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December 15, 1999

Dr. Andrew Beaulieu
Center for Veterinary Medicine
HFV-2
7500 Standish Pl.
Rockville, MD 20855

RE: Citizen's Petition Docket #99P-4613

Dear Dr. Beaulieu:

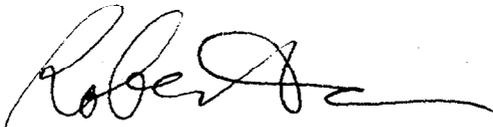
Dairy farmers are now recognizing the financial dangers of Monsanto's genetically engineered bovine growth hormone. The latest issue of *The Milkweed* (December 1999, No.245), a dairy industry newsletter, urges farmers to petition the Food & Drug Administration to revoke the use of Posilac.

Editor Pete Hardin of *The Milkweed* presents evidence that Monsanto created five "freak" amino acids, and carefully points out to dairymen the fraud that Monsanto perpetrated against the FDA. Mr. Hardin also explains that Monsanto fixed the error, but that the hormone that FDA reviewed is completely different from the hormone that is presently on the market. In other words, FDA has an "out."

The scientific merits of our petition to FDA pale in comparison to the gross insult and lie told by Monsanto. There are no gray issues concerning Monsanto's deceit. Their genetically engineered fraud should be immediately taken off the market.

Enclosed please find a photocopy of Pete Hardin's newsletter editorial.

Very truly yours,



Robert Cohen

Enclosures

99 P - 4613

SUP10

Straight Talk

by Pete Hardin

The Hardin Plan — Part 1: Halt Posilac Use

Imagine U.S. dairy farmers as passengers on a ship that has struck a rock and is sinking fast in stormy seas. Milk supplies and imports are exceeding commercial dairy product demand. Cheddar cheese and milk powder prices are at support price levels. Butter could follow soon. Starting in January, many dairy farmers face net farm milk checks in the \$9.50-\$10.50 per cwt. range. If they last very long, these milk prices will kill many producers financially and spiritually.

Huge losses are piling up fast for many marketers—especially operating dairy cooperatives. With commodity prices in the pits and so little demand for raw milk, marketers' margins and inventory losses are huge. *Hundreds of millions of dollars in cheese and butter inventory values have been lost just by Midwest marketers in the second half of 1999.*

Dairy farmers on this sinking ship face tough choices. To try to save the ship, immediate action is needed to lighten the load. A couple percentage points of excess farm milk production must be dumped, pronto. But what, or whom, to throw overboard?

Solution: Immediate FDA ban on Posilac

There's a simple solution to dairy's current dilemma: demand that the U.S. Food and Drug Administration (FDA) immediately ban the sale and use of "Posilac"—Monsanto's recombinant cow growth hormone that boosts milk production in injected cows.

How could that action be pulled off quickly?

A current citizen petition to FDA demands that the agency halt sales of Posilac because the genetically-engineered hormone molecule marketed by Monsanto is DIFFERENT from the molecule on which human and animal safety tests were conducted—tests that led to FDA's approval of the drug. Logic and law dictate that the molecule being marketed should be the exact same one on which pre-approval human and animal safety tests were conducted.

Monsanto's hormone molecule "switcheroo" was revealed in a July 1994 article in the journal *Protein Science*, authored by Bernard Violand, a Monsanto scientist. Violand reported that an unrecognized additional amino acid sequence change occurred in the original production process of Monsanto's recombinant bovine growth hormone. The "freak" amino acid actually appeared at three sites on the hormone's sequence, Violand reported.

Why did not FDA require a full round of new safety tests for the different hormone molecule?

Violand's revelation is not startling news. *The Milkweed* has previously reported this fact. But current events make the switched rbGH molecule's importance great. Those events include: global anti-biotech food fervor, dire farm milk prices, and lack of other short-term solutions to restore farm milk prices. If the dairy industry could immediately throw one item off the sinking ship to save the industry, Posilac is the best candidate. We must immediately eliminate the top couple percentage points of milk production.

Not only should FDA ban sale of Posilac immediately, pending a new round of legitimate human and animal "safety" tests, but all existing inventories of Posilac held by farmers should be confiscated.

A single amino-acid sequence change in a protein molecule can be significant. For example, humans suffering from Sickle Cell Anemia have a single genetic amino acid sequence change.

By law, FDA ought to revoke Monsanto's license to sell Posilac until the manufacturer runs a complete new gamut of human and animal safety tests. Such a dictate to Monsanto would effectively kill Posilac. Monsanto, whose food biotechnology invest-

ments are causing the company to struggle, doesn't have the funds for several years of Posilac safety tests.

Immediate impacts: less milk, higher prices

If FDA yanked Posilac, the impact on milk production would be immediately negative. Prices of dairy products and farm milk would soon start climbing. Here's why:

* Probably 20-25% of all U.S. dairy farms use Posilac, normally on half or less of their lactating cows. Various reports indicate a 6-8 pound daily gain in treated cows' milk production. That's a lot of extra milk.

* Posilac creates a metabolic dependency. Thus, many dairy cattle accustomed to the drug would "crash" for the remainder of their lactations, losing significant milk output.

* A minor, but significant, percentage of U.S. dairy cows are in extended lactations because of high milk and replacement heifer prices, and low grain and beef prices ... and Posilac. A normal lactation for a dairy cow is 300 days. Many cows in extended lactations are milking way over the 300-day norm. Take away the Posilac, and these cows would quickly become hamburger. Milk production would drop.

The Milkweed estimates that prompt removal of Posilac would lower U.S. milk output by 2-4%—enough to restore favorable supply/demand balances and boost farm milk prices. Dairy commodity inventories are not burdensome. But there is too much farm milk for current demand.

Who'd benefit from banning Posilac?

Dairy commodity and farm milk prices would rise, if FDA were to follow its rules and immediately ban Posilac. Dairy at large would enjoy a better image among consumers. Posilac use has created public skepticism about milk's safety. The present wave of anti-food biotech concerns will only worsen this negative perception of dairy products.

Who'd be hurt?

Who would be hurt if FDA immediately banned Posilac? Obviously, such a ban would hurt Monsanto. But that consideration is irrelevant to public safety. Besides, Monsanto already has so many problems that one more wouldn't matter.

Dairy farmers currently using Posilac would suffer a disproportionately high decline in milk production. Of course, dairy's present course is leading to ruin, anyway. The possible financial problems for Posilac users are a minor consideration, in view of the greater public food safety considerations. If some farmers lose money because their cows cannot milk efficiently unless they're poked with a syringe, then maybe those farmers should sue Monsanto.

Larger, western dairies tend to use Posilac more than small and medium-sized family dairies in traditional milk-producing regions like the Northeast and Midwest. Data show that the "surplus" milk destroying dairy prices is coming from western states where dairies are expanding without heed to supply/demand.

Thus, banning Posilac would inflict the economic pain on the sources of the milk surplus problem.

Robert Cohen: Enemy of my enemy?

Credit Robert Cohen with unveiling the significance of Monsanto's rbGH "switcheroo." Cohen, a New Jersey resident, is an ardent dairy critic. He believes dairy products are ill-advised for the adult diet. Cohen originally got into this fray by researching FDA's questionable human safety considerations for Posilac,



The staff hams it up at a full dress review. Louis Hardin (editorial trainee), editor Pete Hardin and Emma Leah Hardin (receptionist) are all smiles.

and extended his concerns to all dairy products. Cohen is about one month into a hunger strike, demanding that FDA immediately yank approval for Monsanto's drug. He vows to maintain the hunger strike until FDA bans sale of Posilac ... or until Cohen "looks death in the eye."

Cohen appeared at the FDA public hearing on food and biotechnology in Washington, D.C. on November 30. That followed a two-hour session he held earlier in the month with FDA officials in Washington. Cohen reports that the ABC television program "20/20" is preparing a show questioning FDA's failure to yank approval for sale of Posilac, and require new safety studies once Monsanto changed the molecular structure of the synthetic hormone.

Ironically, the citizen's petition Cohen filed with the FDA, which demands the agency immediately halt Posilac sales, represents dairy's best short-term solution for saving the souls on its sinking ship. In this case, Cohen is the "enemy of dairy farmers' enemy"—Posilac ... the major source of unneeded milk. Dairy farmers and organizations should vigorously support Robert Cohen's petition. With pending major television coverage of the issue, it's better for dairy's true friends to be ahead of the curve on this volatile issue.

Sadly, as 1999 is about to become 2000, many dairy farmers understand supply-demand and milk pricing little better than did dairy farmers at the close of the previous century. Immediately banning Posilac sales should only be the beginning of a top-to-bottom restructuring of knowledge, attitudes and practices by groups alleging to represent U.S. dairy farmers.

I urge you to contact FDA, your elected representatives, farm organizations, consumer and environmental organizations.

How to Contact FDA

The Milkweed urges all concerned dairy farmers and consumers to immediately contact FDA to express their concern about Posilac's safety, due to the fact that many of the human/animal safety tests conducted for Posilac were done on hormones that contained amino-acid sequences structurally different from the product Monsanto now markets. Concerned persons may contact the FDA at:

Lyle Jaffe, FDA Dockets Mgr.
Re: Docket #99P-4613
FDA
5600 Fishers Lane
Rockville, MD 20852

FAX: 301-827-6870
E-mail: dockets@oc.fda.gov

The Milkweed... December 1999 - 11

The Milkweed

The farmer's milk marketing report

Issue No. 245
December 1999

'Freak' Amino Acid Raises Posilac Safety Doubts

by Pete Hardin

"Posilac"—Monsanto's genetically-engineered, hormone drug that boosts milk production—is *NOT* the exact molecule upon which human and animal safety tests were conducted.

For many years prior to U.S. Food and Drug Administration (FDA) approval of Monsanto's drug, unrecognized changes occurred in the sequence of 191 amino-acids. A single amino-acid change can dramatically alter how a hormone molecule functions. With Posilac, at least three separate amino-acid sequence changes occurred in a "significant portion of ... rbST produced with *E. Coli*," Monsanto reported.

The Milkweed views this matter as an opportunity for concerned dairy farmers and consumers to demand that FDA immediately ban sale and use of Posilac, pending a whole new round of human/animal safety tests. Suspending Posilac sales would immediately halt dairy's surplus milk problem—boosting farm milk prices. And the public image of dairy products would be boosted, since many consumers are skeptical of

Posilac-induced dairy products.

Unrecognized amino-acid sequence changes in Posilac were first acknowledged in a July 1994 article in *Protein Science* by Bernard Violand, a Monsanto researcher. Violand found that one amino-acid was actually appearing at three different sites among the hormone's 191 amino acids.

Violand's article appeared months after FDA approved commercial sale of Posilac. Violand's article indicated that many of the safety tests conducted for Posilac in the 1980s and early 1990s were conducted before this structural problem was identified.

A private individual, Robert Cohen of Oradell, New Jersey, has filed a legal complaint against FDA (a citizen's petition) demanding that the agency immediately halt Posilac. It lists a variety of human health concerns for milk derived from Posilac injections. The docket number of Cohen's petition is #99P-4613.

Concerned persons should contact FDA to urge suspension of Posilac sales. See Page 11.