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1/15 TO JUN - 1999

December 27, 1999

Lyle Jaffe
FDA Dockets Mgmt. Branch
HFA-305
5630 Fishers Lane
Rockville, MD 20852

Re: Docket #99P-4613

Dear Mr. Jaffe:

When Monsanto first presented their research to the FDA for approval of the genetically engineered bovine growth hormone (rbGH), there were also three other pharmaceutical companies with their own different versions of the genetically modified organism.

Monsanto's protein formula was different than the naturally occurring bovine growth hormone. Monsanto's hormone was not an exact version of the natural pituitary extract from a cow. The end amino acid (amino acids are the building blocks of proteins) was just a little bit different than what naturally occurs in nature. Actually, it was VERY different, but Monsanto neglected to reveal all of their secrets until after their drug received official FDA approval.

Monsanto received approval for rbGH on Friday, February 4, 1994. What happened the following Monday provides "smoking gun" evidence to Monsanto's criminal deception. On Monday, a group of Monsanto scientists photocopied, collated and stapled together the most incriminating scientific document in history and sent it to a peer-review journal for publication. On Thursday of that week, the journal *Protein Science* officially received Monsanto's study.

In that paper, Monsanto admitted that they made significant errors in their formula. Monsanto waited until after approval to admit their errors. Monsanto fixed the errors. However, in making this no-win admission, Monsanto also revealed that all of the research submitted to FDA from 1985 until 1993 was performed with a different hormone than the one that is currently on the market. Most of the authors of the study worked for Monsanto. Most, but not all.

A few researchers were with other firms. One researcher, located after three phone calls, told me that he worked for Monsanto nearly two years before the hormone was approved. Then he made a number of career moves, but still received credit for his work in co-authorship. What does this prove? Simply, that Monsanto knew the errors were made, but held off until after approval. By leaving the firm, the co-author placed a time stamp upon when the "crime" was actually known, and when it was committed.

Monsanto's actual genetically engineered bovine growth hormone (trade name = POSILAC) has never been tested on a laboratory animal. Nor have experiments been performed on test herds.

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Before approval, the FDA required Monsanto to perform hundreds of millions of dollars worth of new research. Equivalent in 1989 did not mean that a perfect match existed. The other three pharmaceutical companies elected not to continue with their research. Eli Lilly had created a bovine growth hormone with seven additional amino acids. American Cyanamid created a version with three new amino acids. Now to the theme of this column. UPJOHN's version was an exact duplicate of what naturally occurs in nature. Exact by 1990 standards, that is.

The reason that this holds so much significance is that Monsanto and UPJOHN will soon be merging into one company. UPJOHN's version of the bovine growth hormone was "supposedly" identical to the hormone naturally manufactured in a cow's brain.

UPJOHN has recently applied to FDA for approval of their hormone, based upon the theory of "substantial equivalence." I learned about UPJOHN's application on Thursday, December 23, 1999. Their application is so secret that FDA will not even confirm that it has been made. On that Thursday before Christmas, I requested the file number from an employee at the Center for Veterinary Medicine (CVM), FDA's investigative branch. She put me on hold and spoke to the director, Stephen Sundlof. After a minute, she came back and apologized. "We cannot reveal the file number until the drug is approved." I was stunned by that secrecy. If and when UPJOHN's formula is approved, it will be too late. After that phone conversation, I filed a Freedom of Information Act request for the case file. Will I be denied truth?

UPJOHN's application and FDA's review is based upon substantial fraud, not substantial equivalence. Genetic engineering is not a perfect science. When cow hormones are combined with E. coli bacteria, one of the resulting amino acids often becomes a freak. That amino acid, LYSINE, has an acetyl group added to it. Chemists call this process "acetylation." References in the Violand study indicate that other errors also might have occurred in glutamic acid.

That's one small misstep for Monsanto and UPJOHN, one giant stride backwards for mankind.

Monsanto created five freak amino acids. UPJOHN most certainly did the same. In 1990, FDA reviewers did not have the sophisticated tests necessary to detect such errors. New technology provides those tests today. Rubber stamping UPJOHN's application because of substantial equivalence cannot be allowed to occur. There is no substantial equivalence when mistakes occur. Monsanto should repeat their research. UPJOHN did not receive approval in 1990, and elected not to invest hundreds of millions of dollars to gain approval. They should not be given a free pass today.

Very truly yours,



Robert Cohen

cc: Mr. J. Maryanski
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