

# Boston University Journal of Science & Technology Law

## Legal Update

### Recombinant Bovine Somatotrophin-*Stauber v. Shalala*<sup>†\*</sup>

#### 1. *Introduction*

The use of a synthetic bovine growth hormone, recombinant bovine somatotrophin ("rbST"), has created substantial controversy among consumer groups and the dairy industry.<sup>1</sup> Bovine somatotrophin is a hormone naturally produced by a cow's pituitary gland. Using genetic engineering, scientists can produce an artificial form of this drug, rbST. A dairy farmer can increase his livestock's milk production through the intravenous injection of rbST into his livestock. In November 1993, Monsanto Company received regulatory approval from the Food and Drug Administration ("FDA") for the drug, under the name Posilac. [1]

In *Stauber v. Shalala*,<sup>2</sup> consumers challenged the FDA approval of Posilac on several grounds. First, they argued that the approval was arbitrary and capricious. Second, they said that the FDA had erred in not requiring mandatory labeling of products derived from cows treated with Posilac. Finally, they challenged the FDA's approval of the drug under the National

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\* No. 94-C-0090-C, 1995 WL 467364 (D. Wis., Aug. 4, 1995).

<sup>1</sup> See Marian Burros, Public Still Apprehensive About Bovine Growth Hormone, Orange County Reg., May 26, 1994.

<sup>2</sup> No. 94-C-0090-C, 1995 WL 467364 (D. Wis., Aug. 4, 1995).

Environmental Policy Act.<sup>3</sup> The court granted the defendants summary judgment on all claims. [2]

## 2. Discussion

To determine whether the FDA's approval was arbitrary and capricious, the court considered only the evidence that was presented to the FDA when it reviewed the drug. Further, the court declared that, as long as it could discern a rational basis for the action, it was constrained to uphold it.<sup>4</sup> The court addressed the various health and safety concerns associated with the use of Posilac, and held that the FDA had adequately addressed these issues. In light of the evidence before the FDA, the court upheld the approval, as it was supported by a rational basis.<sup>5</sup> [3]

The court recognized that Posilac does pose a health risk to the treated livestock. These risks include reduced pregnancy rates, ovarian cysts and other reproduction and fertility problems. In addition, Posilac might cause increased body temperature, indigestion, diarrhea and injection site swellings. Most significantly, Posilac increased the risk of mastitis, a bacterial infection of the udder.<sup>6</sup> The FDA determined, however, that none of these risks were substantial, and classified them as "manageable risks."<sup>7</sup> The court noted that it believed that "zero risk" was not required and held that the FDA's findings were not irrational.<sup>8</sup> Even the increase in risk of mastitis was determined to be no greater than that often caused by other factors naturally effecting livestock.<sup>9</sup> [4]

The possible presence of rbST in milk and other dairy products was found not to have any direct health effects on human consumers, as the hormone is inactive when taken orally. The milk pasteurization process destroys ninety percent of the rbST present in cow's milk.<sup>10</sup> The remaining

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<sup>3</sup> 42 U.S.C. §§ 4321-4370d. See *id.* at \*1.

<sup>4</sup> *Stauber*, 1995 WL 467364 at \*9.

<sup>5</sup> *Id.* at \*13.

<sup>6</sup> *Id.* at \*2.

<sup>7</sup> *Id.* at \*3.

<sup>8</sup> *Id.* at \*12.

<sup>9</sup> *Id.*

<sup>10</sup> *Id.* at \*3.

ten percent does not pose a risk to humans as human somatotrophin differs significantly from bovine somatotrophin and bovine somatotrophin will not bind to human receptors. [5]

Despite rbST's lack of direct effects, there is concern over the possible secondary effects of the drug's use on livestock. As already noted, the use of Posilac increases the risk of mastitis in livestock. Antibiotic residue used to treat mastitis can appear in pasteurized milk. Nevertheless, the FDA concluded that there was no risk to human health despite the lack of any long term studies of the effects of ingesting milk that contains increased levels of antibiotic residue.<sup>11</sup> The court accepted the FDA's reasoning that the increased mastitis rates would be minimal and that current regulations adequately control antibiotic levels in pasteurized milk.<sup>12</sup> [6]

RbST also increases the amount of insulin-like growth factor ("IGF-1"), which exists in the same form in both bovines and humans. Although there minimal studies have been conducted, there is no showing that the slight increases in IGF-1 would have any detrimental effects on human health.<sup>13</sup> The FDA relied solely upon a two-week study of rats, conducted by Monsanto. The court found that the plaintiffs had failed to show any reason why further studies were required.<sup>14</sup> The court also accepted the reasoning that the increase in IGF-1 would be very slight, especially when considered in comparison to the levels of IGF-1 already contained in the human body.<sup>15</sup> [7]

The plaintiffs also argued that the FDA had failed to prepare an Environmental Impact Statement in compliance with the National Environmental Policy Act.<sup>16</sup> The court held that an impact statement was not required because the FDA had already accounted for the environmental issues in its decision to approve the drug.<sup>17</sup> As a subsequent Environmental Impact Statement would be duplicative it was not required.<sup>18</sup> [8]

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11 *Id.* at \*4.

12 *Id.* at \*13.

13 *Id.*

14 *Id.*

15 *Id.*

16 42 U.S.C. § 4332 (2)(c). See *id.* at \*15.

17 *Stauber*, 1995 WL 467364 at \*16.

18 *Id.*

The court also rejected the plaintiff's argument that the FDA's decision not to require mandatory labeling was arbitrary and capricious.<sup>19</sup> Labeling would be required only to disclose differences in the performance characteristics or functional properties between products derived from rbST treated cows and products derived from untreated cows.<sup>20</sup> The FDA found no such differences, precluding the need for labeling.<sup>21</sup> The court noted that even though there was great consumer demand for a labeling requirement, it would be misleading to label a product as being different when no significant differences exist.<sup>22</sup> [9]

Although the FDA approval of Posilac may stand, the labeling issue remains unresolved. With the lack of a national labeling requirement, some states have required that products sold in the state be labeled if they are derived from rbST-treated cows. In *International Dairy Food Ass'n v. Amestoy*,<sup>23</sup> the dairy industry sought a preliminary injunction against the enforcement of such a law in Vermont. The plaintiffs challenged the law as unconstitutional under the First Amendment, Commerce Clause, and Supremacy Clause of the Constitution.<sup>24</sup> The court denied the preliminary injunction, based solely on the violation of the First Amendment and Commerce Clause, finding that plaintiffs proved neither likelihood of success on the merits, nor irreparable harm.<sup>25</sup> As the Supremacy Clause argument was not addressed, and the merits were not actually decided, the validity of state labeling requirements remains uncertain. Even with rbST on the market, these labeling requirements, if they are constitutionally valid, may help to protect consumers. [10]

-Adam Brown

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19 *Id.* at \*13.

20 *Id.* at \*14.

21 *Id.*

22 *Id.*

23 No. 2:94-CV-119, 1995 WL 505885 (D. Vt., Aug. 9, 1995).

24 *Id.* at \*1.

25 *Id.*