had conducted and published in excess of 1,500 BST studies using more than 40,000 dairy cows (Muller, 1992; Bauman et. al., 1994). There is no question that BST use increases milk yield and production efficiency. However, there are many factors that affect the magnitude of the milk production response, and study results vary widely. A number of factors have been identified as influencing milk production response in BST research trials:

- the quality of herd management, including the availability and quality of feed;
- the dosage of BST;
- when BST is administered during a cow's lactation, with the largest increases in milk production occurring when BST is administered following the peak in the lactation cycle, 63-90 days following calving;
- the age of the cow, with first-lactation cows having a lower response than older cows; and
- the body condition of the cow prior to the start of treatment, and the cow's initial health before and during treatment.

Numerous studies indicate that quality of herd management will be the major factor affecting a cow's milk production response to BST. Thus, projecting the milk production response on the average commercial dairy farm is somewhat speculative. Studies, under widely varying conditions, indicate that BST can boost milk production per cow 10 to 20 percent during the 245-day period (Muller, 1992; U.S. Congress, OTA, 1991). Under actual farming conditions, this study assumes that BST treatment will increase milk production per treated cow by 1,800 pounds per year (this covers the full lactation period of about 305 days). The 1,800 pound increase is equivalent to a 11.5 percent increase in milk production per cow, relative to the currently projected U.S. annual average output of 15,610 pounds per cow for 1993.

2. **Effects on Low- Versus High-Producing Cows**

Most study results indicate that BST treatment tends to increase milk production per cow by an absolute amount regardless of the cow's initial level of milk production. Thus, cows with low or medium production tend to show a higher proportional response than high-producing cows. However, response varies among herds and within herds, as is the case with untreated herds (Thomas et al., 1991).

3. **Use of BST in the Lactation Cycle**

The milk production response to BST is generally smaller early in a cow's lactation than when administered after peak milk production is attained (Bauman, 1992; Muller, 1992). FDA has

approved Monsanto's BST product (Posilac®) to be administered beginning the ninth week after calving (Monsanto, 1993). Parity (the number of lactations for a given cow) can also affect the magnitude of milk response to BST. Some studies have observed higher levels of milk response in multiparous cows as compared to primiparous (first-lactation) cows, but other investigations have reported similar increases for all parities. Differences probably relate to the extent to which first-lactation cows need to divert nutrients for growth in order to achieve mature size.

4. **Effects on the Butterfat and Nonfat Solids Content of Milk**

On the basis of results from many studies that examined the effect of BST treatment on milk composition, the overall composition of milk (fat, protein, lactose, minerals, cholesterol, and vitamins) over the lactation period is not substantially altered (no statistically significant difference) by treating cows with BST (Muller, 1992). These components fall within the range found in untreated cows. Research results indicate that milk composition is generally far more sensitive to change from diet, state of cow health, inherent genetic factors, and environmental conditions than to BST treatment (Kroger, 1992). The research results indicate:

- there are slight variations in milkfat and milk-protein content immediately after BST treatment, which is common after any feed or metabolic adjustment;
- milkfat, protein, lactose, total solids, and solids-not-fat percentages are unaffected over a full lactation period and not different from those of milk from nontreated cows;
- milk-ash or mineral content, specifically phosphorus and calcium contents, are not altered by BST treatment;
- the meat derived from BST-treated cows tends to have a lower fat content, but is otherwise identical to that from untreated cows (Muller 1992);
- a slight shift in the Kjeldahl nitrogen fractions (casein, whey protein, and nonprotein nitrogen) has been observed in some experiments (this does not affect milk quality, but may affect cheese yields from milk);
- there are no effects on the relative proportions of short-, medium-, and long-chain fatty acids; and
- no changes in free fatty-acid content have been noted; therefore, no influence on off-flavor "rancidity" is anticipated, nor is vulnerability to oxidized flavor development.

5. **Effects of BST on Farmers' Production Costs**

Monsanto, the company whose product FDA has approved for sale U.S. dairy farmers, indicates that BST will be available in packages of 25 doses. Small-dose availability means no dairy farmer should be precluded from using BST on the basis of herd size. The cost per dose of a 14-day, prolonged-release product is expected to be around $5.60, making the cost of a 25-dose package $140 (Monsanto). On a per-cow, per-lactation basis, the cost of BST would amount to $86, or $0.40 per day of treatment.

The Monsanto BST product requires injections at 14-day intervals and will be sold in ready-to-use syringes. Use of the product should not require a specialized person or major training, but will require recordkeeping and analysis to monitor and evaluate herd performance.

The feed rations of cows receiving BST will need to be adjusted to support increased milk production. There is no indication that a cow receiving BST requires a ration that is significantly different than a cow not receiving BST, other than the need for a greater amount of concentrates. Further, a significant milk response has been observed over a wide range of rations, ranging from pasture-based rations to the typical forage/concentrate rations (U.S. Congress, OTA, 1991, p. 4).

It has been reported that BST-treated cows have a greater incidence of mastitis. Subsequent study seems to be leading to the conclusion that the increased incidence of mastitis is directly related to the increased level of milk production. A small but consistent positive relationship between milk production and incidence of mastitis is apparent, and BST does not appear to alter that relationship (Bauman, 1994). Also, the incidence of mastitis is greatest during the early weeks of lactation, a time when BST is not to be administered.

6. **Changes in Production Costs and Returns**

USDA last collected production cost and financial information from U.S. dairy farms in its 1989 Farm Costs and Returns Survey (FCRS). The survey, which was enumerated on individual farms, provides a detailed summary of current production practices, input costs, and financial returns for dairy enterprises. The FCRS sample is representative of the nation's dairy farmers, and the enumerated dairy farms can be classified by size and by region .

The 1989 FCRS was used to estimate how BST use would affect dairy farmers' production costs and returns. The estimated net cash balance per cow for the average U.S. dairy enterprise is used to compare the profitability of using BST. The greater the increase in the estimated net cash balance per cow, the greater the incentive to use BST. The net cash balance is determined by subtracting all cash expenses (including cash farm overhead, taxes, insurance, and interest) from the gross value of production. Gross value of production includes the sale of milk, cull cows, and calves.

The assumptions underlying the calculations are:

- cost of BST estimated at $5.60 per injection, or $86 per treated cow per lactation;
- additional labor costs based on extra time taken to inject BST into cows;
- BST increased milk production per cow by 1,800 pounds per lactation;
- feed rations were changed such that total digestible nutrients (TDN) were increased sufficiently to support the increased milk production. The TDN increase was imputed by increasing concentrates to provide energy and protein required for the increased production, and adjustments in other feed ingredients were made to balance energy and protein intake with requirements (Fallert, et al., 1987); and
- veterinary and medicine costs were not altered. The majority of cow health problems and veterinary costs (approximately 75 percent) are associated with the early portion of the lactation cycle, when BST would not be used (U.S. Congress, OTA, 1991). Thus, to the extent that economics favor a longer lactation cycle with BST use, veterinary costs would be reduced accordingly on a per-cow basis.

Table 1 compares the net cash balance per cow for the average enterprise without and with BST, on the basis of data from the 1989 FCRS. The comparison of the net cash balance using the

assumptions above shows that it would pay to administer BST at 1989 milk prices. Adoption of BST increased the average net cash balance by an estimated 15 to 22 percent, depending on herd size and region.

As a new technology, BST appears to provide early-adopting dairy farmers with the potential to realize an increased net cash return. Actual changes in returns will depend on the extent of adoption by producers and the magnitude of the response within herds. This analysis reflects the perspective of an individual dairy farmer. (The impacts of using BST for all dairy farmers in the aggregate are assessed in a subsequent section.) Even if use of BST results in lower aggregate net dairy income, an individual dairy farmer adopting BST could still be better off than a nonadopting dairy farmer because of the increased net cash returns that can be realized by using BST.

A unique aspect of the BST technology is that a dairy farmer can, in effect, treat adoption of BST as an experiment without being committed to any large fixed investment, any change in facilities, or any material change in management practices. Dairy farmers should be able to judge within a few months whether BST will pay for the particular herds under their management. A farmer who cannot detect positive results can simply stop administering BST. There will not be any residual fixed costs as there would be if facilities or equipment had been purchased and then were abandoned before their cost was recouped.

7. Potential Rate of BST Adoption by Farmers

Surveys of farmers have been used to estimate the potential rate of BST adoption. Studies prior to 1985 predicted fairly rapid and widespread adoption. Post-1985 studies generally showed lower adoption and more concerns expressed by the respondents. It is possible that when output increases were not as large as initially reported and costs related to the technology were significant, farmers were more cautious in their assessments of BST. Reports critical of BST use may also have caused farmers to question adoption.

a. Studies of BST Adoption

Many studies have examined the factors related to adoption of BST technology (see Table 2). Different significant factors appear in each study, so that generalization is problematic. However, noneconomic factors would appear to play important roles in the BST adoption decision (farmer Outreach and age, for example), as do herd management practices, management skill level, and use of other technologies. Studies have been conducted in major milk-producing areas such as California (Zepeda), Wisconsin (Marion, Wills, and Butler), New York (Lesser, Magrath, and Kalter), Georgia (Carley, Fletcher, and Alexander), Kentucky (Gong and Beck), and the Southeast (Kinnucan et al.).

BST adoption can be expressed in terms of farmers or cows. It is very unlikely that every farmer will use BST on all cows in the herd. Initially, farmers will likely use BST on selected cows, reviewing their response to BST treatment and the profitability of BST treatment. This experience will determine the extent to which a farmer expands treatment to other cows in the herd.

Adoption rates from the studies, which were summarized by Yonkers (1992, p. 191), range from 42 to 77 percent of dairy farmers, . generally after one year (Table 2). In Georgia, the adoption rate was estimated to be about 56 percent of farmers within five years (Carley, Fletcher, and Alexander). An Ohio study reported regional adoption rates of 64 percent in the Corn Belt to 80 percent in the Pacific region after ten years; with a national rate of 74.5 percent (Sporleder and Liu). The regional estimates in the OTA study have the Corn Belt as the lowest adopting region at 31 percent of herds after ten years and the Pacific as the highest at 67 percent. A study by the National Milk Producers Federation (1990) estimated that 60 percent of herds, accounting for 42 percent of all U.S. cows, would adopt BST after five years.

The wide range of estimated BST adoption introduces an element of uncertainty into projecting effects of commercial BST use. Until BST products are available and actual observation of farmers' use is possible, analyses of adoption will continue to be speculative.

b. Other Cases of Technology Adoption by Dairy Farmers

The history of technology adoption by dairy farmers has generally been that adoption is not universal (U.S. Congress, OTA, 1991). Of nine technologies introduced in the dairy industry (scientific feeding, Dairy Herd Improvement (DHI) testing, mechanical milking, artificial insemination, electronic farm records, milking parlors, bulk tanks, freestall housing, and embryo transfer), only two were totally adopted (100 percent use) in 1985 -- mechanical milking and bulk tanks. The other technologies in the list ranged from 0.5 to 70 percent adoption (Yonkers, 1992).

8. Projected Effects of BST on Milk Production, Use, Price, Farm Income, and Government Programs

This section provides estimates of BST's effect on the supply, demand, and price of milk in the U.S. market, as well as on the Federal deficit . For several years, approval and use of BST have been assumed in USDA's dairy baselines constructed for the annual President's budget and mid-session review budget updates. These baselines are 5-year projections of milk supply, demand, price, and cash outlays under USDA's milk price-support program. The baseline constructed for this study updates the FY 1994 mid-session budget estimates (FY 1994-FY 1999), but is revised to assume no BST use by dairy farmers. Effects of BST use in this study are obtained by comparing results of using BST with the study baseline results without BST. Because Federal law prohibits the sale of BST for commercial use for 90 days following FDA approval on November 5, 1993, the "BST scenario" assumes that use of BST will begin on February 5, 1994.

Two important assumptions that affect the projected impact of BST use are the response rate of cows treated with BST and the number of cows treated (Fallert, et al., 1987). The following analysis assumes a response of 1,800 pounds of additional milk per cow per year for cows treated with BST. The assumed BST adoption rates are shown in Table 4.

The baseline also assumes that total milk and dairy product consumption does not decline once farmers begin marketing milk from BST-treated cows. Consumption changes only in response to changes in secular demand factors (such as population and income) and changes in milk prices.

Given the assumed response and adoption rates and cost of production estimates, the effects of BST on milk production, marketings, prices, and farm cash receipts from milk marketings were analyzed by comparing results of the BST-treated scenario with the study baseline without BST. The results are summarized in Table 3.

With BST use, milk production would tend to rise, and prices would tend to fall. Changes in annual production (marketings) would be expected to range from +0.5 billion pounds in the first year, FY 1994, to +3.0 billion pounds in FY 1996. Changes in the average all-milk price received by farmers would range from $0.03 lower per cwt in the first year (-3/lOth of l percent), to $0.49 lower in FY l999 (-4.0 percent), an average annual decrease of 2 percent over the six-year period.

By law, the USDA/Commodity Credit Corporation (CCC) is required to raise its support price of milk when net CCC purchases of milk are projected to fall below 3.5 billion pounds in the following year. With BST, net milk purchases under USDA's dairy price-support program would remain above 3.5 billion pounds of milk equivalent until FY 1998. With no BST use, an increase in the CCC support price of at least $0.25 per hundredweight (cwt) would be triggered in FY 1997. With BST use, lower milk market prices beginning in FY 1997 would reflect the effects of both higher milk production and a lower CCC support price for milk.

The change in output per U.S. cow is a function of the adoption rate, since individual cow response is considered fixed at l,800 pounds per cow per year for cows receiving BST. With BST, the impact of a higher output per cow on total milk production would be partly offset by a slightly smaller U.S. national dairy herd. With BST, by FY 1999, the number of U.S. cows would be down about three percent, while milk production per cow would increase by about four percent.

With BST, aggregate farm income (cash receipts from milk marketings) is expected to range from $30 million higher in FY 1994 to $110 million higher in FY 1996 as increased marketings more than offset the milk price reduction. In FY 1997-99, aggregate farm income with BST would range from $250-$680 million lower, primarily as a result of a lower USDA price-support level compared with the non-BST scenario. Over the six-year period, aggregate farm income would decline about one percent, with the annual decline decreasing in later years. Farm income, net of assessments and production costs, would follow a similar pattern (see Table 3). With BST, consumer (buyer) costs for milk between FY 1994 and FY 1999 are expected to decrease between $44 million and $770 million annually -- again due to higher quantities produced and decreases in milk prices.

a. **Impact of BST Use on the Federal Budget**

With the use of BST as assumed above, Federal Government costs would be expected to rise by about $297 million, compared to no BST use, from FY 1994 through FY 1999. USDA's dairy price-support program would likely cost an additional $510 million, FY 1994 through FY 1999, about 40 percent of total dairy program outlays over the same period, and about one percent of total projected Federal crop subsidies for this period. The level of additional outlays would rise to $153 million in FY 1996 and then trend downward, due to lower CCC purchases needed to

support the mandated minimum price of milk. Overall, total CCC purchase costs of dairy products would be higher, relative to the without-BST scenario, as a result of the higher milk production levels.

With the use of BST, the cost of Federal Government domestic feeding programs would be expected to decrease. Reductions in the retail price of fluid milk would decrease the Federal per-participant cost of providing fluid milk, cheese, and infant formula to participants in the Special Supplemental Food Program for Women, Infants and Children (WIC). This would permit WIC, which is funded as a discretionary grant program, to serve additional participants in FY 1994-96. By the end of FY 1996, under the President's program, WIC will be fully funded, and retail price reductions caused by BST would lower the cost of the WIC food package -- thereby lowering the cost of providing WIC to all participants in FY 1997 and beyond. Total savings -- actual or imputed, since WIC is within the Budget Enforcement Act's discretionary spending caps -- are estimated at $64 million over six years, $53 million would be considered by the Administration as actual budget savings, and the remaining $11 million would contribute to full funding for WIC by the end of FY 1996.

The fluid milk price decrease would also lower the cost of the Thrifty Food Plan (TFP), the basis for calculating benefits for the Food Stamp Program, and the average food stamp benefit in FY 1998. Because of TFP calculation rules (the maximum benefit is rounded down to the nearest dollar), changes in the TFP do not translate directly into changes in average food stamp benefits and Federal costs before FY 1998. It is estimated that the changes would save $80 million per year in FY 1998 and FY 1999, and continue at this level in future years.

In addition, introduction of BST would decrease the cost of providing fluid milk and dairy products in the child nutrition programs (National School Lunch Program, School Breakfast Program, and Child and Adult Care Food Program). It would not likely affect Federal costs, however, because program reimbursements are indexed to changes in the Consumer Price Index for Food Away From Home, which is unlikely to fully capture changes in fluid milk prices of the magnitude projected.

Overall, with BST, net annual Federal Government costs would range from $153 million higher to $122 million lower, and average about $50 million higher annually for the six-year study period. For the period FY 1994-2003, Federal feeding programs, with BST, would be expected to achieve savings in each fiscal year after FY 1997, and produce net cumulative deficit reduction over 10 years -- fully offsetting the increased costs of USDA's dairy price-support program for the same period.

b. **Impact of BST on Federal Milk Market Orders**

It is not anticipated that BST adoption will have a significant impact on the Federal Milk Market Order Program, which establishes regional milk prices to provide orderly production and marketing. The estimated increases in U.S. milk production due to BST will boost milk marketed under Federal orders, since about 70 percent of the milk marketings in the country are delivered to plants regulated by Federal milk market orders. At most, these additional marketings might require some loosening of current requirements and diversion limitations under the orders.

However, the Federal Milk Market Order Program has already demonstrated that it is able to make these types of pooling adjustments, such as when milk production was expanding rapidly during the late 1970s and early 1980s.

9. Effects of BST on Farm Structure and Location of Milk Production and Processing

Product testing of BST under the typical conditions required by FDA has produced increases in milk production in the range of 10 to 20 percent for BST-treated cows during the treatment period. However, the increases in milk production depend on good herd management. The individual farm production increases combined with market price and input cost effects raise questions as to BST's structural effects on the U.S. dairy industry.

a. Effects on Farm Structure

The 1987 USDA study of the effects of BST on milk supplies, commercial use, milk prices, dairy industry structure, and the international competitiveness of the U.S. dairy industry concluded that structural changes already under way in the industry would be reinforced, but not fundamentally changed, with the availability of BST (Fallert, et al., 1987). A 1990 update and extension of the 1987 study by USDA (to examine small- and medium-sized farms and the altered export position of the U.S.) reached essentially the same conclusion (Blayney and Fallert). Put another way, recent trends in the structure of the U.S. dairy industry would continue, with or without BST availability and adoption.

Several studies of the effects of BST have been made (and the results released) since the USDA's two studies. None of the studies differ significantly with respect to the major assumptions regarding product availability, product cost, milk . production response per cow, adoption, and feeding practices.

Consolidations of small- and medium-sized dairy operations have been going on for decades (see Table 5). Many technologies have been developed and adopted (or not adopted) by dairy farmers in that time period. BST is another technology being made available for consideration by the nation's milk producers. Its use (or non-use) will be one more factor in the dynamic adjustments going on in the dairy industry, but is not likely to alter the path of adjustment dramatically.

The effects of BST use as it relates to the size of dairy farms has not been fully determined. Analysts generally characterize BST as a "size-neutral" technology: no significant capital or equipment expenditures are required to use the product. BST's characteristics should make it equally accessible to managers of small and large herds. It is also size-neutral in the sense that farmers with small herds will benefit as much with BST adoption on a per-cow basis as farmers with larger herds, so long as managerial ability is equal. This is in contrast to a technology like bulk tanks that became prevalent in the 1950s and 1960s. In many cases, dairy producers had to decide to make substantial investment in bulk tanks, as well as milking equipment and facilities, in order to remain in business. These capital-based technologies tend to favor large producers.

However, if BST is heavily adopted and milk at least some of the smaller farmers that do not adopt BST might be forced out of the dairy business, because they would not be producing

economically sufficient volumes of milk. As one analyst concluded, " . . . we do not know to what extent small dairy farms will be affected by the introduction of BST. It is ironic that we may not even know the answer with certainty after BST becomes available, because of the complex interactions of the myriad of factors affecting farm size and production . . ." (Tauer, 1992).

Should any milk-producing State or region in the country prohibit BST use while all other regions adopt it, dairy producers prevented from using the technology would be disadvantaged, and their production share of the national market would decline. In addition, producers in the region of the ban would be subject to a price decline commensurate with the nationwide decline in prices as other producers adopt the technology (Fallert and Hallberg, 1992). This same phenomenon would apply to producers who voluntarily choose not to adopt BST technology when it is available to them (see Table 3).

Some studies indicate that herd management practices resulting in the most beneficial use of BST are commonly practiced on larger farms, and that these large farm operators are more likely to use BST. Other studies (Fallert et al., 1987; Yonkers, 1989; and Angus, 1989) have shown that small- and medium-sized farms would have higher returns with BST than without it -- the same as large farms.

There are many complex issues related to technology adoption and the structure of dairy farming that are not based on economics. It would appear that a technology like BST that increases output without requiring added capital facilities could be particularly beneficial to producers financially unable or unwilling to readily expand operations, a characteristic that may describe many smaller producers. Producers nearing retirement may also find in BST a way to increase returns without taking on long-term debt.

Some analysts have suggested that small farmers are aware that BST technology could benefit them, but are not, for whatever reason, interested in using it. At no time in the past has the Federal Government prevented a technology from being adopted on the basis of socio-economic factors.

b. **Effects on the Location of Milk Production**

A growing proportion of U.S. milk production is occurring in the West and Southwest. This growing share of production has been ongoing for nearly four decades, and has accelerated in the last 20 years (Fallert, et al., 1993). Several forces underlie the production growth in the West and Southwest, including: favorable climate; economies of size; an adequate labor supply; career development (learning new production skills) within largescale farms; regional economic growth; availability of business management and dairy support systems (technical experts in accounting, financial management, nutrition and feed supply, and veterinarians); and continuing regional population growth, with its associated demand for milk and dairy products. It is not clear that BST will dramatically alter the growth in Western and Southwestern production; other factors are more likely to be the major ones affecting production there. An analysis by Fallert and Hallberg (1992) indicates that if all the nation's dairy-producing regions adopt BST equally, the milk market shares of the different regions would not be affected greatly. The share of the

nation's milk supply produced in the Northeast and Upper Midwest would increase slightly with BST adoption, while that of the West Coast and Southern Plains would decline slightly.

c. Location of Milk Processing

The location of fluid milk processing and dairy product manufacturing plants has tended to be "where the milk is". In recent years, there has been excess processing and manufacturing capacity in the Upper Midwest, while there has been a shortage of capacity in the Southwest. Limited short-run capacity has probably restrained milk production expansion in California, New Mexico, and Texas. Much of the cheese consumed in California comes from Wisconsin, but the butter and nonfat dry milk produced in California more than satisfies the State's demand.

California and New Mexico are increasing their cheese manufacturing capacity, which will provide additional outlets for the area's growing milk production (Fallert, et al., 1993). There is also evidence of increasing cheese manufacturing capacity in Idaho. The Pacific Northwest is another area of growing milk production that will need additional marketing outlets. BST's commercial use is not expected to affect significantly the locational changes in the milk processing industry.

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CHAPTER IV.

EFFECTS ON U.S. CONSUMPTION OF DAIRY PRODUCTS

Consumer response to dairy products from BST-treated cows is critical for assessing BST's broad impact. If consumers reject "BST milk", BST would recede as a commercial product. But could it also lead to reduced consumption of other milk, or ice cream, or other dairy products? Would consumer resistance lead to an oversupply of milk, lower prices for farmers, and higher Federal dairy price-support costs? If a sizable market for milk is indifferent to the issue of BST, will all dairy farmers be required by market forces to use BST, and to expand their herd or abandon dairy farming? Answers to these questions depend, in part, on the attitudes of consumers towards BST.

This chapter describes what is known about consumer attitudes toward BST, and summarizes the evidence from relevant studies and surveys. It briefly reviews recent cases of consumer resistance to food technology, to explain patterns of possible reaction to BST. It offers a judgment on the implication for consumer demand, and presents the results of a recent survey of consumer and health groups on BST.

It is worth noting the difficulty of accurately predicting consumer behavior. Consumer acceptance of milk from BST-treated cows constitutes a major area of uncertainty in assessing the effects of BST use. The available information on consumer reaction consists primarily of consumer surveys, which usually include explanations of BST because many, perhaps most,

consumers were initially unaware of, or had very limited knowledge of, BST. This circumstance makes the subsequent surveys difficult to interpret, because it is uncertain how strongly previously uninformed consumers hold their views. A second source of uncertainty is the "what if" nature of the surveys, because commercial use of BST had not been approved by the FDA at the time the surveys were conducted. Thus, respondents were not faced with the decision to purchase or not purchase products from BST-treated cows. Therefore, it is unclear whether stated intentions with respect to BST will translate to action.

1. **Consumer Attitudes Toward BST**

Consumer views toward biotechnology are generally positive, with 67 percent of consumers in a national sample agreeing that biotechnology will personally benefit them in the next five years (Hoban and Kendall, 1992). Almost three-quarters of over 1,200 respondents believe biotechnology will have a positive impact on farm economic conditions, food quality, and nutrition. Two thirds feel biotechnology will have a positive impact on environmental quality. A survey conducted for the Office of Technology Assessment found that consumers thought the benefits of biotechnology outweighed the risks, and that consumers were willing to accept a relatively high risk to the environment to gain the benefits of genetically engineered organisms (U.S. Congress, OTA, 1991).

Asking people to identify concerns sensitizes them to a potential safety hazard. Therefore, the number of consumers identifying a hazard should be interpreted with caution, since it may overstate public anxiety. In a recent national survey, 35 percent of consumers could not describe a negative effect of biotechnology (Hoban and Kendall, 1992). Concerns volunteered by the remaining consumers included: 24 percent -- possible unpredictable adverse effects; 23 percent -- application of either traditional techniques or biotechnology to humans or animals; 18 percent -- fear of chemicals; 18 percent -- threats to the balance of nature. Acceptance of plant applications is greater than animal applications for both biotechnology and traditional agricultural techniques (Hoban and Kendall, 1992; Hoban, 1990).

Studies of consumer attitudes toward BST began soon after the announcement of its development under FDA's guidelines for new animal drugs. Eleven surveys taken during 1986-1990 were summarized in 1992 (Smith and Warland). The responses were quite consistent, although the surveys varied in the number of topics, the role of the respondent as food shopper, method of survey, representativeness of sample, primary focus, BST information provided to respondents, and survey "tone". First, general concerns about BST use were expressed. Second, respondents supported labeling milk that comes from cows treated with BST. Third, a significant number of respondents indicated that their future milk consumption would likely decrease after introduction of BST in the marketplace.

Other survey results support the conclusions from the Smith and Warland summary. In a 1990 North Carolina survey, farmers, consumers, and industry leaders were surveyed concerning BST (Hoban). The consumer results were similar to those reported by Smith and Warland -- consumers expressed concern about the use of BST and its effects.

A survey of New York households conducted in 1990 identified consumers who said their consumption of milk would decline if BST were approved. They were younger, more aware of BST, consumed larger quantities of milk, questioned BST safety, wanted labeled products, were not price responsive, were philosophically opposed to BST technology, and were unwilling to spend great amounts of energy obtaining more information about the technology. This study concluded that Outreach of the consumers will play a major role in determining demand effects for products derived from use of BST (Kaiser, Scherer, and Barbano).

A more recent survey was commissioned by Johanna Dairies, Inc., a fluid processor located in New Jersey. The general conclusions were the same as those of previous surveys: concerns about BST use, desirability of labeling milk from cows receiving BST, and likely consumption declines (Johanna Dairies, 1993).

The most recent survey was conducted for the Grocery Manufacturers of America (GMA) and followed FDA approval of BST on November 5, 1993. The poll of 1,000 households over the Thanksgiving weekend reported strong milk consumption and consistently high consumer "trust" in the milk supply despite BST approval. No one cited BST as a reason for reduced milk consumption. Two earlier national polls sponsored by the GMA apparently confirm these findings (Grocery Manufacturers of America, 1993).

Other research corroborates low consumer resistance to BST. Monsanto has been conducting an on-going consumer survey from 1989 to the present, focusing on 5,000 female heads of households to track their reactions to BST use. Results indicate that BST has received a lot of exposure, and the attitudes of women who were aware of it have been predominantly negative. Despite that, only nine women (less than two-tenths of 1 percent in this research) have reported reduced milk consumption for themselves or their children that they attributed to "chemical contamination" or "BST". This is in spite of the fact that milk from BST field trials have been present in the consumer supply since 1985, and has been widely reported by the news media. The respondents continued to show high levels of trust in milk safety and generally positive trends in their own and their children's milk consumption (Westgate Research, Inc.).

It is likely that two factors will be important in determining the effect of BST use on consumers and the demand for milk. The first is the degree of consumer trust in public and private , groups who make statements about the safety of dairy products made from milk from BST-treated cows. The second factor is the extent to which consumers will feel strongly enough to reduce milk consumption, even though milk from BST-treated cows has been shown to be safe. Consumer knowledge of BST is limited and can be influenced by both the content and source of information. The Monsanto study showed that at least 25 percent of female heads of households in the U.S. have been aware of BST since 1989.

FDA has been saying for several years that milk from BST-treated cows is safe for human consumption, but some consumers question FDA's credibility. A two-state analysis of consumer attitudes toward BST use to increase milk production efficiency indicated one quarter or fewer had heard of this use (McGuirk and Kaiser, 1991). On the basis of current knowledge and a description of BST, 29 percent to 36 percent considered milk produced from BST-treated animals to be safe, while 40 percent to 45 percent were uncertain. A survey by Hoban and

Kendall (1992) covering biotechnology in general showed consumers more confident (a lot or some trust) in information received from dietitians/nutritionists, farmers or farm groups, and university professors than in information from the Federal or state governments. Biotechnology companies were at the bottom of the list, but still thought trustworthy by close to 70 percent of those surveyed.

More recent research indicates consumers are concerned about BST. However, this concern is at a level comparable to other food safety issues. In California, 41 percent of a consumer sample expressed major concern about the safety of milk from cows given a hormone to increase production (Bruhn, 1993). While this percentage is high, it is within the range of those concerned about other issues. The percentage expressing major concern extended from a low of 24 percent for produce modified by biotechnology, to a high of 50 percent for bacterial contamination; 44 percent were concerned about pesticide

When asked how they decide on safety issues, people indicate they listen to both sides of an argument and then decide for themselves based on what sounds logical (Bruhn, et al., 1992b). The need for a nutrition Outreachal program on the effects of agriculture-related biotechnology and BST in particular seems clear. People at all levels of formal Outreach and science background expressed interest in information about biotechnology, its health impacts, environmental benefits, and risk control (Hoban and Kendall, 1992). Receiving information from more than one source increases credibility, as does citing medical and laboratory reports (Bruhn, et al., 1992b).

The public has a positive attitude toward biotechnology, but many persons have limited background in this area and wish additional. information.

2. Historical Cases of Food-Technology Controversies

While consumer survey evidence indicates that BST will have difficulty gaining acceptance, historical evidence might suggest otherwise. It may seem difficult to believe today, but one of the most serious food safety/new technology debates related to the pasteurization of milk (Tobe, 1967). In the early l900s, opponents argued that the process would create a health risk, and to some extent their efforts succeeded. It was many years before most milk reaching consumers in some parts of the country was pasteurized.

Recent concerns about technology and food safety are difficult to interpret. In general, consumers have identified pesticide and chemical additives or residues as their chief concerns about food. Scares over particular additives or residues have created temporary shifts in consumption away from the affected foods, but consumption has later rebounded. One example is the 1982-83 milk contamination problem in Hawaii. Residues of the pesticide heptachlor were found in the milk supply of Oahu (Kuchler, McClelland, and Offutt; Smith, van Ravenswaay, and Thompson).

More recently, the controversy surrounding daminozide (trade name Alar) temporarily reduced apple consumption. Irradiation of fruits and poultry, another controversial technology, is also

difficult to interpret for clues to BST adoption, because it evokes fear of nuclear accidents and waste, subjects beyond the safety of the food itself (Lee).

Another recent example is the occurrence of E-coli H57:157 in beef in the Pacific Northwest that was fatal to some consumers. This and subsequent incidents of this foodborne pathogen received wide publicity. However, there was no apparent reduction in beef consumption.

Moreover, some uses of biotechnology in food and health products have produced no consumer resistance. The recombinant DNA protein, chymosin, which is now used in 40-60 percent of all U.S. cheese production, was approved by FDA in the late 1980s. Cheese made with recombinant chymosin produces a better quality product and has resulted in no adverse effects on consumers. The introduction of recombinant chymosin was accompanied by minimal public comment, and special labeling is not required. Another example is the recombinant biologic, insulin, which is injected by thousands of people every day to control diabetes with no adverse effects from its recombinant origins.

3. **Labeling BST Milk and Dairy Products**

The labeling of food products relies on standards of identity (the product meets specific requirements), nutrition information, and modifications that might pose health or safety risks. FDA has determined that milk produced from BST-treated cows will not need to be labeled, since there exists no legal basis for special labeling. However, voluntary labeling stating that milk is from cows not receiving BST will be permitted, provided it is "truthful and not misleading" (HHS News, November 5, 1993).

The effect of labeling, like the effect of BST use in general, will depend on the number of consumers who are aware of BST and feel strongly enough about it to translate attitudes into action. Labels indicating the use of biotechnology in producing food products were considered very important by 85 percent of the consumers responding in the Hoban and Kendall study (1992). That level of interest suggests a market for labeled milk will develop. The declining costs of non-labeled milk could discourage some consumers from purchasing milk or dairy products labeled as from cows not treated with BST. However, processing and distribution systems required to market two separate products (voluntary labels versus non-labels) could increase the cost of all fluid milk products, even if voluntary labeling of milk from cows not treated with BST becomes prevalent.

3. **Implications for U.S. Demand for Milk and Dairy Products**

The studies of consumer reactions to the use of BST have focused on fluid milk consumption. If the survey results translate into action, respondents could decrease consumption by 4 to 20 percent. These are percentages of consumers who would stop purchasing milk altogether. A 4 to 20 percent reduction in fluid milk demand is equivalent to a 2 to 8 percent decline in total milk demand. Consumer surveys have not explored the effects of BST on the demand for milk products such as cheese, non-fat dry milk, butter, yogurt, and ice cream. Resistance could be lower for these products than for milk, because the use of the recombinant DNA protein

hormone, chymosin, since l990 in 40-60 percent of all cheese made in the U.S. has caused no perceptible decline in cheese consumption.

Actual changes in demand, however, will depend on the number of consumers who have developed strong persistent, negative attitudes toward BST, and who will translate those attitudes into action by reducing consumption of milk and dairy products from BST-treated cows. Furthermore, since milk from non-BST treated cows is expected to be available to consumers, consumers concerned about BST will be able to purchase milk and dairy products from untreated cows. Consequently, a significant reduction in demand for milk and dairy products due to BST is not anticipated. The degree of stated concern about BST in surveys is similar to stated levels of concern about other food issues. The need for credible nutrition information and Outreach on BST, is substantial, and could likely reduce concerns about BST.

4. **Consumer Comments Concerning BST**

FDA and USDA have received comments from consumers and consumer organizations on the subject of approval and labeling of BST. This feedback has come in the form of written comments to dockets, presentations at advisory committee meetings, and telephone calls.

Consumer comments on FDA dockets regarding BST have run 15 opposed and 1 undecided. FDA received 125 calls from consumers -- all opposing BST -- following the announcement of its approval on November 5, 1993. Several national consumer organizations testified at FDA's two FDA Advisory Committee meetings in opposition to the approval of BST. The primary reasons stated by consumers and consumer groups for opposing BST include:

- small- and medium-size farms will be hurt by BST approval;
- synthetic hormones will change the character of milk;
- BST has no therapeutic benefit;
- BST presents an unnecessary risk to consumers;
- antibiotic use will increase; and
- organoleptic changes will occur in milk from BST-treated cows

Consumer representatives at the FDA Food Advisory Committee's May 6, 1993, hearing concurred that consumers want to know whether milk is from BST-treated cows. They described the source of consumer reaction as:

- fear of new technology;
- lack of long-term data;
- emotional link between milk and children;
- concerns with animal cruelty;
- consumers' right to know;
- distrust of government;
- concern about policies that increase the surplus of milk;
- support for small-scale agriculture; and
- desire to minimize risk wherever possible.

Consumer organizations that have stated positions opposed to BST use include:

- Consumer Policy Institute/Consumers Union;
- Consumer Federation of America;
- Pure Food Campaign (Foundation on Economic Trends);
- The Humane Society of the United States;
- Community Nutrition Institute; and
- New Council on Food Safety. Members of the Council that oppose BST use include:
  - ANTLER Arizona Consumers Council
  - Briar Patch Small Business Network
  - California Food Policy Advocates
  - Community Nutrition Institute
  - Consumer Action for Food and Health
  - Consumer Association of Kentucky
  - Consumer Pesticide Protection Project
  - Consumers United For Food Safety
  - Food and Water
  - Harlem Consumer Outreach Council
  - Hartford Food System
  - Institute for Agriculture and Trade Policy
  - Louisiana Consumers League
  - Minnesota Food Association
  - Mothers and Others for Safe Food
  - NE Task Force on Food, Farm, and Consumer Policy
  - North Carolina Consumers Council
  - Pennsylvania Citizen Consumer PA
  - Institute for Community Service
  - Sustainable Food Center

Other groups sensitive to consumer responses have stated positions in favor of BST use, including:

- Institute of Food Technologists;
- American Dietetic Association;
- Council on Agricultural Science and Technology;
- University of California Biotechnology Research and Outreach Program;
- International Dairy Foods Association;
- American Farm Bureau Federation;
- National Pork Producers Council;
- United Fresh Fruit and Vegetable Association;
- National Cattlemen's Association;
- Grocery Manufacturers of America;
- National-American Wholesale Grocers' Association;
- Consumer Alert;
- Competitive Enterprise Institute; and,
- American Medical Association.

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CHAPTER V.

IMPACTS ON THE ENVIRONMENT

Most discussion of BST's safety considers the direct risk to human health. The impact of any chemical substance on the environment -- the air, soil, and water around us -- can affect human and animal well-being no less significantly. How could BST use affect the environment? Could it be harmful, perhaps causing toxins to accumulate on farms over a period of years? Or would it ameliorate the environment, by reducing the number of cows needed to produce a given amount of milk? How widely have scientists studied BST's impact on the environment, and how much do we know for certain?

A large body of literature produced by environmental scientists has considered the various potential ways that BST could help or harm the environment. Analysts have studied the impact of BST use on feces, urine, nitrogen, and phosphorus outputs by cattle; cropland for feed; soil erosion losses; air pollution; and requirements for irrigation water and fossil fuel energy. These studies have concluded that use of BST would have slight, net beneficial effects on resource utilization and environmental impact per unit of milk produced, because the same quantity of milk would be produced with fewer cows. In fact, there is no significant dissent in the scientific community about the overall beneficial nature of BST to the environment, though there are differing views about the degree of impact. The least is a neutral impact. The magnitude of beneficial effects would depend on the extent of adoption and the average milk production response to BST. The scientific studies on BST have encompassed the range of management and environmental conditions that characterize milk production around the world.

A required part of FDA's new animal drug application assessment of the potential environmental impacts of manufacturing and using the drug (FDA, 1985; Jones and Matheson, 1993). Under the National Environmental Policy Act (NEPA), FDA requires applicants to conduct the necessary scientific studies to determine a new drug's potential impacts on the environment, and to describe them in a publicly available document called an environmental assessment (EA). FDA verifies the soundness of the environmental studies by audit and inspection and, on the basis of the verified information, draws its own conclusions about the potential environmental impacts. In the case of the manufacture and use of BST in dairy cows, the FDA found that there were no significant environmental impacts (either adverse or beneficial) to be expected. The finding of no significant impact (FONSI; FDA, 1993) and the EA (Monsanto, 1992) provide a synthesis of the potential environmental impacts considered in the decision whether to approve BST for use in dairy cows. (Both documents are available for public inspection at the FDA Dockets Management Branch under Docket Number 93-27876.)

BST is manufactured through a fermentation process using a recombinant DNA-containing bacterium, Escherichia coli K-12. The fermentation site in Austria is designed and operated at the level of biocontainment recommended in the National Institutes of Health (NIH) Guidelines for Research Involving Recombinant DNA Molecules (NIH, 1986). FDA has inspected the site where BST is manufactured and found that the firm properly operates, maintains, and monitors the facility consistent with the biocontainment level BLl-LS, described in the NIH Guidelines, and is in full compliance with Austrian emissions requirements.

Monsanto conducted tests on the recombinant production E. coli strain to confirm that it exhibited similar biological characteristics to non-recombinant E. coli K-12 strains (Monsanto EA, 1992). The tests measured how long the production strain would survive (compared to other E. coli strains) when introduced into environmentally relevant microcosms and also measured whether the novel genetic material (the recombinant DNA coding for BST) could be transferred under these conditions to other microorganisms residing in the microcosms. The results of the studies show that there were no significant differences in the die-off rates between the recombinant and non-recombinant E. coli K-12 strains tested, and that the recombinant DNA coding for BST was not transferred to other microorganisms. The sensitivity of measuring a transfer event in the test system was 1 transfer in 27 million bacterial cells. These studies were conducted under the FDA Good Laboratory Practices regulations and inspected, audited, and verified by FDA.

BST is packaged in individual dose syringes. Consequently, one syringe (and needle) is used and becomes waste each time a dairy. cow is injected. The Monsanto EA (1992) discusses the disposal of unused product and of expended syringes, some of which might contain small quantities of BST. To prevent exposure to the product and the contaminated used syringes, the firm included instructions on the product container for the proper handling of used and waste syringes. The handling instructions provide adequate information for dairy farmers who will be using the product to provide for the safe and legal disposal of used syringes. In addition, Monsanto is providing dairy farmers with an optional waste management program that provides farmers with a postage-paid, mail-back kit. Dairy farmers can mail spent syringes and needles to a medical waste treatment facility where the contents will be destroyed by incineration or by sterilizing and shredding.

1. **Direct Environmental Impacts**

No direct adverse environmental impacts are expected as the result of BST use in the U.S. BST itself is not persistent in the environment. Consequently, accidental releases into waterways or soils during its manufacture, transportation, or administration do not pose a threat. Air emissions are not expected because of BST's very low vapor pressure. The use of BST does not produce harmful residues in milk, manure, or urine. Consequently, the use of BST does not result in increased loadings of residues into the environment.

2. **Indirect Environmental Impacts**

The use of BST can have indirect impacts on the environment through changes in land use and the U.S. dairy industry. Since fewer cows are required to produce a given amount of milk, the overall indirect environmental impacts of BST use are positive. BST use should reduce total herd feed requirements, manure production, and methane production, though these might increase slightly per cow. If larger dairy herds become relatively more viable, there is a potential for manure production to be more concentrated in some areas, which may cause some negative impacts locally. These changes in the structure of the dairy industry have been underway for several decades. The use of BST should have little effect on the regional location of milk production or on the size distribution of dairy farms (Fallert et al., 1987).

If, however, BST use were to accelerate the trend toward larger herds and the resulting concentration of manure production, any potential impact on water quality should be addressed by existing and proposed water pollution control programs.

Very large dairy operations (greater than 700 animals) are generally regulated as a point source of water pollution under ~ current law, and are subject to regulations controlling emissions of manure. Smaller operations can, in certain circumstances, also be regulated as a point source, but are not as a general rule. The majority of smaller operations are covered by nonpoint source (NPS) pollution programs.

Currently, various programs attempt to address NPS pollution --USDA provides financial incentives to farmers to reduce NPS pollution under the 1990 Farm Bill; NOAA and EPA administer a program under the Coastal Zone Amendments and Reauthorization Act (CZARA), which requires the use of Best Management Practices (BMPs) (i.e., manure pits, soil conservation tillage, and crop nutrient management plans) in certain areas; section 319 of the Clean Water Act authorizes EPA to fund State NPS programs. The effectiveness of these programs varies considerably from state to state.

In the context of the pending Clean Water Act reauthorization, the Administration is considering a broad watershed- and risk-based approach to control of non-point source pollution. States would develop and implement strategies to address water pollution on a watershed-by-watershed basis. Expansion of the use of BMPs to areas outside of the Coastal Zone would be one of several instruments available for the control of NPS pollution. Control of NPS pollution from dairy farms within this broader context could help to reduce localized negative impacts resulting from concentration of manure production.

Overall, it is expected that the nationwide impact of BST use on water quality should be positive -- with increased milk yield per cow, the production of a given quantity of milk would require fewer cows, and hence generate less manure. This would reduce the total volume of manure that would need to be managed under existing and proposed programs.

a. **Feed Intake Requirements**

By increasing milk production per cow, by more than the additional feed required, BST reduces overall feed intake per unit of milk produced. Because BST does not change the efficiency with which feed energy is used for maintenance or milk synthesis (Eisemann et al. 1986 and Tyrrell et al. 1982), feed intake requirements are reduced by diluting the maintenance requirement across a larger production level. Johnson et al. (1992) performed a detailed analysis indicating that overall feed intake requirements would be reduced by about nine percent if BST were completely adopted and the number of cows declined to keep the amount of milk produced constant. This nine-percent reduction comprised 13-percent reductions in alfalfa and corn silage intake, and a less than one-percent increase in grain consumption (principally cracked corn and soybean meal).

b. **Methane Production**

Methane emissions from cows and manure are reduced as the result of the reduced herd size. Johnson et al. (1992) estimate a nine-percent reduction in methane emissions directly from dairy cows due to both increases in productivity and changes in cow nutrition. EPA (1993b) estimates about a three-percent reduction in methane emissions associated solely with increased productivity (implications of changes in cow nutrition are estimated separately in EPA (1993b)). Given that U.S. dairy cows emit an estimated nine million metric tons of carbon equivalent (MMT C) per year (EPA, 1993a), the emissions reduction associated with BST use would be about 0.27 to 0.81 MMT C per year.

Reductions in methane emissions from manure have not been quantified to date. Reductions in total feed consumption, and improvements in cow nutrition, will reduce manure production.

Consequently, there is the potential that methane emissions from manure will be reduced. Methane emissions from manure could increase if an increasing amount of manure is handled in liquid manure management systems without methane recovery. However, there is no indication that BST use would have an impact on the manner in which manure is managed.

c. Feed Production

The environmental benefits of reduced feed production include reduced water, energy, and cropland requirements. The reduced demand for cultivated feeds, such as alfalfa and corn silage, may reduce pressures on soils and the use of agricultural chemicals. Overall, alfalfa and other similar cropland could shift to other crops, so that the total impact would be negligible.

While it has been estimated that with BST use the higher-producing dairy cows will require increases in grain intake, these increases will be almost completely offset by reductions in the number of cows required to produce a given amount of milk. Overall, the grain intake requirements per unit of milk production increases only slightly, by less than one percent (Johnson et al., 1992). This increase is small relative to the reductions expected in corn silage requirements per unit of milk, so that overall impacts are expected to be negligible. The future level of national milk production will have a much more important impact on total grain requirements for dairy production than will the change in nutritional requirements caused by BST use.

d. Other Environmental Issues

BST use will also affect other aspects of the environment. The reduction in manure production will reduce the overall manure load on soils. This reduction will also reduce manure handling, costs for farmers. However, manure handling problems-are generally very local in nature. For example, if BST use enables individual farmers to expand the number of cows in their operations, the manure production from individual farms may increase, resulting in an increase in manure loading at these farms. Existing manure management requirements should limit the adverse impacts from such an increase, however.

It has also been estimated that BST use will increase the rate of decline in the number of dairy cows and dairy producers in the U.S. As milk production per cow has increased in the U.S. over

the past 30 years, the number of cows has dropped dramatically. This trend is expected to continue, with or without BST use, and BST will have a small impact relative to the increases in dairy cow productivity expected to be achieved by other means in the next 10 to 20 years (EPA, 1993b).

Generally, the decline in cow numbers and producers has no specific environmental impact. It has been suggested, however, that larger producers have an increasing competitive advantage over smaller producers, and that BST could magnify this advantage. Because of their larger concentration of animals, large producers can have local environmental impacts on soil and water resources. However, BST use is not capital intensive, and consequently can be used by small producers with relative ease. Consequently, the use of BST is not expected to increase the direct advantage that large producers have over small producers.

The impacts of BST use on riparian damage and biodiversity are negligible. Reductions in feed production and the size of the U.S. dairy herd may reduce pressures on sensitive riparian areas or key habitats, but such potential benefits will likely be extremely small.

As summarized in the 1991 report by the Office of Technology Assessment (OTA), a gain in production efficiency would reduce environmental pollution. For a given quantity of milk, a gain in production efficiency would mean less feed, less fertilizer, less pesticide use, and fewer animals. With fewer animals, there would be less fecal waste, urinary nitrogen, and methane gas.

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CHAPTER VI.

EFFECT ON U.S. EXPORTS

International trade will be increasingly important for U.S. agriculture in the years ahead. Export markets for U.S. dairy products have been expanding in recent years, and offer the important prospect of significant growth for dairy products. Will use of BST in U.S. milk production encourage or threaten the dairy industry's hope of becoming a world supplier? How much risk is there that foreign consumers will reject U.S. dairy products? Do other countries consider BST to be safe, or are they intent on discouraging its use? What do moratoria on BST use imply for the free trade of other products?

This chapter considers the international trade dimension of BST use. It assesses the likely impact of BST on U.S. export markets. It describes the official attitudes towards BST around the world, and particularly in the European Union (formerly the European Community). Finally, it explains the issue of nontariff barriers to trade, and BST's relationship to this issue.

1. **Status of Approval in Other Countries**

Approximately 25 countries have approved of the use of BST, and more may follow in view of FDA's recent approval of Monsanto's BST product.

BST use has not been formally banned by any major dairy-importing country, although major dairy exporters maintain a moratorium on its use. Many dairy-importing countries have approved the use of BST: Algeria, Brazil, Bulgaria, Costa Rica, the Czech Republic, the Former Soviet Union, Honduras, India, Jamaica, Mexico, , Namibia, Pakistan, Romania, the Slovak Republic, South Africa, and Zimbabwe. Several countries appear content to observe the U.S. experience before acting on BST approval, and others have shown greater interest in BST since FDA approval.

The countries that have withheld approval of BST use are not major dairy importers. Only Argentina, a minor dairy exporter, is known to have instituted legal bans on both domestic BST use and imports of dairy products from countries using BST. The three leading dairy exporters -- the European Union (EU), New Zealand, and Australia -- have delayed BST use in their own countries.

In New Zealand and Australia, which have a combined share of about one-fourth of world dairy product exports, BST has not been approved. Approval is not expected in New Zealand and perhaps not in Australia, although the main reasons are different from the EU case. The two countries are the lowest-cost milk producers in the world and claim they do not need BST to remain competitive (Baker, et al., 1990). Both countries also use pastures more intensively in their feeding than do the U.S. and the EU. In 1992, the Australian Agricultural and Veterinary Chemicals Council declined to approve BST, but did not cite any scientific objections. Following approval of BST in the U.S., Australian authorities received inquiries from the private sector indicating interest in a formal request for approval. It remains to be seen if U.S. approval will lead Australia to change its policy on BST use. New Zealand does not doubt the scientific basis for BST use by other countries, but BST is not licensed for use in New Zealand. Official New Zealand sources question whether BST would be effective in raising milk production in pasture-fed cows.

The EU, which supplies about 50 percent of world dairy product exports, has had a moratorium on BST use since 1990, despite scientific study results that would normally lead to approval. The EU is expected to extend its current moratorium through December 1994. The moratorium applies to the marketing and use of BST in the EU, but not BST production in the EU for export to other countries, or imports of dairy products from countries having approved BST.

One reason for the moratorium is to protect the EU from perceived social and economic changes that might result from adoption of BST. The problem in the EU is a practical one: it has a huge structural dairy surplus that requires billions of dollars worth of surplus disposal expense annually to subsidize exports and domestic use.

To manage its dairy surplus, the EU established marketing quotas in 1984. Because the quotas, scheduled to be in effect through the year 2000, are meant to limit production, the Commission of , the EU argued that a productivity-enhancing product such as BST is unnecessary and undesirable as long as the quotas are in place.

On a scientific level, the EU is in agreement with FDA that BST is safe. The UK Medicines Commission reviewed BST's safety, finding in January 1993 that milk and meat from cows receiving BST are safe for human consumption. In addition, the EU Committee for Veterinary Medicinal Products found no scientific grounds -- safety, quality, or efficacy -- on which to ban BST.

EU Commission agricultural officials have asserted that the main justification for the EU moratorium seems to be the potential effect of BST on European dairy farm structure and its impact on EU outlays. On the basis of results from an internally-conducted study, the EU Commission assumes large farms will benefit most from BST. It states that this contradicts one of the fundamental aims of the EU's Common Agricultural Policy (CAP) reform agreed to in May 1992, to offer direct support to the small- and medium-sized farms in rural areas. In addition to the socioeconomic impact of introducing BST, some have pointed out that greater dairy yields would lead to greater slaughtering of cows at a time when the EU beef market is experiencing difficulty, with overflowing intervention stocks and spending on disposal of surplus beef considerably over the EU budget.

EU Commission survey evidence also indicated the possibility of a consumer backlash against BST. However, the results of the Commission's study have not been universally accepted. In an attempt to move against the Commission proposal, the European Federation of Animal Health (FEDESA) published, in June 1993, an extensive review of the socioeconomic issues surrounding the debate on the approval of BST for use in dairy cows (Bent and Buckwell of Wye College, University of London). The results indicate that the aggregate effect of BST would be negligible in socioeconomic terms, and a benefit to individual producers under some circumstances.

The economic benefits of BST approval may be smaller in Europe than one might expect. At the producer level, the alternative uses of released resources are less profitable than in the U.S., and are seriously constrained by environmental, welfare, and supply management considerations that are now operating on all the major land-using agricultural activities in the EU. Similarly for consumers and government expenditures, the benefits from BST could not be realized due to the hindrance of current agricultural policy instruments.

Even if one accepts the findings of the EU Commission study, the concern about increasing meat supplies with improved productivity is clearly only a short run issue for the EU. If the EU market price and quota system were restructured to rationalize the increase of higher-producing cows, more milk could be produced from fewer cows. In the near term, more cows would be slaughtered, increasing beef supplies. However, increasing productivity in the longer term would reduce not only cow beef from culled cows, but also the meat currently produced from calves produced by these cows.

In response to concerns of EU Commission agricultural authorities, the Commission proposed that when the moratorium in effect on BST expires at the end of 1993, a seven-year extension of the moratorium be enacted by the EU Council. This period was chosen to coincide with the term of the current EU dairy quota regime, and would have explicitly linked BST approval to nonscientific criteria.

In December 1993, the Council of Agriculture Ministers rejected the Commission proposal. Instead, it approved a one-year extension of the moratorium. The only rationale stated for the extension was "to continue to study the various implications of the eventual decision which must be taken and notably, the consequences for international trade and the new situation created by the decision of the United States to authorize the placing on the market of BST as of 1 February 1994".

The Council reportedly took into account a broader perspective than just the effect of BST on the EU dairy and meat programs. It considered the potential chilling effect of a longer ban on future investment in biotechnology in the EU, as well as the potential incompatibility of such a measure with the EU's international obligations.

2. **Impact on Export Markets**

The approval of BST is expected to have little effect on U.S. dairy exports, which have increased significantly during the past decade. In 1982, U.S. dairy exports totaled $352 million, increasing to $762 million in 1992. Markets with potential future import growth for dairy products include East Asia, Eastern Europe, Central and South America, Mexico, South Asia, and many developing countries. Since nearly half of the U.S. dairy exports go to countries that have already approved BST for commercial use, BST adoption is not expected to have any effect on exports to those countries (see also Table 6). BST use has also been approved in the former Soviet Republics and in several Central European countries, a number of which have received U.S. butter donations.

In the highly competitive international dairy product market, some export market competitors not approving BST may allege that their dairy products have a quality or safety advantage. They may also claim that the safety and wholesomeness of U.S. dairy products have been compromised by the use of BST. While these , allegations may occasionally be effective, price and other commercial considerations are expected to continue to be the factors of greatest importance in determining U.S. export sales, particularly in developing country markets.

TABLE 6: MAIN U.S. EXPORT MARKETS THAT HAVE APPROVED BST AND THE VALUE OF THEIR 1992 U.S. DAIRY IMPORTS (Source: Bureau of Census, 1992)

Importer - Imports (millions $)

Mexico - 160.2

Former Soviet Union - 128.5

Algeria - 32.2

South Africa - 5.5

Brazil - 4.0

Honduras - 3.8

Romania - 1.9

U.S. dairy product exports to the 12 EU countries amounted to about $37 million during 1992, 5 percent of total U.S. dairy product exports. High-value specialty dairy products and industrial dairy ingredients such as rennet casein and whey products constituted most of these exports. However, with BST already approved for use in several major U.S. export markets, and more expected to follow, the ability of U.S. dairy farmers to capitalize on short-term international market opportunities depends critically on their ability to have access to all markets and not be excluded by local trade barriers labeled as "sanitary" and "phytosanitary" measures.

Milk productivity gains attributable to BST use in the U.S. while other countries ban BST use could lead to lower prices and increased U.S. competitiveness in international markets, especially given the superior management skills of U.S. dairy farmers. Conversely, other countries could gain a competitive edge over the U.S. dairy industry if they approved BST while its banned in the U.S.

3. **BST and Free Trade**

There is no conflict between BST use and any international obligations or proposed trade agreements. To the contrary, the exhaustive study of the safety, quality, and efficacy of BST under standard FDA procedures lends credibility to the product. A country wishing to ban imports of dairy products originating in the U.S. or another country that uses BST would incur the risk of a trade dispute because the ban would be seen as a nontariff barrier. Such a country would face potential trade retaliation unless there was a scientific basis for the ban.

International trade of meat, poultry, and dairy products depends on objective, science-based regulations. The three regulatory criteria internationally accepted for animal products are safety, quality, and efficacy. Imposing additional criteria, such as social and economic considerations, significantly alters free trade principles. These additional criteria, sometimes referred to as a "fourth criterion", are subjective and frequently used to erect non-tariff barriers to trade. Consistent, widely-recognized, and widely-accepted international standards and trade regulations are critical to avoid protectionist non-tariff barriers to trade -- particularly dairy product trade.

If the EU were to exclude U.S. dairy products because of BST, the U.S. would be justified in protesting that the EU was using unfair trade restrictions, as the product has been declared safe by both FDA and the EU Committee for Veterinary Medicinal Products. Such a dispute would be dealt with under applicable GATT provisions. The Treaty Text Sanitary and Phytosanitary (S?) Decision elaborates on Article XX(b) of the GATT, which allows Contracting Parties (CPs) to apply measures that may be inconsistent with the GATT, but that are necessary to protect human, animal, or plant health. The Decision obligates countries to ensure that health-related food and agricultural regulations that affect trade are based on scientific principles, and are not inconsistent with available scientific evidence. Contracting Parties agree not to use S? measures

as disguised trade restrictions. This section asserts that any CP will retain the right of national sovereignty to establish S? measures in protecting its citizen's health and safety. However, it states that CPs, when establishing these S? measures, will use science as a basis for the measures in order to minimize trade impediments, and will not arbitrarily discriminate against imports.

Given the clear scientific evidence of BST safety and the recent momentum established by the success in the GATT negotiations, it seems unlikely that the EU and other U.S. trading parties would risk increasing trade tensions by banning dairy imports from countries using BST.

BST approval removes some uncertainty about U.S. dairy trade with Mexico, which had already approved BST for commercial use. The U.S. status as a net exporter of dairy products to Mexico is expected to be enhanced by NAFTA, as Mexican population and income growth outpace milk productivity gains for years to come. Had BST not been approved in the U.S., there would have been an incentive to expand dairy operations in Mexico. Those dairies could have reaped the productivity gains from BST and sold dairy products back into the U.S. over the increasingly open border. There would still have been a question of whether the increased productivity from BST use would be sufficient to overcome Mexico's competitive disadvantage in milk production with respect to the U.S. With U.S. approval of BST, however, the question is moot.

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CHAPTER VII.

BIOTECHNOLOGY AND RELATED INDUSTRIES

Biotechnology research and product development promise many benefits, from new employment opportunities and economic growth to treatment for devastating diseases. In agriculture, biotechnology suggests a new era, improving food safety and nutrition, increasing commodity yields and reducing production costs, and maintaining an adequate food supply produced under more sustainable, environmentally friendly conditions. This would allow U.S. farmers and ranchers to compete better internationally and help feed an additional 2 billion people over the next two decades -- the estimated increase in world population during this period.

While BST is not the first use of recombinant DNA in food or health products, it is one of the first major commercial biotechnology products to be used in the U.S. food and agricultural sector and the first to attract significant attention. Its performance and the reaction of consumers and policy-makers to it could have an impact on the future of the agricultural biotechnology industry in the U.S., particularly the future of animal biotechnology in production agriculture. The first commercial agricultural biotechnology products will be of particular significance since these products will:

- influence public attitudes about other emerging products and applications;
- establish substantive and procedural precedents in the legislative and regulatory arenas; and

- affect the future willingness of the private sector to invest in similar product research and development (Kalter, 1985; National Research Council, 1987; Office of Technology Assessment, l99ld).

If BST is allowed to compete in a free market and enjoys a high adoption rate, it should have a positive effect on private sector investment in agricultural biotechnology. However, if BST is not allowed to enter the market for public policy reasons (or it is not accepted by the public), private sector investment could be discouraged. France apparently opposed the recent moratorium on BST in the EU in order to prevent erosion of its biotechnology leadership.

In the 1993 Omnibus Budget Reconciliation Act, Congress enacted a moratorium on the sale of BST for 90 days following its approval by FDA. This action departed from existing Federal policy on biotechnology. This policy, the 1986 "Coordinated Framework for Regulation of Biotechnology", states that regulation of products of recombinant DNA technology will not differ fundamentally from unmodified organisms or from conventional products, because existing laws and programs are considered adequate for regulating the organisms and products developed by biotechnology. The Administration will continue to base its regulatory policy on this coordinated framework, and will make refinements to facilitate commercialization of biotechnology products while providing ample opportunity for public comment.

A critical question about market and government responses to BST is whether these responses will extend beyond the immediate product area to affect all biotechnology, a sector in which U.S. industry leads the world. For example, if BST fails, either because of government restrictions or a lack of public acceptance, will the negative experience dampen the prospects of other agricultural biotechnology products such as pest-resistant cotton plants, or livestock genetically engineered to produce leaner meat? Will the negative impact extend beyond agricultural biotechnology to new drugs for the treatment of AIDS or cancer? Will the U.S. continue its leadership in biotechnology into the next century, or will actions affecting the agricultural sector diminish its world leadership and opportunities?

1. **Implications for Investment in Biotechnology**

a. **Economic Potential of the Biotechnology Industry**

It is predicted that the use of biotechnology in the health care, food, chemical, energy, and environmental clean-up sectors of the U.S. economy would grow rapidly in the l990s -- from a $4 billion domestic industry today to several tens of billions of dollars by the early 21st century (1993 U.S. Industrial Outlook, President's Council on Competitiveness, 1991). There are estimates that , biotechnology could surpass the computer industry in sales. The U.S. is currently the world leader in biotechnology; however, a strong spirit of competitiveness surrounds biotechnology internationally, and many foreign governments in Europe and Asia have incorporated biotechnology into their industrial policies for economic development.

Currently, the U.S. biotechnology industry is dominated by applications in the medical sector, which is well along with commercialization of products and a positive record of consumer

acceptance. In contrast, the pace of development in the agricultural biotechnology sector lags behind, in spite of its long-term economic potential. There are several reasons for this lag:

- a disparity in Federal research funding where, in FY 1992, 42 percent was invested in human health compared to S percent in agriculture;
- more difficult technical barriers in the agricultural sector, which increases uncertainty of outcome; consumer acceptance; and
- greater uncertainty in regulatory procedures for foods and products used in the environment.

Thus, the agricultural biotechnology sector generally i~ being fragile and financially vulnerable since it has of major success stories or consumer acceptance.

Biotechnology is one of the most research-intensive industries in our economy. Because many biotechnology products being developed for the pharmaceutical and agricultural industries require lengthy development and regulatory approval leadtimes, these products require large expenditures over many years to bring them to market. Relatively few biotechnology companies are profitable at this point in the industry's evolution. Most of the industry consists of small companies, with products still under development and no sales revenues. To continue their operations pending product introduction, these companies are heavily dependent upon outside equity investment. For that reason, any development that affects the availability of venture capital is likely to have a significant impact on the industry itself.

b. **Factors Influencing Financial Markets for Biotechnology**

A primary determinant of an industry's cost of capital is the degree of uncertainty over whether the companies in that industry will be profitable. The impact of uncertainty is particularly ~ important in the biotechnology industry because of the length and size of the investment necessary to bring new products to market. As a result, small changes in expectations can produce large fluctuations in the cost of capital. The private-sector National Biotechnology Policy Board recently cited the uncertainties affecting capital investments in the industry:

- technical uncertainty concerning the outcome of research and development efforts;
- uncertainty concerning the potential commercial success of new products produced by the research;
- uncertainty concerning risks of liability resulting from new products;
- uncertainty concerning the protection provided by intellectual property laws for these new products; and
- the "lemon effect" in which stock prices are broadly depressed and the cost of capital rises when investors suspect there are "lemons" among public offerings of the securities of biotechnology firms.

Because agricultural biotechnology is not as well established as medical-sector biotechnology, these uncertainties and risks are seen as greater. The injection of additional uncertainty as the result of public policy decisions or a lack of public acceptance of BST products might well have a disproportionate effect on the availability of capital in this sector.

Most analysts would say that, prior to market introduction, FDA approval of BST use has had little, if any, detectable effect on biotechnology capital markets. Other external factors have contributed more strongly to the broader biotechnology stock index, including issues related to health care reform. At the same time, evidence that the Federal Government is considering special restrictions on an agricultural biotechnology product, which has already passed through regulatory scrutiny, could have a negative impact on the availability of private sector funding for such ventures.

2. Impact of the BST Moratorium

It is difficult to quantify the effect of the current moratorium; however, it is possible to identify certain impacts. These include both short-term effects, which are already being felt, and possible longer-term effects, if the moratorium is extended beyond 90 days.

a. Short-Term Impacts

Four companies have reportedly invested as much as $1 billion over 12 years to develop BST. Monsanto is the only company so far that has obtained approval from FDA to market BST, under the trade name Posilac®. Thus, Monsanto should feel most of the immediate effects of the current 90-day moratorium.

One important effect of the moratorium on Monsanto has been in lost BST sales. It appears that Monsanto would have been the only supplier of BST during this period, and would have derived benefits both from the sales of the product and its status as first manufacturer and marketer of the product. Monsanto is also likely to have lost the other advantage of being first to market -- an opportunity to improve its production and distribution of the product and an opportunity to build market strength before the introduction of competing products.

It is difficult to estimate the more general short-term impact of the current moratorium on the biotechnology industry. Given Monsanto's disadvantage, the moratorium in the short-term may actually assist the three other companies that have developed BST products, if their products are approved by FDA soon after the expiration of the current moratorium. However, the precedent of a congressionally imposed moratorium on one of the first biotechnology products in the agricultural sector has sounded an cautionary note for investors and developers of such products.

b. Longer-Term Impacts

An imposition of a longer-term moratorium could have a major, negative impact on agricultural biotechnology, in particular applications of biotechnology to the livestock sector. Anecdotal evidence suggests that concerns over the lengthy regulatory review process and public debate on BST have already significantly dampened research and development of animal biotechnology products. A company developing porcine somatotropin (PST), which would be used to produce lower-fat pork products, has discontinued its efforts due to the high cost of obtaining regulatory approval, and other uncertainties.

Agriculture has not enjoyed the same level of public or private investment as pharmaceutical and health-related biotechnology. This is especially true for animal biotechnology, which receives about two percent of Federal research funding An estimated eight percent of private-sector investment in biotechnology research and development is being devoted to animal agriculture (Ernst and Young, 1991). Given this relatively small base of financial support, the animal biotechnology industry would almost certainly be hurt by a lengthy moratorium.

Two of the most likely effects of such a moratorium would be further constraint on the ability of small biotechnology firms to raise capital for research and development of animal biotechnology products, and a drying-up of the research pipeline as academic and Federal researchers channel their basic research projects into areas deemed more acceptable. In addition, a lengthy moratorium would prevent the growth in employment anticipated to result from introduction of the new product. It is estimated around 400 new jobs would be generated by BST suppliers following its introduction to the market. A U.S. ban on BST use could cause the loss of thousands of jobs if American biotechnology firms seek a more receptive governmental climate outside the U.S.

3. **Public Acceptance of BST and the Impact on the Industry**

When the moratorium is lifted, the fate of BST, as with other products, will be determined by the market. As one of the first agricultural biotechnology products to come to market, BST faces intense scrutiny. If dairy producers use BST and there are not serious concerns raised by the public about the safety of products from BST-treated cows, this will be a positive signal to the agricultural biotechnology industry. Thus, public acceptance of products derived from BST-treated cows have the potential to open the market for other agricultural applications of biotechnology.

Although immediate reactions to BST will be critical, long-range outcomes will also be important. For example, any adverse effect that might be attributable to the use of BST, or is rumored to be associated with the drug, could have a serious impact on the commercial viability of this and other products. Should the post-market surveillance program conducted by Monsanto detect increased levels of antibiotic residues in milk, or other unexpected results, public acceptance will be jeopardized.

In the U.S. today, perceptions gained through media messages can compete with facts concerning food production issues. The credibility of the messenger affects perceptions and judgments on these issues (Byers, 1991). The lengthy debate about BST in the press and Congress may have already influenced public attitudes. Opinion surveys about biotechnology in the U.S., as well as other countries, indicate distinctly different levels of reservations about different applications of biotechnology. For example, health care application ranks highest in acceptability. To date, use in animal agriculture engenders greater reservation than applications in the plant sector (Hoban, 1993; Eurobarometer, 199l) -

4. **Implications for U.S. Economic Activity and Competitiveness**

The U.S. biotechnology industry currently leads the world in the development of new products. This has been acknowledged by Western European biotechnology executives who have lobbied their political leaders to create a more favorable environment for biotechnology in the European Union, in order not to be left behind as the biotechnology industry develops in the U.S. (SAGB 1992). The long-term competitive strength of the U.S. biotechnology industry and its contribution to our economy will be determined by a large number of interrelated factors. Among these factors are the strength of the overall economy, national tax and financial policies, the legal and regulatory environments in which the industry operates, the extent of public and private investment in relevant research, and the extent of intellectual property protection available to the industry.

The challenge for the coming years is to extend U.S. leadership in the biotechnology industry and ensure that its products are safely and effectively applied to a wide variety of economic activities, enhancing the nation's current economic competitiveness. One key sector that stands to benefit from modern biotechnology is agriculture. Agriculture accounts for 15 percent of the U.S. gross domestic product, and is a key export earner, with foreign sales recently exceeding $40 billion annually. Biotechnology can assist in developing U.S. agricultural competitiveness through increased productivity of traditional farm and forestry products, as in the case of BST, and through value-added uses of farm and forestry products in the industrial and manufacturing sectors.

While BST is likely to be only a minor part of the revolution in medicine and agriculture that biotechnology produces, the manner in which BST is treated by regulatory authorities and, ultimately, by the public may well have an important influence on the pace and direction of that revolution.

Whatever the outcome of BST in the U.S., it is inevitable that biotechnology in a broad diversity of sectors will continue to develop both here and abroad. The projected economic and social impacts of BST on the agricultural economy and the biotechnology industry are minor, taken in the context of the tremendous global potential for changes generated by applications of this new technology. Key questions are: what will be the pace of development, and who will be the leaders? BST's fate is a factor in the answers to these questions.

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APPENDIX

Chronology of Major BST Studies and Events

1936 Russian scientists reported that injecting dairy cows with crude bovine pituitary extracts of BST increased milk yield (Asimov, et al.). However, wide-spread commercial use of the extracts was never seriously pursued since only very small and impure amounts were obtainable from cows at slaughterhouses.

1950s Scientists injected U.S. children with pituitary extracts of BST with the hope of treating hypopituitary dwarfism. It was found that supplemental BST did not stimulate growth and had no effect on humans.

1970s Recombinant DNA technology was developed, leading to volume production of BST.

1979 Professor Dale Bauman at Cornell University conducted the first study in which high-producing cows were supplemented with pituitary BST.

1982 Recombinantly produced human insulin was introduced. It was found to be identical to natural human insulin and was made by a process similar to that used for BST.

1982 Professor Bauman at Cornell University conducts and reports results from the first study in supplementing cows with recombinant BST.

1982 Four major companies openly acknowledged that they were developing and experimenting with synthetic BST, and later authorized FDA to provide information to the public concerning their new animal drug applications (NADA's).

1984-5 FDA ruled that milk and meat from BST-treated cows is safe for human consumption, and that milk and meat from BST-treated cows in experimental herds could be marketed for commercial consumption with no withdrawal period.

1984 First report was issued on the economic impacts of BST (Kalter. et al.).

1985 The first long-term study (188 days of lactation) with BST was reported for lactating dairy cows. Daily BST (sometribove) injections increased milk production up to 41 percent (Bauman et al.).

1986 In June, there was a hearing before the Subcommittee on Livestock, Dairy and Poultry of the House Committee on Agriculture, to review the possible impacts of the bovine growth hormone (BGH) on the dairy industry.

1987 In September, Jeremy Rifkin, president of the Foundation on Economic Trends, petitioned FDA to conduct studies on the safety and economic consequences of BST. FDA denied the petition in March 1988, stating that sponsoring companies must provide data on the safety and effectiveness of a new drug. Also, under the Federal Food, Drug, and Cosmetic Act, the FDA does not have authority to consider the economic impact of new drugs.

1987 Also, in September, a "National Invitational Workshop on Bovine Somatotropin" was held in St. Louis, Missouri sponsored by the USDA Extension Service. Some 24 papers and/or presentations were made in five separate sessions:

- BST: An Emerging Technology
- BST Research Update
- Herd Management Considerations

- Economic and Social Impacts, and
- Workshop -- Wrap-Up Session

1987 In October, USDA published a BST study requested by the Secretary of Agriculture on the likely effects of BST at the national, regional, and farm-levels (Fallert, et al.). The study concluded that structural changes already under way in the U.S. dairy industry would be reinforced, but not fundamentally changed, with BST availability.

1987 A BST-symposium was held in Germany. Proceedings were published as "Landbauforschung Volkenrode", Ellendorff, Farries, Oslage, Rohr and Smidt., (ISSN 0376-0723, Jan. 1988).

1988 A seminar on the use of somatotropin in livestock production was held in Brussels as part of the European Community (EC) program for the Coordination of Agricultural Research. Proceedings were published in a book "Use of Somatotropin in Livestock Production", edited by Sejrsen, et al., 1989).

1989 A conference organized by Cornell University's Cooperative Extension Service, Dairy Management Division, and Department of Animal Science entitled "Advanced Technologies Facing the Dairy Industry: BST" was held. Economic, social, and scientific issues were discussed. Thirteen papers were presented and then published in the proceedings.

1989 In July, Samuel Epstein, M.D., a professor of occupational and environmental medicine at the University of Illinois, Chicago, wrote a report on "Potential Public Health Hazards of Biosynthetic Milk Hormones", which received considerable media attention.

1989 In August, Jeremy Rifkin and other individuals and organizations petitioned FDA to provide locations of BST test sites, halt sales of milk and meat products from BST studies, and conduct studies on economic and animal and human safety effects of BST. FDA denied the petition in March 1990, because the location of the test sites is proprietary information. Also, there was no basis for halting sales of food products from BST-treated cows because FDA had determined that these products were safe for human consumption. In addition, FDA does not have authority to consider the economic impact of new drugs.

1989 Also in August, Jeremy Rifkin wrote 12 major supermarket chains citing Epstein's report. He reported that five chains and a major ice cream company agreed to refuse milk from BST-treated cows.

1989 Again in August, the BST Worldwide Symposium "BST --From Promise to Practice" was held in Lexington, Kentucky, August 4-5, 1989. Eight invited papers were, presented at the symposium giving a comprehensive, worldwide review of the effects of BST in lactating dairy cows (and published in The Journal of Dairy Science, Volume 74, Supplement 2, 1991).

1989 A book was published in the EC "Use of Somatotropin in Livestock Production" Elsvier Press; edited by K. Sejrse, M. Vestergaard and A. Neiman-sorensen.

1989 Various states (Wisconsin, Vermont, Minnesota, Maine, and New York) proposed legislation to ban BST, or label dairy products from BST-treated cows. Moratoria on BST use were passed in Wisconsin and Minnesota, but have since expired.

1990 The EC established a moratorium on BST approval until the end of 1990 so it could obtain results from additional studies commissioned on potential social and economic impacts.

1990 In February, one of the first studies evaluating the environmental effects of BST was published: "Introduction of Bovine Somatotropin: Environmental Effects". Staff paper 90-13, Department of Agricultural Economics, Purdue University, February 19 9 0 .

1990 In May, the National Milk Producers Federation study, "The Impact of Bovine Somatotropin (bST) on the U.S. Dairy Industry" was released.

1990 In June, USDA published an updated BST study (Blayney and Fallert). This study was requested in the spring of 1989 by Senator Patrick Leahy, Chairman of the Senate Committee on Agriculture, Nutrition, and Forestry. He requested the Economic Research Service update and extend the 1987 BST study and to emphasize the effects on small- and medium-sized dairy operations and the potential for developing export markets for U.S. milk and dairy products that might result from adoption of BST.

1990 Except for the implications of the more open international trade conditions in 1990 and the implications for international trade of dairy products, the 1990 study found the findings of the 1987 study still valid.

1990 In the August 24th issue of Science magazine, FDA scientists summarized more than 120 studies that examined the human safety of BST, concluding that there were no increased safety concerns in the composition of milk from BST-treated cows.

1990 A peer-reviewed paper was published in the Journal of the American Medical Association (JAMA), which affirmed the human safety aspects of BST.

1990 An international symposium "Biotechnology for Control of Growth and Product Quality in Meat Production: Implications and Acceptability" was held in Washington, D.C. (at Rockville, Maryland) on December 5-7. Some 30 papers were presented at the conference and published in a book in 1991 by the Centre for Agricultural Publishing and Documentation (Pudoc), Wageningen, Netherlands, under the same title as the symposium. The sponsors of the program were: the Commission of the European Communities; United States Department of Agriculture (Agricultural Research Services; Animal and Plant Health Inspection Service; Cooperative State Research Service; Economic Research Service; Extension Service; and Food Safety and Inspection Service); Food and Drug Administration Center for Veterinary Medicine; the Dairy Industry; and the National Pork Producers Council.

The symposium was organized in six sessions:

- Perspectives of Introducing Biotechnology in Meat Production.

- Biotechnologies Affecting Growth and Product Quality.
- The Target Animal: Safety, Welfare and Requirements.
- Human Safety.
- Social and Consumer Acceptance, and
- Environmental and Socio-Economic Implications.

1990 The National Institutes of Health reviewed the data on BST and found that there should be no alarm raised about the milk from cows receiving BST. A panel of 13 veterinarians, toxicologists, pediatricians, and statisticians drew the conclusion in a two-day meeting held December 6-7 that there was no human safety risk from BST use.

1991 The Journal of the American Medical Association (JAMA) published a special communication, "NIH Technology Assessment Conference Statement on Bovine Somatotropin" and a Council on Scientific Affairs' report, "Biotechnology and the American Agricultural Industry",. Both affirmed the human safety of milk from BST-treated cows .

1991 The Journal of Clinical Endocrinology and Metabolism published a peer-reviewed paper, "The Efficacy and Safety of Growth Hormone for Animal Agriculture", which affirmed the efficacy and human safety of BST use.

1991 The Congressional Office of Technology Assessment (OTA) study "U.S. Dairy Industry at a Crossroad: Biotechnology and Policy Choices". OTA indicated that "the dairy industry will lead U.S. agriculture into the biotechnology era of the 1990s, and also will feel the first profound impacts of emerging technologies. Recombinant DNA techniques, cell culture and antibody methods are but a few of the new biotechnology techniques that will produce technologies that will sustain or accelerate the historical 2-percent annual increase in milk output per cow...."

1991 In December, Jeremy Rifkin petitioned FDA concerning allegations of serious animal health problems at the University of Vermont due to the use of Monsanto's BST product. FDA denied the petition in November 1992 because substantial errors in the identification of treated versus control cows were found in the report making the allegations.

1992 In February, HHS' Office of the Inspector General (IG) released a report on its audit of FDA's review of BST. The investigation was requested by Congressman John Conyers. The IG confirmed FDA's position on the human food safety of BST products. It concluded that there was no evidence that FDA or Monsanto had manipulated or suppressed animal health data. The IG also concluded that FDA lawfully and publicly disclosed data it had reviewed on the human food safety of BST products, and that FDA and Monsanto had appropriately withheld animal health data on BST.

1992 In August, a report to Congress was submitted by the General Accounting Office (GAO) entitled "Recombinant Bovine Growth Hormone -- FDA Approval Should be Withheld Until the Mastitis Issue is Resolved". The study, requested by Senator Leahy and other U.S. legislators, focused on a review of FDA procedures and protocols for evaluating BST. GAO concluded that all critical guidelines were followed by FDA in its review. GAO agreed that BST did not

represent a direct human , food safety risk, but raised a concern about the potential for increased antibiotic residues in food products from cows treated for mastitis.

1992 The 38th Joint Expert Committee on Food Additives (JECFA) of the World Health Organization and the Food and Agricultural Organization of the United Nations confirmed the human food safety of recombinant BST products.

1992A journal article, "Bovine Somatotropin: Review of an Emerging Animal Technology" was published in the December issue of The Journal of Dairy Science. (Bauman). The paper references 97 published papers in the author's review of the BST technology development.

1992A book was published "Bovine Somatotropin & Emerging Issues: An Assessment" Westview Press; edited by Milton C. Hallberg of Pennsylvania State University. This comprehensive book encompasses five parts:

- Biotechnology and Society.
- Bovine Somatotropin and the Animal.
- Bovine Somatotropin and the Dairy Sector.
- Bovine Somatotropin and the Market Place, and
- Policy Conclusions.

.....The book was reviewed in several journals, including: USDA's "The Journal of Agricultural Economics Research" Vol. 44, No.2; "The American Journal of Agricultural Economics" February 1993; "The Veterinary Record" June 5, 1993; and "Rural Sociology" vol. 58, No.1; Spring 19 9 3 .

1993 In January, the drug regulatory bodies of the European Union (EU, formerly the European Community) issued a scientific report, "Final Scientific Report of the Committee for Veterinary Medicinal Products on the Application for Marketing of Somatech and Optiflex 640". This report concluded that food products from BST-treated cows were safe and that there was no scientific basis for EU regulatory bodies not to approve BST for commercial use.

1993 Also in January, the UK Medicines Commission made the determination that milk and meat from cows receiving BST are safe for human consumption.

1993 As reported by GAO in August 1992, FDA found evidence in the submitted clinical trials that cows treated with Monsanto's BST product, Sometribove, have a slightly , increased incidence of mastitis. In March, an FDA committee met to discuss concerns raised by GAO that antibiotic treatments for mastitis could lead to increased antibiotic residues in milk. The committee concluded that adequate safeguards are in place to prevent unsafe levels of antibiotic residues from entering the milk supply.

1993 In May, FDA sponsored a joint public meeting of the Food Advisory Committee and the Veterinary Medicine Committee to discuss issues surrounding the labeling of foods derived from BST-treated cows. No official conclusions on labeling were drawn at the end of the meeting.

Later, at the November 5, 1993, announcement of FDA approval of BST, a decision on labeling foods derived from BST-treated cows was also announced. On the basis of public meetings and its review of the facts, FDA concluded "that it lacks a basis under the statute to require special labeling of these foods [from BST products]. Food companies, however, may voluntarily label their products provided the information is truthful and not misleading. 'There is virtually no difference in milk from treated and untreated cows,' said FDA Commissioner David A. Kessler, M.D. 'In fact, it's not possible using current scientific techniques to tell them apart. We have looked carefully at every single question raised, and we are confident this product is safe for consumers, for cows and for the environment.'"

1993 In June, a report was published by Wye College, University of London, "The Socio-Economic Effects of Bovine Somatotropin (BST) -- A European Review" F.B.U. Occasional Paper No. 20 by M.J.M. Bent and A.E. Buckwell of the Department of Agricultural Economics. The paper reviews the socio-economic issues surrounding the debate on the approval of BST for use on dairy cows .

In addition to conclusions related to production, consumer, and other general economic effects, the overall conclusion is "...a ban on the use of BST in the EC on socio-economic grounds is difficult to justify.

- Socio-economic impact is an inappropriate criterion for licensing veterinary products. The socioeconomic impact will vary with the economic environment. Determination of 'acceptable' or 'desirable' impacts is subjective and not amenable to scientific measurement.
- Notwithstanding the criticisms of the socio-economic criterion, the socio-economic impact of BST use in the EC is likely to be negligible in aggregate, though of benefit to individual producers under some circumstances. Benefits to consumers and taxpayers cannot be realized due to the hindrance of current agricultural policy instruments."

1993"Somatotropin (BST): International Dairy Federation Technical Report" by D.E. Bauman, B.W. McBride, J.L. Burton, and K. Sejrsen. (This report has been cleared for publication in the International Dairy Federation Bulletin in January 1994. It was commissioned and reviewed by the International Dairy Federation Group A22.) The report indicates that unprecedented numbers of technical papers, abstracts, short communications, and reviews of recombinant bovine somatotropin (BST) have been published in the past decade spanning its effects on milk production and composition, reproductive efficiency, and general health of dairy cows. The authors indicate that more recently, articles have addressed the issues of hormone concentrations in milk (specifically BST and its related peptide, insulin-like growth factor 1), and functional capacity of the immune system of BST-treated cows. The purpose of the report was to summarize technical and biological implications of somatotropin use in the lactating dairy cow. The authors stated, "Our literature search indicated that over 1500 scientific studies on BST have been published and investigations have encompassed the range of management and environmental conditions which characterize worldwide dairy production...."

1993 On November 5th, the Food and Drug Administration (FDA) announced approval of the new animal drug sometribove, a BST product for increasing milk production in dairy cows .

According to the news release of the U.S. Department of Health and Human Services, sometribove increases milk output by supplementing a cow's natural BST, a hormone produced in the pituitary gland. It went on to say that milk from treated cows has been found to have the same nutritional value and composition as milk from untreated cows.

"This has been one of the most extensively studied animal drug products to be reviewed by the agency," said FDA Commissioner David A. Kessler, M.D. "The public can be confident that milk and meat from BST-treated cows is safe to consume." But FDA took additional steps to ensure that any unsafe residues in the milk of BST-treated cows are detected well before the milk or its products reach the grocery shelves. For example, Monsanto, the drug's sponsor, offered to conduct a post-approval monitoring program that extends over a two-year period. Sometribove is manufactured by Monsanto. It will be marketed under the trade name Posilac®.

However, the sale of BST will be delayed for 90 days following FDA's November 5th approval, due to a provision in the Omnibus Budget and Reconciliation Act (OBRA) passed by Congress in August 1993.

The Administration, at the request of Senators Russell Feingold (D-WI), Patrick Leahy (D-VT), and Herbert Kohl (D-WI), and Representatives David Obey (D-WI) and Bernard Sanders (I-VT), informally agreed to conduct a study of the economic and social impacts of BST. The study is to be completed 45 days after the November 5th approval.

1993 The EU continued moratoria on BST use over the 1990 through 1993 period. The EU is expected to extend its current moratorium through December 1994. The moratorium applies to the marketing and use of BST in the EU, but not to BST production in the EU for export to other countries, or to imports of dairy products from countries having approved BST.

1993 On February 3, Monsanto can initiate sales of its bovine somatotropin, Posilac®.

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There is a substantial literature on the production, economic, socioeconomic, ethical, and policy implications of biotechnology in agriculture and on BST specifically. It was not the purpose of this study to report extensively on each study or report. Instead, the study often uses review articles and reports that summarize results and arguments. The citation of certain references instead of others is not to be viewed as acceptance or rejection of any one particular study or report. This study used the most readily accessible and, in many cases, less technically oriented information for the basis of the study.

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