

# A PUBLIC HEALTH RESPONSE TO ELANCO'S "RECOMBINANT BOVINE SOMATOTROPIN (rbST): A SAFETY ASSESSMENT"

## Introduction

Elanco, a division of the Eli Lilly Company, first presented its statement "Recombinant Bovine Somatotropin (rbST): A Safety Assessment," at a conference July 14, 2009. The report, which was not published in a peer-reviewed journal, was sponsored and paid for by Elanco, the current manufacturer of Posilac<sup>®</sup>, the trade name for recombinant bovine growth hormone (rbGH or rbST).

The Elanco/Eli Lilly report says that rbST provides environmental and economic benefits and attempts to deflect public concern that rbST is not safe for cows and humans.

## Executive Summary

Numerous mistakes, misrepresentations of fact, and omissions seriously undermine the report's credibility:

1. Many statements, especially regarding human and animal health, are simply incorrect.
2. Other statements, while not technically incorrect, misrepresent the facts.
3. The report omits numerous significant scientific studies and documents contradicting the conclusions of the authors.
4. Citations listed in the end notes sometimes don't support arguments made in the text.

The report is purported to be authored by "a group of independent scientific experts." Every one of the authors was paid directly by Elanco to work on this report and/or received consulting fees from Elanco/Eli Lilly. Two of the authors have received compensation from Monsanto, the developer of rbST.

The compelling arguments against rbST use, grounded in animal and human health concerns, are well-documented. Opponents of rbST, including more and more consumers, have extensive scientific data to support their claims that the hormone should be discontinued. This response concentrates on the major issues raised by the report.

## Animal Health

Elanco/Eli Lilly Statement: Under **Q. 24: Is rbST harmful for cows?** the report says "*The health effects were extensively studied before rbST was approved by the FDA.*"

Response: The implication of the above remark, and throughout the report, is that rbST is not harmful to cows. However, FDA has recognized that rbST adversely affects animal health, while Canada and the European Union declined to approve rbST based on adverse animal impacts.

*The FDA, which approved rbST, requires a package insert that lists 16 harmful medical conditions that rbST increases. This is never mentioned in the Elanco/Eli Lilly report. Some examples:*

“Use of POSILAC may result in reduced pregnancy rates and an increase in days open . . .”

“Cows injected with POSILAC may have small decreases in gestation length and birth weight of calves.”

“Use of POSILAC may result in an increase in digestive disorders such as indigestion, bloat, and diarrhea.”

“ . . . cows injected with POSILAC had increased numbers of enlarged hocks and lesions (e.g. lacerations, enlargements, calluses) of the knee (carpal region), and second lactation or older cows had more disorders of the foot region.”

“In some herds, use of POSILAC has been associated with increases in somatic cell counts.”

“Cows injected with POSILAC are at an increased risk for clinical mastitis (visibly abnormal milk). The number of cows affected with clinical mastitis and the number of cases per cow may increase . . . Use of POSILAC is associated with increased frequency of use of medication in cows for mastitis and other health problems.”

Other U.S. data showing that rbST harms cows are also not mentioned in the report. The USDA’s National Animal Health Monitoring System 2002 study said that “cost and animal health were major concerns” identified in all regions of the country by farmers.<sup>1</sup> A 2008 study on the California dairy industry found that “current and prospective users still had concerns about the effect of rbST on the health of their herds . . .” and in a survey found that 15% of farmers cited high veterinary costs as a “very important” reason for disadopting rbST.<sup>2</sup>

Second, both Canada and the European Union explicitly turned down use of rbST due to adverse animal health impacts. The Canadian Veterinary Medical Association Expert Panel of rbST, set up by Health Canada, found that that use of rbST was associated with an increased risk of various animal health problems: mastitis up by 25%, infertility by 18%, lameness by 50%, and culling by 20-25%<sup>3</sup>. Health Canada announced in January 1999 that it “had to reject the request for approval to use rbST in Canada, as it presents a sufficient and unacceptable threat to the safety of dairy cows.”<sup>4</sup> A scientific committee in the European Union found that “BST use causes a substantial increase in levels of foot problems and mastitis and leads to injection site reactions in dairy cows. These conditions, especially the first two, are painful and debilitating, leading to significantly poorer welfare in the treated animals. Therefore from the point of view of animal welfare, including health, the Scientific Committee on Animal Health and Animal Welfare is of the opinion that BST should not be used in dairy cows.”<sup>5</sup> The European Union subsequently turned down approval of rbST.

**Elanco/Eli Lilly Statement:** Under **Q. 29, “Does the change in use of rbST over the years affect mastitis cases in dairy cows?”** the report says *“These studies found no evidence that commercial use of rbST represented a significant concern for mastitis or antibiotics.”*

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<sup>1</sup> USDA/APHIS, Bovine somatotropin Info Sheet, May 2003.

<sup>2</sup> An H and Butler, L, “Update on rbST use in the California dairy industry,” Giannini Foundation of Agricultural Economics, U. of California, 2008.

<sup>3</sup> Report of Canadian Veterinary Medical Association Expert Panel on rbST. Prepared for Health Canada, November, 1998. At: [http://www.hc-sc.gc.ca/dhp-mps/vet/issues-enjeux/rbst-stbr/rep\\_cvma-rap\\_acdv\\_tc-tm-eng.php](http://www.hc-sc.gc.ca/dhp-mps/vet/issues-enjeux/rbst-stbr/rep_cvma-rap_acdv_tc-tm-eng.php)

<sup>4</sup> Institute of Food Science and Technology Information Statement on Bovine Somatotropin. 2004, p. 5 at: [www.ifst.org/document.aspx?id=113](http://www.ifst.org/document.aspx?id=113)

<sup>5</sup> Report on Animal Welfare Aspects of Use of Recombinant Bovine Somatotropin. Report of the Scientific Committee on Animal Health and Animal Welfare. March 10, 1999. At: [http://ec.europa.eu/food/fs/sc/scah/out21\\_en.pdf](http://ec.europa.eu/food/fs/sc/scah/out21_en.pdf)

Response:

It's revealing to note the total omission of all the official studies that concluded rbST significantly increased mastitis rates. The official data used to gain approval for Monsanto's (now Elanco's) rbST product in the U.S. —the eight pivotal *pre-approval* trials authorized by the FDA testing 487 cows— found that rbST increased the risk of clinical mastitis by 79%.<sup>6</sup> In part due to the concern over adverse animal health impacts of rbST, approval was conditioned on a *post-approval* monitoring program (PAMP). The PAMP involved monitoring some 28 herds and a total 1,128 cows and found that rbST use increased the risk of mastitis overall by 32%.<sup>7</sup> The PAMP study also demonstrated that more drugs were used to treat the increased cases of mastitis, as the total duration of antibiotic treatment for mastitis was 2.3 times as high in primiparous rbST-treated cows compared to controls, and 1.3 times as high in multiparous cows. Both effects were highly statistically significant ( $P < 0.01$ ).

As previously stated, both the European Union and Canada officially rejected the use of rbST on animal welfare grounds. For Monsanto's version, the Canadian panel found a 25% increase in mastitis.<sup>8</sup> The European review cited results of meta-analyses that showed relative increases ranging from 14% - 79%.<sup>9</sup> The late veterinarian David Kronfeld, PhD, author of four studies on rbST's effects on cows, quoted the European review asserting "these estimates describe an increase (in mastitis incidence) which is not only statistically significant but also biologically relevant and of considerable welfare concern."<sup>10</sup>

Elanco/Eli Lilly Statement: Under **Q. 31, "Does rbST shorten a dairy cow's lifespan in the herd?"** the report concludes "*These follow-up studies show an increased milk production when rbST supplements are used but there were no differences in cow health, culling or longevity.*"

Response: This question, and the quote cited, deal directly with longevity and culling rates. Yet the report cites studies that don't contain evidence supporting the statement. Out of seven studies footnoted, three (Tauer and Knoblauch,<sup>11</sup> Wells et al<sup>12</sup> and Santos et al<sup>13</sup>) don't measure longevity or culling at all. The Wells study even says its design "negated our ability to evaluate possible associations between BST treatment and premature culling (including that related to lameness)."

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<sup>6</sup> Freedom of information summary for Posilac, FDA, November 1993, Section 6-J.

<sup>7</sup> Hansen M et al, "Potential Public Health Impacts of the Use of Recombinant Bovine Somatotropin in Dairy Production," Consumers International submission for the Scientific Review by the WHO/FAO Joint Expert Committee on Food Additives, September 1997. At:

[http://www.consumersunion.org/pub/core\\_food\\_safety/002272.html](http://www.consumersunion.org/pub/core_food_safety/002272.html)

<sup>8</sup> Dohoo I et al, Report of the Canadian Veterinary Medical Association expert panel on rbST, [www.hc-sc.gc.ca](http://www.hc-sc.gc.ca), Section 7.

<sup>9</sup> Broom D et al, Report of the European Union Scientific Committee on Animal Health and Animal Welfare on Aspects of the Use of Bovine Somatotropin, At: [http://ec.europa.eu/food/fs/sc/scah/out21\\_en.pdf](http://ec.europa.eu/food/fs/sc/scah/out21_en.pdf)

<sup>10</sup> Kronfeld D, Recombinant bovine somatotropin and animal welfare, Journal of the American Veterinary Medical Association, June 1, 2000, 216(11):1719-1720.

<sup>11</sup> Tauer L and Knoblauch W, The empirical impact of bovine somatotropin on New York dairy farms, Journal of Dairy Science, June 1997, 80:1092-1097.

<sup>12</sup> Wells SJ et al, Effect of long-term administration of a prolonged release formulation of bovine somatotropin (sometribove) in clinical lameness in dairy cows, American Journal of Veterinary Research, August 1995, 56(8):992-996.

<sup>13</sup> Santos JEP et al, Effect of bST and reproductive management on reproductive performance of holstein dairy cows, Journal of Dairy Science, April 2004, 87:868-881.

Also, once again, the report ignores the official evidence to the contrary. Data from the “Post-Approval Monitoring Program study in the USA reported a [statistically significant] higher culling rate in multiparous cows treated with BST [sic].”<sup>14</sup> The Canadian Veterinary Medical Association Expert Panel of rbST, set up by Health Canada, found that that use of rbST increased culling rates by 20%-25%.<sup>15</sup> The effect was especially evident in multiparous cows.

There are various reasons for culling cows: low production and health problems in reproductive systems, mastitis, lameness, somatic cell count and others. These are precisely the health problems that the FDA and many others concluded occurred with rbST use. It only stands to reason that cows injected with rbST would be culled at a higher rate, just as the data from the official PAMP show.

Finally, it should be noted that most major animal welfare agencies in the country, including the Humane Society of the U.S., Humane Farming Association and Farm Sanctuary, have all endorsed discontinuing rbST.<sup>16</sup>

## Human Health

Elanco/Eli Lilly Statement: Under **Q. 3: “What evidence do we have that shows milk from cows supplemented with rbST is safe for humans?”** the report says *“its (rbST’s) safety for human consumption is endorsed by more than 20 leading health organizations in the United States – including the National Institutes of Health, American Academy of Pediatrics, American Cancer Society, American Medical Association – and internationally – including the World Health Organization (WHO) and Food and Agricultural Organization (FAO).”*

Response: It’s telling that no documentation and no dates are provided for this statement. Upon closer examination, a more complete and complicated story emerges:

National Institutes of Health: It’s accurate that NIH said that milk from rbST-treated cows was as safe as that from cows not injected with it. But it’s important to note that this came from a 1990 report that did not have access to data on mastitis levels associated with rbST use and said that its review did not include consideration of such data. Furthermore, NIH concluded that more animal and human research was needed. One of the six recommendations for further research in the report was “Determine the acute and chronic actions of IGF-I, if any, in the upper gastrointestinal tract.”<sup>17</sup> Since the NIH report, as shown in this paper, significant research has documented significant problems with mastitis and new information on IGF-1.

American Academy of Pediatrics: It’s incorrect that AAP endorses rbST’s safety. It has never done so and has no current official policy.

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<sup>14</sup> Report on Animal Welfare Aspects of Use of Recombinant Bovine Somatotropin. Report of the Scientific Committee on Animal Health and Animal Welfare. March 10, 1999, p. 20At: [http://ec.europa.eu/food/fs/sc/scah/out21\\_en.pdf](http://ec.europa.eu/food/fs/sc/scah/out21_en.pdf).

<sup>15</sup> Dohoo I et al, A meta-analysis review of the effects of recombinant bovine somatotropin, Canadian Journal of Veterinary Research, October 2003, 67(4): 252-264.

<sup>16</sup> North R et al Know Your Milk: Does It Have Artificial Hormones? Physicians for Social Responsibility, Oregon Chapter, 2008, [www.oregonpsr.org](http://www.oregonpsr.org).

<sup>17</sup> National Institutes of Health, NIH Technology Assessment Conference Statement on Bovine Somatotropin, Journal of the American Medical Association, March 20, 1991, 265(11): 1423-1425.

American Cancer Society: It's incorrect that ACS endorses rbST's safety. Its opinion, while saying there isn't yet evidence on an rbST/cancer link, says "The evidence for potential harm to humans is inconclusive . . . The American Cancer Society (ACS) has no formal position regarding rBGH."<sup>18</sup> Although ACS's position is officially neutral, it does state that "The available evidence documents adverse health effects from rBGH on cows" and "The increased use of antibiotics to treat rBGH-induced mastitis does promote the development of antibiotic resistant bacteria . . ."

American Medical Association: It's incorrect that AMA endorses rbST's safety. It hasn't taken any formal position. Rather, it has questioned the safety of rbST/rBGH. In March 1991, the Council on Scientific Affairs of the AMA published a paper in the *Journal of the American Medical Association* entitled "Biotechnology and the American Agriculture Industry," and the section that talked about human health impacts of rBGH use stated, "Further studies will be required to determine whether ingestion of higher than normal concentrations of bovine insulin like growth factor is safe for children, adolescents, and adults."<sup>19</sup> Furthermore, the past president of the AMA, Dr. Ron Davis, wrote in the April 2008 AMA newsletter that "Hospitals should . . . use milk produced without recombinant bovine growth hormone."<sup>20</sup> The American Cancer Society also noted Davis's statement on its website.

WHO and FAO: It's incorrect that WHO and FAO endorse rbST's safety. They have never taken a stance. The Joint Expert Committee on Food Additives (JECFA) is an advisory committee jointly administered by WHO and FAO. Highly influenced by FDA officials promoting rbST, JECFA issued an opinion saying it could be used without appreciable health risk.

However, JECFA reports to the Codex Alimentarius Commission, which makes final decisions on food standards. Significantly, Codex considered a standard for rbST twice, in 1997 and 1999. Both times, no consensus could be reached by member nations that rbST was safe for human consumption, as the report admitted. Codex will be addressed in more detail later in this paper.

Finally, the report ignores the many agencies that have officially opposed rbST on animal and human health concerns. Among others, they include the American Nurses Association, Center for Food Safety, Consumers Union (publisher of Consumer Reports), Physicians for Social Responsibility – Oregon chapter, Food and Water Watch and Health Care Without Harm, a coalition of over 460 organizations in 52 nations that promotes safe and healthy practices in hospitals.

There are other organizations that still accept the FDA's approval of rbST. But there is obviously no consensus that it's safe.

Elanco/Eli Lilly Statement: Under **Q. 17: How is IGF-1 broken down by the digestive process, and is any of it absorbed intact?**" the report says: "*The majority of IGF-1 is broken down by the digestive process.*"

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<sup>18</sup> American Cancer Society, American Cancer Society Statement – Recombinant Bovine Growth Hormone, [http://www.cancer.org/docroot/PED/content/PED\\_1\\_3x\\_Recombinant\\_Bovine\\_Growth\\_Hormone.asp?sitearea=PED](http://www.cancer.org/docroot/PED/content/PED_1_3x_Recombinant_Bovine_Growth_Hormone.asp?sitearea=PED),

<sup>19</sup> American Medical Association (AMA), Council on Scientific Affairs. 1991. Biotechnology and the American agricultural industry. *JAMA*, 265: 1429-1436.

<sup>20</sup> Davis R, Making health care greener, American Medical Association eVoice, April 24, 2008, copy available at <http://www.psr.org/chapters/oregon/safe-food/recombinant-bovine-growth.html>.

Response: If IGF-1 were to exist by itself, it's accurate that most would be broken down by digestion. But this ignores significant scientific data that the majority of IGF-1, in the presence of casein, the main protein in milk, survives digestion and enters the bloodstream where it can have effects on cancer. One rat study, published in 2005, found that IGF-I, in the presence of casein, easily survived digestion in the stomach, enabling it to pass into the small and large intestine.<sup>21</sup> The presence of casein also had some protective effect in the duodenum and dramatically increased the half-life of IGF-I in the intestine. Another rat study done in 1997 clearly demonstrated significant gastrointestinal absorption of recombinant human IGF-I (rhIGF-I) (human IGF-1 and bovine IGF-1 are identical) in the presence of casein: "a considerable amount of rhIGF-I was absorbed into the systemic circulation and that the bioavailability was 9.3%. . . . The coadministration of aprotinin and that of casein enhanced the bioavailability further: 46.9% and 67.0%, respectively"<sup>22</sup>. Other post-approval studies have also documented that casein protects IGF-1 from digestion.<sup>23 24</sup>

Elanco/Eli Lilly Statement: Under **Q. 16: What is the effect on human health of IGF-1 in milk from cows supplemented with rbST?**" the report says *"Because the body produces so much IGF-1, the amount that is absorbed, if any, does not cause a detectable increase and body tissues are exposed to no more IGF-1 than if no milk was consumed."*

Response: It's accurate that the body produces much more IGF-1 than available from dietary sources, but again, this statement alone is misleading. IGF-1 is a hormone, and even in minute amounts, hormones can have significant health effects. There have also been several studies that document that IGF-1 levels in milk are at a high enough level to affect human health, even without the additional IGF-1 generated by rbST.<sup>25 26 27</sup> For example, a team of scientists at Brigham and Women's Hospital and Harvard Medical School in Boston used data from a large, long-term (25 years) study of more than 1,000 nurses who recorded their diets carefully and who were then watched for changes in health. The study found that higher serum levels of IGF-I were found in the women who consumed the most dairy products and noted that other studies had found such a link. These results raise the possibility that milk consumption could influence cancer risk by a mechanism involving IGF-I."<sup>28</sup>

Elanco/Eli Lilly Statement: ". . . IGF-1 has never been shown to transform a healthy cell into a cancer cell."

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<sup>21</sup> Xian C et al, Degradation of IGF-1 in the adult rat gastrointestinal tract is limited by a specific antiserum or the dietary protein casein, *Journal of Endocrinology*, 1995, 146:214-225.

<sup>22</sup> Kimura T et al, Gastrointestinal absorption of recombinant human insulin-like growth factor-1 in rats, *Journal of Pharmacology and Experimental Therapeutics*, 1997, 283:611-618, p. 611.

<sup>23</sup> Anderle P et al, In vitro assessment of intestinal IGF-1 stability, *Journal of Pharmaceutical Sciences*, Jan. 2002, 91:1.

<sup>24</sup> Hoppe C et al, Differential effects of casein versus whey on fasting plasma levels of insulin, IGF-1, and IGF-1/IGFBP-3.

<sup>25</sup> Heaney R et al, Dietary changes favorably affect bone remodeling in older adults, *Journal of the American Dietetic Association*, October 1999, 99:1229-1233.

<sup>26</sup> Holmes M et al, Dietary correlates of plasma insulin-like growth factor 1 and insulin-like growth factor binding protein 3 concentrations, *Cancer Epidemiology, Biomarkers and Prevention*, Sept. 2002, 11(9):852-861.

<sup>27</sup> Steinman G, Mechanisms of Twinning: VII: Effect of diet and heredity on the human twinning rate, *Journal of Reproductive Medicine*, May 2006, 51(5): 405-410.

<sup>28</sup> Holmes M et al.

Response: This is a classic example of a technically correct statement that misrepresents the facts and gives the misleading impression that IGF-1 isn't associated with promoting cancer. It has been firmly established that it both causes cells to divide at an accelerated rate and delays programmed cell death (apoptosis), both of which promote cancer.<sup>29 30</sup> Moreover, all the mechanisms of action of IGF-1 aren't totally understood.

Elanco/Eli Lilly Statement: Under **Q. 11: What are the breast cancer incidence trends in the United States over the last 30 years or so?"** the report says *"Adjusted incidence rates for breast cancer cases in the United States are lower today than they were in 1994 when rbST commercial use began."*

Response: Using these statistics to imply there is no correlation between rbGH use and breast cancer is faulty logic at its worst.

First, by viewing the entire graph from 1975 to 2005,<sup>31</sup> it's immediately apparent that the period from 1994 to 1999 (the introduction and major increase in use of rbST) saw an increase in incidence of 1.7%. Then, from 1999 to 2005, there was a decrease of 2.2%. The USDA reported that 22.3% of U.S. cows were injected with rbST in 2002.<sup>32</sup> But by the USDA's 2007 follow-up report, only 17.2% of cows were injected.<sup>33</sup> Although the years don't match precisely, it's apparent that there was an increase in breast cancer incidence after rbST's introduction and initial promotion and a decrease in breast cancer incidence as rbST was being used less. If attempting to make a connection between rbST and breast cancer, a closer look at these statistics points to the *exact opposite implication* of the Elanco/Eli Lilly report.

We do not believe, however, that any correlation can be drawn from these figures. Breast cancer, like most cancers, has many risk factors, including obesity, age, smoking, diet, genetic predisposition, late or no pregnancy and environmental toxins. Furthermore, it often occurs without any apparent cause. Finally, also like most cancers, it can take years or decades to develop. If rbST was increasing breast cancer rates (or any other cancer), those exposed in the late 1990's or early 2000's may not develop the disease as a result until many years later.

Based on the factors cited above, the inclusion of the graph on the probability of girls born between 1997 and 2005 being diagnosed with breast cancer decades into the future has no relevance whatsoever.

Elanco/Eli Lilly Statement: **Under Q 20: "Are the levels of antibiotics in the milk of rbST-supplemented cows elevated?"** the report says: *"The levels of antibiotics in the milk of rbST-supplemented cows are not elevated."*

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<sup>29</sup> Moschos S, and Mantzoros C, The role of the IGF system in cancer: from basic to clinical studies and clinical applications, *Oncology*, Nov. 4, 2002, 63(4): 317-332.

<sup>30</sup> Yu H and Rohan T, Role of the insulin-like growth factor family in cancer development and progression, *Journal of the National Cancer Institute*, Sept. 20, 2000, 92(18): 1472-1489.

<sup>31</sup> National Cancer Institute, <http://progressreport.cancer.gov/popups/d2b.html>.

<sup>32</sup> USDA/APHIS, Info Sheet – Bovine Somatotropin, May 2003, <http://www.aphis.usda.gov/vs/ceah/ncahs/nahms/dairy/dairy02/Dairy02BST.pdf>.

<sup>33</sup> USDA/APHIS, Dairy 2007, October 2007, p. 79.

Response: As shown above, there is a wealth of data that rbST increases mastitis rates, as even the FDA admits, and approximately 80% of conventional dairy farmers use antibiotics to treat mastitis.<sup>34</sup> It's accurate that milk is tested for antibiotic use and if antibiotic levels detected are too high, the milk won't be accepted for processing. Unfortunately, farmers sometimes use antibiotics that are not being tested for, and this milk can enter the U.S. food supply.<sup>35</sup>

Both increased incidence of mastitis and more severe or longer-lasting cases of mastitis can lead to greater antibiotic use. In a Vermont study, there were more than seven times as many cases of mastitis in rbST-treated cows compared to controls (29 vs. 4), while the average length of antibiotic treatment was almost six times as long (8.9 days vs. 1.5 days), leading to a 43-fold increase in the total duration of antibiotic treatment for rbST-treated cows, compared to controls.<sup>36</sup> In the PAMP trial, which consisted of 28 herds and 1128 animals, total duration of antibiotic treatment for mastitis was 2.3 times as high in primiparous rbST-treated cows compared to controls, and 1.3 times as high in multiparous cows; both effects were highly statistically significant ( $P < 0.01$ ).<sup>37</sup>

Moreover, whenever antibiotics are used, some bacteria are selected out that are resistant, and these bacteria can enter humans through the milk (pasteurization kills most, but not all, bacteria), meat, soil, water and air. "The additional antibiotic use due to rbST use cannot help but increase antibiotic resistance in humans."<sup>38</sup>

Organizations such as the Physicians for Social Responsibility, American Nurses Association and Health Care Without Harm all have cited concerns about rbST increasing antibiotic resistance. And even though the European Union officially banned the use of rbST on animal health grounds, its Scientific Committee on Veterinary Measures relating to Public Health concluded that ". . . secondary risks associated with the use of rbST in dairy cows are . . . an increased use of antimicrobial substances in the treatment of rbST related mastitis which might lead to an increased risk of residue formation in milk and to the selection of resistant bacteria."<sup>39</sup>

Elanco/Eli Lilly Statement: **Under Q30: "Does the change in use of rbST over the years correlate to changes in antibiotic-resistant bacteria in cows?"** the report says "*Even in herds not using rbST, there is no evidence supporting the view that use of therapeutic antibiotics leads to resistant strains of mastitis-causing bacteria in dairy cows.*"

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<sup>34</sup> Zwald AG et al, Management practices and reported antimicrobial usage on conventional and organic dairy farms, *Journal of Dairy Science*, 2004, 87:191-201.

<sup>35</sup> *New York Times*, Tests for drugs in milk still lag, G.A.O. says, August 6, 1992.

<sup>36</sup> Pell, A.N., Tsang, D.S., Howlett, B.A., Huylet, M.T., Meserole, V.K., Samuels, W.A., Hartnell, G.F., and R.L. Hintz. 1992. Effects of a prolonged-release formulation of sometribove (n-Methionyl Bovine Somatotropin) on Jersey cows. *Journal of Dairy Sciences*, 75: 3416-3431.

<sup>37</sup> Hansen M et al, "Potential Public Health Impacts of the Use of Recombinant Bovine Somatotropin in Dairy Production," Consumer Union presentation for the Scientific Review by the Joint Expert Committee on Food Additives, September 1997. At: [http://www.consumersunion.org/pub/core\\_food\\_safety/002272.html](http://www.consumersunion.org/pub/core_food_safety/002272.html)

<sup>38</sup> *Ibid.*

<sup>39</sup> European Union Scientific Committee on Veterinary Measures relating to Public Health, "Report on public health aspects of the use of bovine somatotrophin – 15-16 March 1999.

Response: This statement is simply false. There is a wealth of scientific data demonstrating otherwise. Among many others, a 2000 study asserted “To safeguard public health, the selection and dissemination of resistant bacteria from animals should be controlled. This can only be achieved by reducing the amounts of antibiotics used in animals.”<sup>40</sup> A 2007 study from the University of Tennessee said “. . . it is clear that use of antibiotics can over time result in significant pools of resistance genes among bacteria, including human pathogens . . .”<sup>41</sup> And a 2008 review confirms that “Antimicrobial resistance may spread from animals to humans by transfer of resistant bacteria from animals to humans and resistance genes from animal bacteria to human pathogens.”<sup>42</sup>

The sole reference the Elanco/Eli Lilly report cited was a report that said there wasn’t evidence that could “support a widespread, emerging resistance among mastitis pathogens to antibacterial drugs.”<sup>43</sup> It’s valid that it’s very difficult to precisely quantify how much antibiotic resistance is transferred from cows to humans, as numerous researchers attest. But this is an entirely different point than saying that no problem exists. Even the source the report cites says “. . . *resistance to antibacterial drugs among mastitis pathogens has been well documented for four decades. . .*” (emphasis ours).

These points are clear:

1. rbST increases mastitis.
2. Mastitis increases antibiotic use.
3. Antibiotic use increases selection of antibiotic resistant bacteria in cows.
4. This antibiotic resistance can be transferred to bacterial pathogens in humans.
5. Antibiotic resistance in humans is an extremely dangerous, and growing, problem.

The Elanco/Eli Lilly report makes every effort to avoid one of the major concerns regarding rbST – the increase of antibiotic resistance in humans exacerbated by mastitis-induced antibiotic use in cows.

Elanco/Eli Lilly Statement: **Under Q 23: Why has Codex not approved rbST for supplementation in dairy cattle?** the report says “*The policy statement regarding rbST has reached Step 8 (final step) of the Codex process but has not yet passed Step 8. It is at this level that all 180 countries vote for or against the policy becoming a universal standard.*”

Response: The reason that rbST has been held at Step 8 in the Codex process for the last 10 years is simple: there is no consensus on the safety of rbST. The U.S. and its allies argue that there is enough evidence to show that rbST is safe for cows and humans. The European Union, and a number of other countries, disagree with the U.S. and do not think the data show rbST to be safe for cows and humans. Until such time as there is scientific consensus, the policy statement/standard for rbST will remain “parked” at the Codex Alimentarius Commission (CAC). The rbGH/rbST standard is on the agenda for each CAC meeting, but never gets voted on or approved due to the lack of scientific consensus.

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<sup>40</sup> Van den Bogaard AE and Stobberingh EE, Epidemiology of resistance to antibiotics. Links between animals and humans, International Journal of Antimicrobial Agents, May 2000, 14(4): 327-335.

<sup>41</sup> Mathew AG et al, Antibiotic resistance in bacteria associated with food animals: a United States perspective of livestock production, Foodborne Pathogens and Disease, Summer 2007, 4(2):115-133.

<sup>42</sup> Sundsfjord A and Sunde M, Antimicrobial resistance after antibiotic use in animals – impact on human health, Tidsskr Nor Laegeforen, Nov. 6, 2008, 128(21):2457-2461.

<sup>43</sup> Erskine R et al, Bovine mastitis pathogens and trends in resistance to antibacterial drugs, National Mastitis Council research committee report, , NMC annual meeting proceedings, Madison, WI, 2004, pp. 400-414.

Most nations espouse the Precautionary Principle, a fundamental principle of public health, and an elaboration of the old saying “Better safe than sorry.” It says that where a substance (such as a new drug or chemical) raises threats of serious or irreparable harm to human health or the environment, precautionary measures should be taken, even if all cause and effect relationships are not fully established.

## Environmental impacts

Elanco/Eli Lilly Statement: Under **Q. 33: “What is the environmental impact of using rbST?”** the report says “. . . *innovative food production practices like rbST that increase the efficiency of food production while mitigating the environmental impact will be of even greater importance in the future for the global production of food.*” The argument is that more milk can be generated by fewer cows injected with rbST, thereby reducing manure and the need for food, water and husbandry. It would then lessen the environmental impact.

Response: The Elanco/Eli Lilly report takes its various estimates on a single study done by Capper et al. and co-authored by individuals receiving compensation from Monsanto. The entire study is based on the premise that cows can produce more milk more efficiently, that is, more milk from the same amount of feed. But this is incorrect. They produce more milk, but they have to eat more to do it, as any farmer could confirm. When Monsanto asked the FDA to declare that rbST increased efficiency, FDA said that Monsanto’s data failed to show this.<sup>44</sup> The FDA’s own environmental assessment found no significant differences on greenhouse gas generation or manure levels, even citing one study saying “the manufacture and transport of POSILAC will result in incremental increases in carbon dioxide and methane emissions.”<sup>45</sup>

Another factor the Capper et al study doesn’t address is the higher culling rate of cows injected with rbST, necessitating more cows for milk production.

## Economic impacts

Elanco/Eli Lilly Statement: Under **Q. 35: “What is the economic impact of drinking milk from cows supplemented with rbST?”** the report says “*The economic benefits of rbST are partitioned between the technology supplier, dairy producers, processors, retailers, consumers and the different levels of government.*” It then cites specific figures, saying that “*the withdrawal of rbST would increase milk prices by . . . \$0.06 to \$0.12 per gallon of milk, and \$0.075 to \$0.15 per pound of cheese.*”

Response: We have never seen these figures showing the supposed benefits of rbST. They are not footnoted and we would be very surprised to see that any credible study has been done to quantify these “benefits.”

On the contrary, there have been several studies done on profitability for dairy farmers using rbST. While Monsanto’s promotional materials trumpeted significant profits, virtually all independent studies show the same thing: there is no guarantee of profitability at all. It’s instructive that the

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<sup>44</sup> Richard Lehmann, FDA, letter to Terence Harvey, Monsanto, dated April 3, 1988 on NADA 140-872.

<sup>45</sup> EA on Methionyl Bovine Somatotropin, POSILAC, FDA, <http://www.fda.gov/cvm/Documents/BSTEFONSI.pdf>.

Tauer/Knoblauch 1998 study on New York dairy farms referenced by the report actually contradicts the supposed economic benefits to farmers, saying changes to net farm income were “not statistically different from zero.”<sup>46</sup>

A 2002 study of Connecticut farmers using rbST also concluded “there is no evidence that it increases profits on a per cow basis.”<sup>47</sup> A 2004 nationwide study confirmed the statewide results on rbST use, finding “The impact on financial performance . . . was not statistically significant.”<sup>48</sup> It’s no surprise that a review of various studies found that 25-40% of farmers who tried rbST had decided it wasn’t worth it: “Part of the explanation for this high level of abandonment is likely to be the profit associated with use of the technology.”<sup>49</sup>

Moreover, the costs consumers pay for conventional milk are largely determined by the processors and retailers, who will charge whatever the market will bear. It is absurd to argue that rbST is saving consumers millions of dollars.

Finally, it’s important to note that cows have become more productive independently of rbST. Below is a graph<sup>50</sup> showing this. There are two notable observations one can make from these figures:

- The commercial introduction of rbST in 1994 had no significant effect on the rate of increase of milk per cow, which the graph starts tracking in 1970.
- The height and subsequent decline of rbST use in the early and mid 2000’s also had no significant effect on cow productivity, which kept increasing.

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<sup>46</sup> Tauer L and Knoblauch W, The empirical impact of bovine somatotropin on a group of New York dairy farms, *Journal of Dairy Science*, June 1997, 80(6): 1092-1097.,

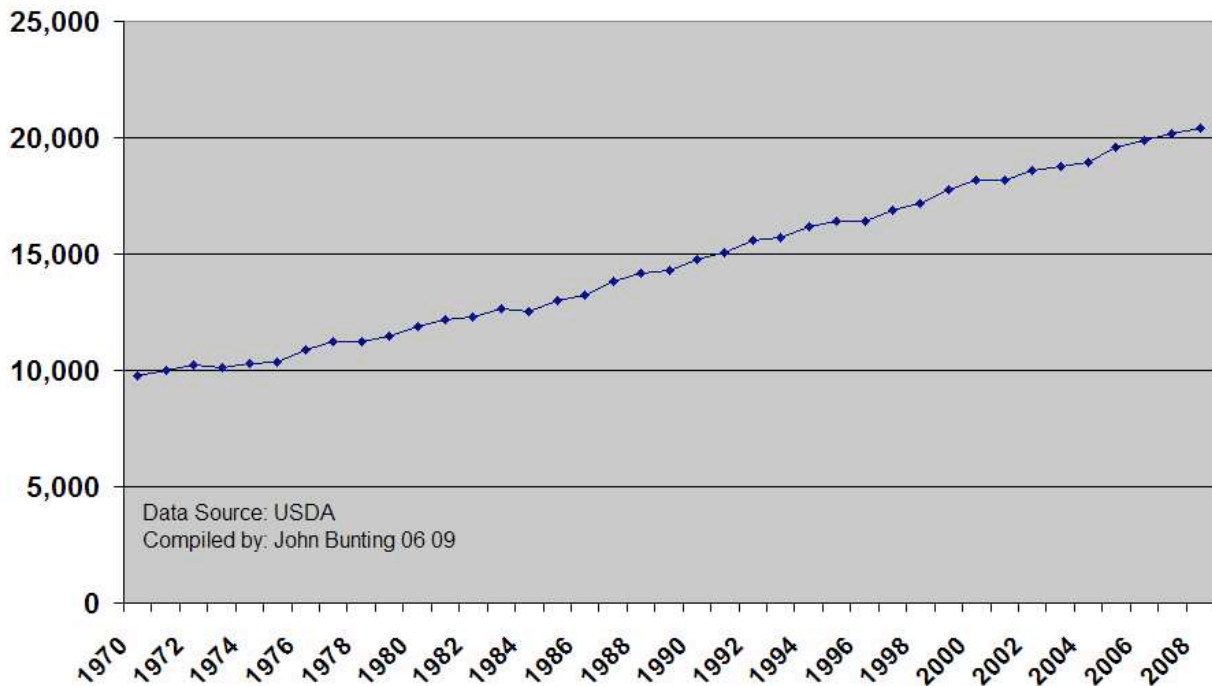
<sup>47</sup> Foltz J and Chang H, The adoption and profitability of rbST on Connecticut dairy farms, *American Journal of Agricultural Economics*, 2002, 84: 1021-1032.

<sup>48</sup> McBride W et al, The adoption and impact of bovine somatotropin on U.S. dairy farms, *Review of Agricultural Economics*, 2004, 26(4): 472-488.

<sup>49</sup> Barnham B and Foltz J, rbST adoption in the United States: that was the juggernaut . . . that wasn’t – recombinant bovine somatotropin, *Choices*, Summer 2002.

<sup>50</sup> USDA figures, graph created by John Bunting, June 2009.

## Milk Per Cow



There certainly is evidence that rbST can induce cows to produce more milk. However, it's apparent that this has been a relatively minor factor in nationwide production levels.

### Conclusion

The Elanco/Eli Lilly rbST report is not credible. Its conclusions are based on information that is incorrect, misleading and biased toward acceptance of the hormone, while omitting significant scientific data that provide a compelling case against its use.

Over the past five years, there has been a growing consumer revolt against rbST, with the result that more and more processors are discontinuing its use to satisfy their customers. When one examines the facts closely, it becomes increasingly clear why both individuals and businesses are avoiding dairy products produced with this hormone.

## **Contributing authors:**

### **Martin Donohoe, MD, FACP**

Adjunct Associate Professor, School of Community Health - Portland State University  
Member, Board of Advisors - Oregon Physicians for Social Responsibility  
Chief Science Advisor, Oregon PSR Campaign for Safe Food  
Senior Physician, Internal Medicine, Kaiser Sunnyside Medical Center  
<http://www.publichealthandsocialjustice.org>

### **Samuel Epstein, MD**

Chairman, Cancer Prevention Coalition  
Professor Emeritus of Environmental and Occupational Medicine, U. of Illinois School of Public Health  
Author or co-author of 270 peer-reviewed articles and 12 books, including *The Politics of Cancer* and *What's in Your Milk?*  
Winner of several awards, including the 1998 Right Livelihood Award for international contributions to cancer prevention, 1999 Bioneers Award, 2000 Project Censored Award and 2005 Albert Schweitzer Golden Grand Medal for Humanitarianism  
Former President of the Society for Occupational and Environmental Health and the Rachel Carson Council

### **Michael Hansen, PhD**

Senior Staff Scientist, Consumers Union (Publisher of Consumer Reports)  
Represents Consumers International, a federation of more than 250 organizations in 110 countries at Codex Alimentarius and other international meetings  
Appointed to FAO/WHO Joint Expert Committee on Food Additives (1998), which looked at rbGH  
Appointed to FAO/WHO Joint Expert Committee on Safety Assessment of Foods Derived from Genetically Modified Animals, including Fish (2003), and to Joint FAO/WHO Expert Consultation on Safety Assessment of Food Derived from Biotechnology (2007)  
Formerly served on the USDA Advisory Committee on Agricultural Biotechnology and California Department of Food and Agriculture Food Biotechnology Advisory Committee  
Author of CU's 1990 report on rbST, *Biotechnology and Milk: Benefit or Threat?*  
Author of CU's *Pest Control for House and Garden* and co-author of *Pest Management at the Crossroads*

### **Rick North, MA**

Project Director, Oregon Physicians for Social Responsibility's Campaign For Safe Food  
Former Executive Vice President, American Cancer Society – Oregon Division  
Presenter on rbST to numerous conferences and companies, including Starbucks, Dannon, Breyers, Sysco, Bon Appetit, Darigold, Organic Valley, Chipotle Restaurants and others

### **David Wallinga, MD, MPA**

Director, Food and Health Program, Institute for Agriculture and Trade Policy  
William T. Grant Foundation Distinguished Fellow in Food Systems and Public Health, University of Minnesota School of Public Health  
Board of Scientific Counselors, Centers for Disease Control and Prevention, National Center for Environmental Health  
Formerly served on U.S. Environmental Protection Agency's Science Advisory Board, Integrated Human Exposure Committee

**Organizations endorsing this response:**

Allergy Kids Foundation  
Breast Cancer Action  
Cancer Prevention Coalition  
Center for Environmental Health  
Center for Food Safety  
Consumers Union  
DES Action USA  
Family Farm Defenders  
Food and Water Watch  
Humane Farming Association  
Humane Society of the U.S.  
Institute for Agriculture and Trade Policy  
Institute for Responsible Technology  
Massachusetts Breast Cancer Coalition  
National Family Farm Coalition  
Organic Consumers Association  
Physicians for Social Responsibility, Oregon  
Rodale Institute  
Sierra Club