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May 5, 2000

Dockets Management Branch  
Food and Drug Administration  
Department of Health and Human Services  
Room 1-23  
12420 Parklawn Dr.  
Rockville, MD 20857

**PETITION FOR RECONSIDERATION**  
**Docket No. 99P-4613**

The undersigned submits this petition for reconsideration of the decision of the Commissioner of Food and Drugs in Docket No. 99P-4613.

A. Decision Involved/ B. Action Requested

We respectfully disagree with the science and lack of review demonstrated by your ten-page rejection of our petition #99P-4613 to remove Posilac from the market. FDA has contradicted their major conclusion made which led to the approval of the bovine growth hormone. The pasteurization fraud was completely ignored, and your own analysis demonstrates that genetically engineered milk and the milk it replaced is substantially different. In addition, your analysis demonstrates that laboratory animals did indeed demonstrate antibody production through oral ingestion of rbGH. Finally, your assessment of safety for animals and humans has been contradicted by your own recent ten-page response. It would be appropriate to now have a final hearing in a debate-like forum.

C. Statement of Grounds

See attached letter to FDA Commissioner Jane Henney

Signature 

Name of Petitioner Robert Cohen

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May 8, 2000

FDA Commissioner Jane Henney  
Parklawn  
5600 Fishers Lane  
Rockville, MD 20857

Dear Commissioner Henney:

Per statute #10.33, I am respectfully submitting an appeal to the denial of citizen petition #99P-4613 issued on April 20, 2000. I am requesting a formal hearing for the following reasons:

FDA delivered a ten-page letter denying the citizen petition to revoke Monsanto's bovine growth hormone. That letter contains inaccuracies and incorrect conclusions. There is evidence of fraud, deception, and there may have very well be criminal activity at FDA. Does breastfeeding work? According the FDA letter of denial, breastfeeding cannot possibly be of any biological significance to human infants. FDA's decision and my comments:

PAGE ONE

FDA wrote:

"Safety routinely covers the safety of the food products to humans, and safety to the target animals. In addition to these requirements, the sponsor must prove that they can consistently manufacture the drug to a specific purity, potency and quality."

My comment:

I have submitted documents to FDA that name IGF-I as the key factor in prostate, lung, and breast cancers. IGF-I is identical in humans and cows. IGF-I survives digestion. IGF-I in the blood serum of milk drinkers increases by a factor of 10%.

FDA concluded that rbGH treatment for cows was safe, causing no changes in their physiology. I submitted data to FDA proving that, while cows lost on average 100 pounds during lactation, their body organs were under great stress and increased enormously in size.

Monsanto did not prove that they can consistently manufacture the drug to a specific purity. Evidence was submitted to FDA that a contamination of 1,650 pounds occurred during the manufacture process of rbGH prior to approval. As of this writing, FDA remains in violation of federal statutes by refusing to comment on whether or not Monsanto informed them of this manufacturing error which we learned from an internal Monsanto memorandum published in THE MILKWEED.

PAGE TWO

FDA wrote:

"The FDA has previously maintained and continues to maintain that levels of IGF-I in milk whether or not from rbGH supplemented cows are not significant when evaluated against the levels of IGF-I endogenously produced and present in humans."

My comment:

IGF-I manufactured in the human body is either rapidly destroyed or rapidly binds to IGF-I receptors. In homogenized milk, IGF-I protein molecules are encapsulated in micronized liposomes and protected from rapid breakdown by milk casein.

PAGE THREE

FDA wrote:

"Reported percentage increases in IGF-I concentrations in milk of rbGH supplemented cows can be misleading because the levels of IGF-I in milk are so low prior to any increase...The 80% increase in IGF-I levels you refer to in the petition falls in this same range of 2-3ng/mL."

"You cite new evidence demonstrating that levels of IGF-I increase in the blood serum after humans consume milk. The new evidence is an article by Heaney, et al. published in October 1999. This article states that there is a 10% increase in serum IGF-I levels in the milk groups. (The milk groups consumed three servings of milk per day for 12 weeks.) However, the study reported in this article made no effort to identify whether the milk products consumed by the participants were from dairy farms that used rbGH treatment...the 10% increase in serum IGF-I reported in this study cannot possibly be due directly to IGF-I absorption from milk."

My comment:

As to the first point, people do not drink milliliters of milk. By stating that a 2-3 ng/mL increase is "low" or "misleading," FDA continues to mislead. There are 2,000-3,000 nanograms in a liter, and the 80% increase in IGF-I levels was tested during fourteen different lactation cycles.

While Heaney's study made no effort to identify whether milk consumed was genetically engineered, the study did demonstrate that a result of milk drinking produced a galactic effect on the human body by increasing IGF-I blood serum levels by a factor of 10%. One may naturally assume that growth hormones present in milk initiated pituitary stimulation so that human subjects naturally produced increased amounts of IGF-I.

Monsanto scientists (Collier, et. al.) admitted that there were no bGH receptors in bovine mammary tissue, and hypothesized that the effect of the bovine growth hormone is aided by the IGF-I receptor. The implications of this are obvious. Cows treated with rbGH produce milk containing increased levels of bGH and IGF-I. Humans drinking genetically engineered milk consume increased levels of powerful growth hormones, which have been proven by Heaney's study to produce changes in blood serum IGF-I levels.

Heaney's IGF-I study was financed by the dairy industry and the National Fluid Milk Processors, and revealed a secret that FDA believes "cannot possibly" be true. By sponsoring this study, the dairy industry has hoisted their own petard.

PAGE 4

FDA wrote:

"...any elevation of IGF-I levels in milk resulting from rbGH administration were not of any human health concern due to the lack of significant oral absorption of IGF-I under normal physiological circumstances in humans."

"This amount, even if it all survived digestion (and there is insufficient credible evidence that it does), could not reasonably elevate human plasma levels by even 1%."

"Your petition also asserts that there is a connection between increases in levels of IGF-I and cancer...It must be noted that while large percentage increases in IGF-I concentration in human plasma are reported in association with some tumors, the authors of these articles do not reach the conclusion that IGF-I caused the tumors...none of the three articles empirically demonstrates a causal relationship."

My comment:

In human studies, IGF-I was administered in a non-protected pill or powder form. IGF-I in homogenized milk is protected from digestion, and the bioavailability of IGF-I is enhanced.

FDA claims that there is no evidence that IGF-I was elevated in human plasma "by even 1%." The real science (Heaney's study) indicates a ten percent increase.

Each of the three studies indicates that IGF-I levels in blood serum are elevated in various cancers. FDA claims that none of these articles "empirically" demonstrates a

causal relationship. But hundreds of other studies cite IGF-I's mechanism as being endocrine, autocrine, and paracrine.

## PAGE 5 - THE BIG LIE

FDA wrote:

"The FDA was, of course, fully aware of the modification of the N-terminal amino acid of rbGH with a methionine (the established name of the product, methionyl somatotribove, reflects that knowledge). We recognize that you have not taken issue with the incorporation of the methionine, conceding that it is not a health concern because it does not interfere with the tertiary structure of the protein nor does it impact the biological activity of the protein. FDA was also aware of the potential for an acetylated lysine at position 144 as well as other positions as reported by Violand, et. al. in 1994. The FDA was informed of the latter potential difference between natural bGH and the sponsor's rbGH in 1987, six years prior to approval. {We note that you submitted an FOIA request for documents from January 1, 1990 to the present (which we considered to be December 20, 1999, the date your FOIA request was filed) regarding the "five different amino acids created during the process of genetically engineering [Monsanto's] bovine growth hormone". We had no documents from that time period and we so advised you in our FOIA response.}"

"When Monsanto informed the FDA in 1987 that a small percentage of their rbGH product contained modified amino acid components, they did so by reporting on the electrical charge states of the resultant proteins."

"We note, in passing, that amino acid modifications of this kind are probably not appropriately referred to as "freak amino acids" as you refer to them in your petition. Rather, acetylation is a recognized naturally occurring post-translational event in proteins. In any event, only a small percentage of the total rbGH produced is post-translationally modified in this manner."

My comment:

In the forgoing the FDA wrote:

"We recognize that you have not taken issue with the incorporation of the methionine, conceding that it is not a health concern..."

On August 24, 1990, FDA (Juskevich and Guyer's SCIENCE paper) published a review of bovine somatotropin, and in that review, cited the work of Jerome Moore and established that a different amino acid at the end of a protein chain (N-terminus) would not affect the characteristics of that protein. While my knowledge of protein science is not equal to that of the experts, I accepted Moore's assessment and conceded that this error would not pose a threat to human safety. Other errors would.

However, Jerome Moore cited other human diseases that could occur if an amino acid differed in the middle of a protein chain. The best knowledge of FDA scientists, at that point in time, demonstrated their belief that there were no such errors and concluded that the genetically engineered hormone was virtually the same as the naturally occurring pituitary extract.

FDA states that they were aware of the potential for an acetylated amino acid at position #144. This is laughable. The author of this FDA document continues the lie by writing:

"The FDA was informed of the latter potential difference between natural bGH and the sponsor's rbGH in 1987, six years prior to approval."

The errors were not assayed or discovered until after FDA's 1990 review. If they had been, Juskevich and Guyer would have reported those differences. FDA claims that they had such documentation in their file as early as 1987, six years prior to approval, which is an outright lie.

I was charged \$725 for a Freedom of Information Act search, which proved that nothing was in the file. If a document has now mysteriously appeared, it would be appropriate for the FBI and the GAO to analyze ink samples and fingerprints.

FDA writes that the errors that I refer to are not appropriately called freak amino acids. FDA claims that they are naturally occurring events, and only a small percentage of the bovine growth hormone is incorrectly modified this way.

"Freak amino acid" was a term used by Monsanto's own scientist Bernard Violand, and FDA is incorrect in stating that this error occurred in only a small percentage of the bGH. In fact, more than 40% of the proteins produced contained one or more of these freak amino acids.

PAGE 6

FDA wrote:

"As stated earlier, FDA was aware of the change in the manufacturing process prior to its approval of the product and believed the change did not result in a different product such that the research with the product prior to the manufacturing change was invalid. We note that during the new animal drug development process, it is the usual case that sponsors make continued improvements in the manufacturing process. If those changes result in only biologically inconsequential health variations, we consider the products to be the same."

My comment:

I have never before heard the expression "biologically inconsequential variations," and I am offended by the arrogance of the author of this phrase. Monsanto utilized an

enormous amount of resources, teams of scientists, millions of dollars, taking eighteen months to filter out these "biologically inconsequential variations," which FDA now considers to be "the same." Does FDA consider increased cancer rates to be biologically inconsequential variations?

PAGE 7

FDA wrote:

"We also made a site visit to the sponsor to examine batch records. These records are not required to be submitted to the new animal drug files."

My comment:

This statement contradicts FDA regulations and page one of FDA's ten-page letter. On page one, FDA wrote:

"...the sponsor must prove they can consistently manufacture the drug to a specific purity, potency and quality."

On page seven they lie by stating that such records are not required.

I submitted evidence to FDA that Monsanto manufactured a "phage contamination of 1,650 pounds of rbGH." Did Monsanto inform FDA? FDA still has not responded to my Freedom of Information Act request regarding that error, and as of this writing, are in violation of federal statutes which require a 20-day response to a Freedom of Information Act request.

On page 7, FDA completely ignores the most important criteria used for approval. FDA relieved Monsanto from performing further toxicology studies in 1990 because of their conclusion that most of the bovine growth hormone was destroyed by pasteurization. In fact, the FDA commissioner testified before Congress that such further research would be inconsequential because heat treatment destroyed the bovine growth hormone in milk. Normal pasteurization requires 15 seconds at 162° Fahrenheit. FDA applied 30 minutes at a temperature reserved for a 15-second process, only destroyed 19% of the bovine growth hormone and lied by stating that most of it was destroyed. It is curious that FDA completely ignores the greatest example of their fraud and deceit.

PAGE 8

FDA wrote:

"Like most dietary proteins, rbGH is degraded by digestive enzymes in gastrointestinal tract and not absorbed intact."

My comment:

## DOES BREASTFEEDING NOT WORK? THAT IS FDA'S BELIEF

This conclusion was also the same explanation given to me on April 21, 1995 when I first met with FDA scientists at the Center for Veterinary Medicine in Rockville, Maryland. My response then was to ask them whether breastfeeding works by passing lactoferrins and immunoglobulins to nursing infants. Their response was that milk hormones are degraded by digestive enzymes and not absorbed intact.

One day FDA and science will recognize that milk is a hormonal delivery system. Milk was designed to buffer gastric acidity so that the substances so contained would survive the first phase of digestion. Homogenization of cow's milk has made the existing hormonal delivery system more efficient. Fat molecules (liposomes) are made between 10 and 100 times smaller after they are passed through fine filters at extremely high pressure, and protein hormones are encapsulated inside these micronized liposomes enabling them to bypass the gut where they are absorbed intact into the bloodstream.

PAGE 9

FDA wrote:

"Administration of subcutaneous or oral rbGH resulted in a significant increase in plasma antibody concentration."

My comment:

In 1999, Canada turned down Monsanto's application for the genetically engineered bovine growth hormone. Canadian scientists observed a vast array of biological effects from oral ingestion of rbGH, including tumor growth. As a result of the Canadian review, a group of consumer advocates led by Andrew Kimbrell sued for the removal of the genetically engineered bovine growth hormone. In her denial, the Secretary of Health and Human Services, Donna Shalala (who posed for a milk mustache advertisement and had close ties to the dairy industry and to Monsanto while working at the University of Wisconsin), commented that the Canadian scientists misinterpreted the data.

FDA's admission that "oral rbGH resulted in a significant increase in plasma antibody concentration" confirms the Canadian observation and adds ridicule to Shalala's condemnation.

FDA states that there are no other biological effects observed in the Richard, Odaglia and Deslex study. I have the original study. FDA reported that the study lasted for 90 days, and this lie is part of their crime. The study lasted for 180 days. Monsanto successfully lobbied to have a law passed that would punish me by fifteen years in a federal prison and a \$10,000,000 fine should I release that study (Public Law #104-294, the Economic Espionage Act of 1996).

It is time for fraud and deception to end. FDA is part of the problem. They had an opportunity to do the right thing and have not. I have formally requested a public hearing and will work closely with Congress and investigatory agencies to make this a better nation for all Americans.

Very truly yours,

A handwritten signature in black ink, appearing to read 'Robert Cohen', written in a cursive style.

Robert Cohen

cc: see separate list

**Bill Summary & Status for the 106th Congress**

Item 1 of 1

**PREVIOUS: COSPONSORS | NEXT: COSPONSORS  
HOME | HELP | ABOUT COSPONSORS****H.R.3377**Sponsor: Rep Kucinich, Dennis J. (introduced 11/16/1999)

Latest Major Action: 11/30/1999 Referred to House subcommittee

Title: To amend the Federal Food, Drug, and Cosmetic Act, the Federal Meat Inspection Act, and the Poultry Products Inspection Act to require that food that contains a genetically engineered material, or that is produced with a genetically engineered material, be labeled accordingly.

**COSPONSORS(51), ALPHABETICAL** (followed by Cospंसors withdrawn): (Sort: by date)

<u>Rep Andrews, Robert E.</u> - 3/28/2000	<u>Rep Barrett, Thomas M.</u> - 2/1/2000
✓ <u>Rep Bonior, David E.</u> - 11/16/1999	✓ <u>Rep Brown, Sherrod</u> - 11/16/1999
<u>Rep Carson, Julia</u> - 3/28/2000	✓ <u>Rep Clay, William (Bill)</u> - 2/1/2000
✓ <u>Rep Conyers, John, Jr.</u> - 2/1/2000	✓ <u>Rep DeFazio, Peter A.</u> - 11/16/1999
✓ <u>Rep Delahunt, William D.</u> - 2/1/2000	✓ <u>Rep Doyle, Michael E.</u> - 11/16/1999
<u>Rep Faleomavaega, Eni F. H.</u> - 2/15/2000	✓ <u>Rep Gutierrez, Luis V.</u> - 2/1/2000
✓ <u>Rep Hinchey, Maurice D.</u> - 11/16/1999	<u>Rep Jones, Stephanie Tubbs</u> - 4/12/2000
<u>Rep Kildee, Dale E.</u> - 3/1/2000	✓ <u>Rep Kilpatrick, Carolyn C.</u> - 2/1/2000
✓ <u>Rep Kleczka, Gerald D.</u> - 2/1/2000	<u>Rep Lantos, Tom</u> - 3/16/2000
✓ <u>Rep LaTourette, Steve C.</u> - 2/1/2000	✓ <u>Rep Lee, Barbara</u> - 11/16/1999
✓ <u>Rep Lewis, John</u> - 2/1/2000	✓ <u>Rep Lipinski, William O.</u> - 11/16/1999
✓ <u>Rep Maloney, Carolyn B.</u> - 11/18/1999	✓ <u>Rep Markey, Edward J.</u> - 2/1/2000
✓ <u>Rep Martinez, Matthew G.</u> - 11/16/1999	✓ <u>Rep McDermott, Jim</u> - 11/16/1999
✓ <u>Rep McGovern, James P.</u> - 2/1/2000	<u>Rep McKinney, Cynthia A.</u> - 2/1/2000
✓ <u>Rep Metcalf, Jack</u> - 11/16/1999	✓ <u>Rep Miller, George</u> - 2/1/2000
✓ <u>Rep Mink, Patsy T.</u> - 11/16/1999	✓ <u>Rep Moakley, John Joseph</u> - 2/1/2000
✓ <u>Rep Nadler, Jerrold</u> - 2/1/2000	<u>Rep Neal, Richard E.</u> - 3/1/2000
✓ <u>Rep Norton, Eleanor Holmes</u> - 11/16/1999	✓ <u>Rep Olyer, John W.</u> - 2/1/2000
✓ <u>Rep Owens, Malor R.</u> - 2/1/2000	✓ <u>Rep Pallone, Frank, Jr.</u> - 2/1/2000
<u>Rep Rangel, Charles B.</u> - 2/15/2000	✓ <u>Rep Rivers, Lynn N.</u> - 11/18/1999
✓ <u>Rep Sanders, Bernard</u> - 11/16/1999	✓ <u>Rep Schakowsky, Janice D.</u> - 11/16/1999
<u>Rep Sherman, Brad</u> - 2/15/2000	✓ <u>Rep Smith, Christopher H.</u> - 11/16/1999
✓ <u>Rep Stark, Fortney Pete</u> - 11/16/1999	✓ <u>Rep Udall, Mark</u> - 2/1/2000
<u>Rep Udall, Tom</u> - 3/1/2000	✓ <u>Rep Waters, Maxine</u> - 11/18/1999
<u>Rep Weiner, Anthony D.</u> - 2/15/2000	✓ <u>Rep Woolsey, Lynn C.</u> - 11/16/1999
✓ <u>Rep Wynn, Albert Russell</u> - 2/1/2000	

SENATOR BARBARA BOXER

Robert Cohen  
560 Oradell Ave.  
Oradell, NJ 07649

Fold at line over top of envelope to  
the right of the return address

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