

Confidential Monsanto Research Files Dispute Many bGH Safety Claims

© Copyright 1990 The Milkweed

by Samuel S. Epstein, M.D. and Pete Hardin

Monsanto files containing research data from bGH trials completely disprove many claims asserted about the synthetic milk hormone.

The authors have reviewed confidential industry files submitted to the Food and Drug Administration as part of the New Animal Drug Applications.

Until these bGH tests files were uncovered, it's been difficult to refute misleading assertions by bGH manufacturers, university scientists contracted to these chemical companies, and FDA officials.

These interlocking groups claim:

*No increase in milk hormone levels.

*No adverse reproductive or other toxic health effects in treated cows.

*Milk from bGH cows is safe for humans.

In fact, the Monsanto bGH test files reveal the following:

*Milk bGH (somatotropin) levels in groups of treated cows appear in concentrations up to 1000 times higher than found in control samples. In tests for two-week bGH injections, bGH hormone levels in cows' milk skyrocketed immediately following treatments.

*bGH-treated cows' key organs were significantly larger than those of control animals in Monsanto tests. Cows receiving bGH injections showed significantly larger hearts, livers ovaries and thyroids. Major size increases of treated cows' organs resulting from bGH tests conducted over 40 weeks poses serious doubt about longer-term health effects to dairy cows from administration of the recombinant hormone.

The authors are, respectively, a professor of environmental and occupational medicine in the School of Public Health at the University of Illinois Medical Center-Chicago, and the editor/publisher of The Milkweed.

*Several Monsanto bGH trials concluded that growth hormone caused major reproductive problems in treated dairy cows.

*At Monsanto's research farm in the St. Louis suburbs, a 1985-86 bGH trial on 82 cows shows the company treated lactating dairy cows with numerous illegal drugs and anti-biotics. Those drugs include: Banamine, Di-Trim, Gentamycin, Ivomec, Oxytet, Piperallin, Rompun and Vetislud.

Over eight to nine months of the 1985-86 test, Monsanto employees administered illegal drugs to lactating dairy cows over 150 separate times. Milk from Monsanto's research farm is marketed to Mid-America Dairymen and generally disposed to fluid processors in the St. Louis area.

*Photographs of the injection sites from necropsied cattle shows bGH-injections cause significant damage to the carcass, at progressively higher doses. Needle damage to the cow's carcass creates problems for slaughterhouses as federal meat inspectors hold up carcasses showing needle marks for several days, pending further tests for illegal drug residues.

Almost comically, Monsanto's research farm employees appeared at times like the "Keystone Cops," trying to administer twice-monthly bGH injections. Many bGH needles broke off in the cows, as the animals flinched while receiving injections.

*Mastitis problems are higher in bGH-treated cows. One cow given bGH at a five-times normal dose level received over 120 injections of legal and illegal anti-biotics in an eight-month period. Monsanto did not calculate statistical differences between treated cows and control cows for mastitis, in the '85-86 Dar-denne, MO study as could be best determined from available files.

These Monsanto files are but a few of many submitted to FDA by bGH manufacturers. Ultimately, FDA is expected to approve commercial use of bovine growth hormone, in spite of data such as revealed these few Monsanto's files.

The Monsanto bGH files reveal a first-time public glance at what really goes on behind the scenes in at least one company's bGH research. These findings are shocking. To afford readers a chance to make their own determinations, *The Milkweed* reproduces many of the key, damning documents.

Small wonder Monsanto affixed to the first page of each research report the following warning:

"Company Confidential"

"This document is the property of Monsanto Company and the recipient is responsible for its safekeeping and disposition. It contains CONFIDENTIAL INFORMATION which must not be reproduced, revealed to unauthorized persons or sent outside the Company without proper authorization."

High bGH levels in treated cows' milk

During bGH tests, details are kept daily regarding milk volume, butterfat, protein ... and somatotropin (growth hormone) content. Most conveniently, Monsanto file 140/872 (Vol. 90), pages 29417-29423 contains day-by-day somatotropin content in the milk of groups of cows treated with a half dozen different bGH formulations. Remember company claims about how the milk from bGH-treated cows is "the same?" Forget that. Monsanto's own files contradict that lie.

Daily mean somatotropin levels for various Monsanto bGH formulations are reproduced in Table 1. Readers can easily note large differences between somatotropin levels in control cows versus bGH-treated animals' milk. Somatotropin levels are measured in nano-grams (parts per billion). While that seems a small amount, those levels are significant because somatotropins are active at levels of a few parts per billion.

Of significant note: in Monsanto's experiments dealing with two-week bGH injections, immediately following treatments, the hormone content of treated cows' milk skyrockets to as much as 1000 times control animals' milk hormone levels. The data listed are averaged for entire groups of treated cows versus controls.

Monsanto (and other manufacturers) are working on bGH delivery systems (injections) that will supply at least a 14-day volume of hormone into treated cows. That's so farmers don't have to use a needle on their cows daily. Daily injections are viewed as too time-consuming and expensive.

If bGH were ever commercially approved, a farmer would tend to inject his cows at about the same time every two weeks. That could lead to the entire farm bulk tank being filled with hormonally-supercharged cows' milk.

continued on page 4

Table 1 Somatotropin (bGH) Levels in Milk in Groups of Control and bGH-Treated Cows

Hormone levels (parts per billion) in Control vs. Treatment Groups

Day of Study	Control	MBS Pellets	NaALAVAl	NaALAVAlHIS	NaMBS	ZnMBS/HH	ZnMBS/Q
0	0.19577	0.11716	0.2643	0.0640	0.13126	0.08807	0.6283
1	0.06104	0.00000	3.8459	7.8745	1.20525	0.87220	0.5363
2	0.04016	0.66804	8.4245	14.2849	4.22168	2.57434	2.0153
3	0.03893	0.28566	6.7800	10.7888	1.96977	2.07170	2.9557
4	0.00952	0.05654	11.2450	9.9904	4.04125	1.25826	4.2275
5	0.06932	0.22421	11.3817	12.2356	4.20745	4.34668	6.5981
6	0.09314	0.47084	9.6868	7.4985	5.07196	4.91860	6.4016
7	0.00000	0.01268	6.0958	3.4893	2.73232	4.26100	4.8077
8	0.29891	0.73798	4.3629	2.9741	3.70725	4.98847	6.2800
9	0.00000	0.14495	1.9805	1.0722	2.62665	4.21366	4.7213
10	0.40815	0.66174	0.8860	0.3832	1.52750	2.33868	2.6350
11	0.14060	1.22214	1.4134	0.4510	1.69536	2.51043	3.1948
12	0.61684	1.65600	1.3996	0.6423	1.79982	2.68211	2.8864
13	0.10098	2.07693	1.3603	0.8283	2.66016	3.62322	3.3956
14	0.21689	0.56357	0.2633	0.0660	1.24105	1.91343	2.1578
15	0.29096	3.65204	7.1140	12.1335	5.67692	4.83445	5.4758
16	0.09070	1.28298	5.7024	8.8360	3.84364	3.04654	2.2476
17	0.07559	2.05291	6.7107	8.7464	4.39387	4.11052	3.9006
18	0.13790	2.76171	8.0808	7.9274	5.43118	5.19416	5.4829
19	0.00000	2.21240	8.6846	11.4633	6.12982	4.97917	7.9363
20	0.30428	1.79884	6.9404	7.3978	4.84249	6.04730	7.6052
21	1.38520	2.06817	5.4589	4.9373	3.99861	5.73216	6.9639
22	0.32268	6.13634	6.3922	7.9477	5.79917	7.13861	8.6426
23	0.12842	3.60406	3.3088	3.1294	3.22579	4.42903	4.7502
24	0.02700	3.09686	2.3080	2.7154	2.50531	2.72682	4.0212
25	1.46420	4.09999	2.6602	1.7446	2.62228	2.15928	3.5760
26	0.01575	1.81383	1.3541	0.2727	0.91273	0.96594	1.7656
27	0.11436	1.63923	0.8505	0.4723	1.17683	0.95391	1.7261
28	0.14064	2.76229	2.5084	1.1047	2.41880	2.67949	3.8510
29	0.14042	2.05312	8.8577	12.7035	5.31511	3.53508	4.7464
30	0.06737	1.42304	8.6213	12.0244	7.64494	3.93432	5.6313
31	0.12518	1.60208	8.4536	8.2427	6.38176	4.22017	6.2265
32	0.00000	0.86823	6.3272	6.8617	5.78637	4.51245	5.6579
33	0.02284	1.06210	9.2929	9.2320	6.28409	7.49231	9.0241
34	0.57522	1.40577	9.0804	10.9802	5.58061	7.71183	12.1700
35	0.01467	0.38056	5.7556	4.9763	2.79669	6.80052	7.0482
36	0.17279	1.08512	5.5048	4.2770	3.38138	6.30222	6.8437
37	0.03073	1.80194	4.6843	4.7665	3.85380	5.45469	6.8496
38	0.22458	1.38164	3.6675	3.3952	3.16404	3.80043	6.5206
39	0.08030	1.46267	2.8141	2.6664	2.94272	3.50563	5.5874
40	0.00000	1.19256	2.7435	1.6328	1.92378	2.40615	5.7887
41	0.07900	2.12581	2.1359	2.2757	2.55819	2.75783	6.3554
42	0.63619	3.34593	2.0382	2.3866	2.89134	2.85741	7.2390

The tables above compare the daily mean concentrations of somatotropin (growth hormone) contained in cows' milk between a control group and six separate bGH formulations. These results are contained in Monsanto's New Animal Drug Application No. 140-872, Volume 90, pages 29418-29425.

Except perhaps for "MBS Pellets," all other Monsanto bGH versions reported here are two-week treatments. In these tests, treated cows received recombinant hormones on days 1, 15, and 29.

bGH-treated groups' somatotropin levels in milk are clearly higher than the control groups'

hormone levels. On some days, bGH-treated groups register over 1000 times more somatotropin present in milk than found in the control group's milk. In the Monsanto files studied, the company offered no statistical analysis to FDA regarding somatotropin presence in milk.

Despite such research data available to them, Monsanto spokesmen (and high-level FDA employees) have consistently claimed bGH-produced milk's are hormone levels are the same as natural cows' milk. Those assertions about bGH-derived milk being the same as natural milk are clearly untrue, as Monsanto's own data displays.

Confidential Monsanto Research Files Dispute

Pathology

Following Monsanto's trials of two-week injections on 82 cows at the company's Dardenne, MO research farm in 1985-86, 35 test animals were slaughtered and necropsied. Hazleton Laboratories of Madison, WI conducted pathology analyses. (See Table 2).

Cows treated with Monsanto's two-week injections of CP115099-F registered lower body weights, but not sufficiently lower to establish statistical significance.

Despite the fact that treated cattle received bGH injections every two weeks for approximately eight months, major differences were found in the relative sizes of important organs between control and treated cows:

- *Treated cows adrenal glands were larger than non-treated cows.
- *Treated cows kidney's were larger than non-treated cows'.
- *Hearts of bGH-cows weighed significantly more than untreated animals'.
- *Liver weights for all treated cows were larger than for control cows' livers.
- *Ovary sizes in treated cows were ostensibly larger than ovaries in control cows. Pregnancy rates were significantly lower among bGH-treated animals in this Monsanto study. Microscopic analysis of uteri showed that treated cows showed a larger absolute number of microscopic lesions.

These same necropsies showed that treated cows weighed less at time of slaughter than control cows.

"Although the terminal body weights of groups given CP115009-F were somewhat less than those of the controls, the magnitude of the differences in absolute organ weight, and organ-to-body weight and organ-to-brain percentages suggest that CP115099-F increased metabolic activity in these organs. These changes were considered to be harmless physiological shifts as supported by clinical pathology results and increased milk production."

Monsanto is using short-term measures (increased milk production) to extrapolate "safety" of recombinant bovine growth hormone treatments. The relative health of treated animals during subsequent lactations is of greater importance to the dairy farmer than just "increased milk production" during a short-term treatment period.

No findings regarding bone mass density were recorded in the necropsies. Significant size increases for key organs and glands in bGH-treated dairy cows (treated for only eight months) are dismissed by Monsanto as "harmless physiological shifts."

Significant increases in key organs' size during a modest time-frame of bGH-treatments is cause to wonder about possible negative effects of longer-term bGH treatments to dairy cattle.

Enlarged key organs such as heart, liver, ovaries thyroids forebode longer-term health problems for treated dairy animals. The liver size is a crucial concern, since the liver synthesizes growth hormone within the body. Abnormally-large liver size could indicate future potential dysfunction.

Reproductive failure

Another significant revelation in Monsanto's bGH trial files shows serious reproductive failure. Tests designed to measure reproductive results of bGH-administration unequivocally demonstrated that reproductive failure resulted from using Monsanto's bGH.

These conclusions are at variance with reassuring, contrary statements made about treated cows' reproductive performance by company spokespersons, university researchers and FDA officials.

The aforementioned Monsanto test at its Missouri research farm concluded: "... pregnancy rates were significantly lower among CP115099-F treated animals than the contemporary controls." Monsanto notes that pregnancy rates were not lower than rates normally observed in the dairy industry. That's statistical bunk. Reproduction data from that test shows Monsanto counted as pregnant many test cows which were pregnant before the treatments began! When comparing reproduction rates from control vs. treated animals for animals not pregnant prior to the treatments, Monsanto's bGH conception rates is 52%. That does not measure up to standards associated with successful dairy farm management. *The Milkweed* summarizes pregnancies in the 1985-86 Monsanto test:

PREGNANCIES ESTABLISHED IN TREATED COWS VS. CONTROL COWS

X=dose level	TREATMENTS			
	Control	1X	3X	5X
Pregnant	13	9	7	9
Non-Pregnant	1	9	6	8
Totals	14	18	13	17

95% of control cows open at the start of the trial became pregnant.

52% of bGH-treated cows open at the start of the trial became pregnant.

Animals not confirmed pregnant by the 140-day mark of their lactation were considered "open." Monsanto's files note: "Interestingly, regardless of treatment group, approximately two-thirds of all pregnant animals became pregnant during the treatment period."

Ninety-five percent of control group cows were confirmed pregnant at the 140-days. Only 52% of treated cows became pregnant during the eight-month Monsanto trial. Two treated cows were necropsied during the test, due to health problems.

Several other studies reported in the Monsanto files note adverse reproduction problems in treated animals.

Illegal drug treatments

Using illegal drugs in lactating dairy cows is a topical issue. FDA is drawing up financial penalties to assess offending dairy farmers. FDA officials are even claiming that milk inspectors can enter farmers' houses (without search warrants) to ferret out alleged illegal drugs. Perhaps if FDA really wants to find a potential source of illegal animal drugs in the public milk supply, what better place to start than Monsanto's St. Louis area research farm.

Illegal drug use by Monsanto employees on bGH test cows is documented for FDA, in Monsanto's NADA files. Drugs used to illegally treat milking cows at Monsanto's research farm include: Banamine, Di-Trim, Gentamycin, Ivomec, Oxytet, Piperallin, Rompun and Vetislud.

Records do not indicate whether milk from Monsanto research cows treated with illegal drugs was withheld from the market. Some anti-biotics may be used for treating lactating dairy cows, if strict FDA rules on withholding milk and meat from market are followed.

Using non-approved anti-biotics on milking cows is scandalous. Problem is: because FDA has not approved using Banamine, Di-Trim, etc. for lactating dairy cows, the agency has not developed any guidelines for how long milk from cows treated with such drugs must be kept from market. Just how long it takes for un-approved drugs to be eliminated from cows' milk and meat is not determined.

One cow (#85704) at Dardenne, MO received over 120 drug treatments in a single lactation. Nearly half of those treatments were with illegal drugs.

Table 2

Summary of Absolute Organ Weight Data (g) Cows Sacrificed at or near End of Lactation

	Group 0 6	Group 1X 12	Group 3X 10	Group 5X 11
<u>Terminal Body Weight</u>				
N=	6	12	10	11
Mean =	723416.66667	682333.33333	685688.80000	675818.18182
SD =	88679.432038	81975.144052	58622.665402	55021.483408
<u>Left Thyroid</u>				
N=	6	12	10	11
Mean =	17.44617	20.09200	21.04740	26.99327
SD =	3.663581	4.822524	6.230329	11.561502
<u>Right Thyroid</u>				
N=	6	12	10	11*
Mean =	17.71167	17.44850	20.01240	29.57682
SD =	3.614046	5.176904	5.367572	16.760477
<u>Liver</u>				
N=	6	12	10	11
Mean =	10875.00000	10875.00000	12256.40000	12178.72727
SD =	1464.155046	1276.981526	1450.773219	1210.389532
<u>Heart</u>				
N=	6	12	10	11
Mean =	3416.66667	3416.66667	4080.90000	4085.00000
SD =	735.980072	596.708141	516.938950	811.642902
<u>Left Adrenal</u>				
N=	5	12	10*	11*
Mean =	17.24180	20.38383	25.70890	25.73655
SD =	2.114426	5.186912	3.683569	5.119998
<u>Right Adrenal</u>				
N=	6	11*	10*	10*
Mean =	15.28583	18.89191	21.73640	23.29270
SD =	1.330597	3.061293	2.321770	4.939470
<u>Left Kidney</u>				
N=	5	12	10	10*
Mean =	897.05999	979.74999	1195.05001	1249.13000
SD =	149.936654	137.597485	247.059849	305.644836
<u>Right Kidney</u>				
N=	6	12	10*	10*
Mean =	761.66665	865.88333	1109.25000	1179.38000
SD =	99.540430	137.184379	215.427726	303.958720
<u>Left Ovary</u>				
N=	6	12	10	11
Mean =	11.37183	12.13183	13.49330	13.85909
SD =	6.718326	5.821294	6.111290	3.491495
<u>Right Ovary</u>				
N=	6	12	10	11
Mean =	11.92317	15.97725	16.93200	17.18645
SD =	3.784737	3.599741	7.385783	8.148091

Many bGH Safety Claims con't.

Test cattle or otherwise, it's absolutely illegal to treat lactating cows with non-approved drugs and anti-biotics. What with the elaborate records kept at Monsanto's research farm, perhaps a thorough review of other company records could indeed determine if illegally-treated cows' milk were withheld or sold. If withheld, for how long?

Punctured carcasses

A picture is worth 1000 words. Look at the accompanying pictures.

One factor reducing the relative economics of farmers using bovine growth hormone is if the cull value of treated cows is reduced. More than once in Monsanto's bGH research files, the company admits that bGH-treated cows were "leaner" than control cows. In other words, farmers who cull bGH-treated cows will be marketing lighter-weight cows.

Lighter cull weights are just the beginning of the slaughter problem for bGH-treated dairy cows.

Federal inspectors at meat packing plants are required to divert carcasses showing needle marks for extensive tests to determine possible anti-biotic residues. Those tests are both costly and time-consuming -- up to several days. While the testing goes on, the carcasses wait, hanging on a side-rail.

Needlemarks, anybody? It won't require 20/20 eyesight to see the needlemarks on bGH-treated cows, if the pictures from Monsanto's files indicate damage wrought by bGH injections. bGH-injected cows could be worth much less at slaughter, because needlemark polkadotted carcasses cause meatpackers to delay processing while costly, time-consuming tests are run. (See Table 3).

Early Withdrawals Periods for Milk, Meat

Researchers have known for 25 years that bovine somatotropin fragments could be active in humans. That finding was published in 1965. Quoting from Elanco's New Animal Drug Application (Somidobove Sustained Release Injection) Volume 7, No. 7, page 4608: (1987):

"Tryptic digests of bGH produces some metabolic effects in hypopituitary humans similar to those effects noted after administration of HGH" (human growth hormone).

At the time FDA approved Monsanto's first bGH trials at Cornell University, agency documents show human safety questions resulted in cautionary withdrawal periods for milk and meat following bGH injections.

At the Cornell trials, FDA stipulated in 1982 that treated cows' milk could not be consumed for five days following final injections. And bGH-treated cows' meat could not be sent to slaughter for 15 days following the last injection.

The above-mentioned tryptic bGH digests may have been the reason for caution in FDA's establishing withdrawal periods for bGH-induced milk. A January 26, 1982 letter from FDA's Dr. Judith Juskevich (Bureau of Veterinary Medicine) to Monsanto acknowledged higher hormone levels in bGH-treated cows blood:

Previous studies reported in the literature have determined serum bGH in dairy cattle following dairy injection of pbGH. Peel, *et al.* (J. Nutrition 111:1662, 1981) injected cows with 44 mg of bGH and found plasma values as high as 57 ng/ml (preinjection 6 ng/ml). Bines, *et al.* (Brit. J. Nutrition 43:179, 1980) injected cows with 30 mg of bGH and observed peak plasma levels of 17.3 ng/ml (preinjection = 3.7 ng/ml). Both studies demonstrate that serum bGH drops rapidly in the 24 hours after the last injection and, although the levels may still be elevated, they are within the normal physiological range. Over the entire 24 hour period post-injection the mean serum concentration of bGH was 31 ng/ml

continued on page 6

Table 3 "Laboratory Animal Health Data"

STUDY: 100-DDC-COW-PJE-85-010 SENT DATE: 31OCT85
DATE: 30OCT85:12:20:00 OBSERVER: PKE
STATUS: Farm Record - Current ENTRY INITIALS: KAC

85773-COW JERKED NEEDLE WITHIN MUSCLE AT SITE A AND SITE I. BLEEDING AT SITE I. -PKE

85026-NEEDLE WAS JERKED WITHIN MUSCLE-SITE A-DURING INJECTION. -PKE

85794-SYRINGE #0528-COW VERY EXCITED AND SYRINGE FELL ON THE GROUND. REPLACED WITH SYRINGE 0154-SITE RIGHT SEMITENDINOUS-IS PROXIMAL. -PKE

LEFT GLUTEUS DISTAL SITE BLEEDING ON 85685 0537 SYRINGE REPLACES SYRINGE 0531-NEEDLE DROPPED OFF. -PKE

85004-SYRINGE 0524 CAME APART PRIOR TO INJECTION. IT WAS REASSEMBLED & USED. -PKE

85074-NEEDLE BROKE ON SYRINGE 0313 AT SITE A. BLEEDING OUT OF SITE G. EXTREMELY NERVOUS ANIMAL.

85790-SYRINGE 0739 REPLACED WITH SYRINGE 0544 DUE TO NEEDLE COMING OFF AT INJECTION SITE I. -PKE

85004 SYRINGE 0506 CAME APART PRIOR TO INJECTION & WAS REASSEMBLED & USED TO INJECT. -PKE

Companies testing new animal drugs are required to keep extensive animal health records. In this section, *The Milkweed* reproduces the daily "Laboratory Animal Health Data" entered for October 21, 1985. That day was the first date for bGH-treatments in Monsanto's test at Dardenne, Missouri.

Opening day jitters? Of proximately 80 cows receiving injections, Monsanto employees entered 11 problems treating the cattle for the test's first day.

Cows in this text received injections every two weeks. Cows receiving treatments at three and five times recommended doses received, respectively three and five injections every two weeks.

The following photographs show injection sites for four groups of cows in a bGH test conducted by Monsanto at the farms Dardenne, MO research farm in 1985-86. The photos, top to bottom, show selected injection sites of necropsied cows. The photos were taken following necropsies conducted by Hazelton Laboratories of Madison, WI.

Cows receiving bigger bGH injections show progressively larger carcass damage. In meat plants, gov't inspectors side-track livestock carcasses showing needlemarks. Those carcasses are delayed pending further tests for antibiotics, etc., that can last up to one week. Cull dairy cow carcasses showing such wounds would be suspect at the slaughterhouse.



Figure 1
Cow 85762--Control group. Injection site A.

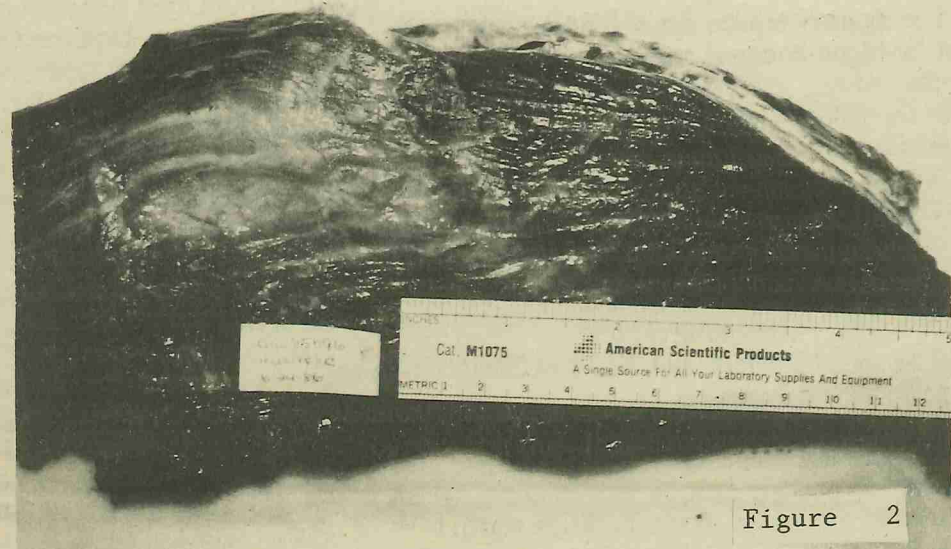


Figure 2
Cow 85689--1X treatment group. Injection site B. Cow received 600 mg. dose of Monsanto's zinc methionyl bovine somatotropin prolonged release product, CP115099-F.

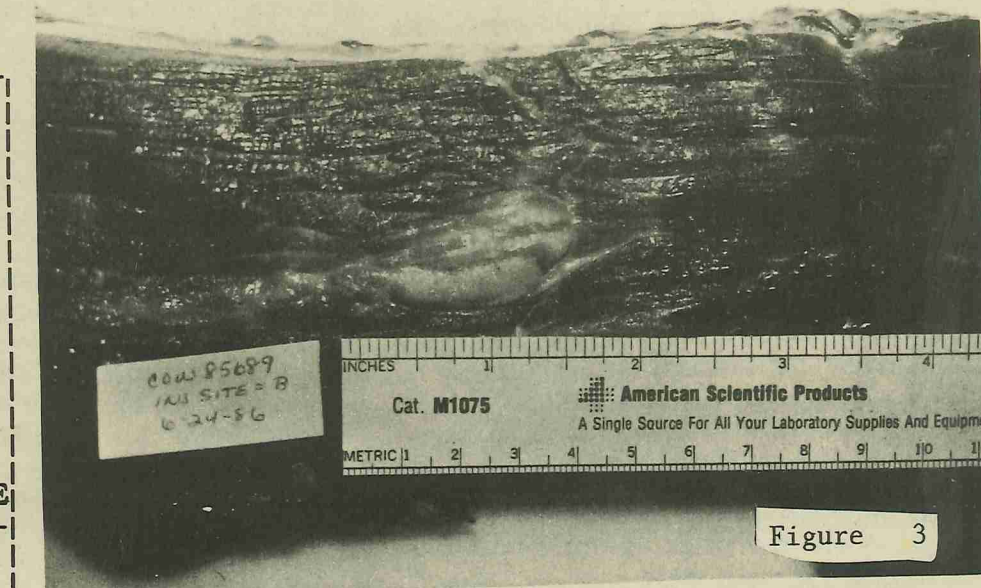


Figure 3
Cow 85796--3X group. Injection site C. Cow received three times 600 mg. dose of CP115099-F every 14 days.

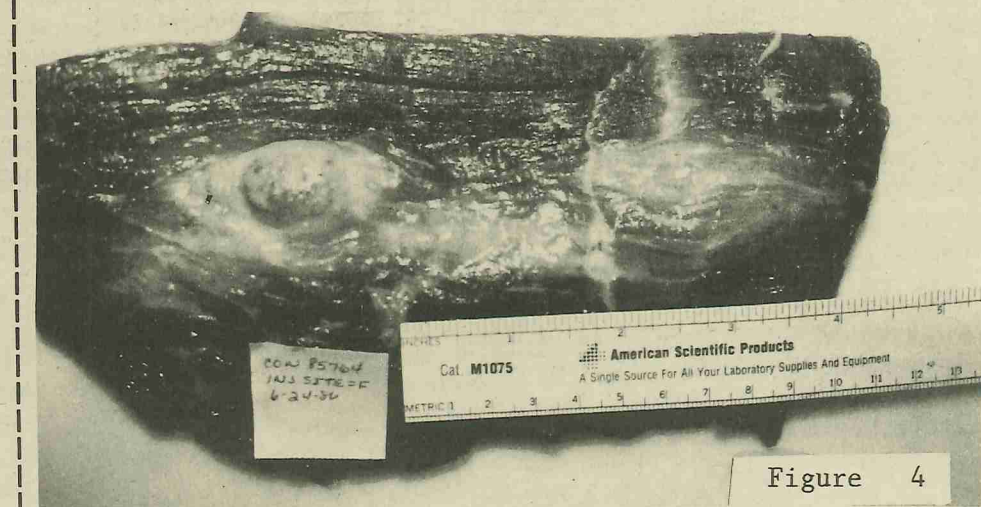


Figure 4
Cow 85764--5X. Injection site F. This animal received five times control group's 600 mg. dose of CP115099-F every two weeks. Note obvious damage to carcass.

bGH Files, continued

(Peel, *et al.*) which compares with the normal peak value of 27.3 ng ml found by Vilatos and Wangness.

"Based on these data, in conjunction with the rapid degradation of bGH (t 1/2 approximately 7.2 hours, as calculated from a fractional disappearance rate from the data of Peel, *et al.*), and the probable lack of oral activity of such small quantities of bGH, DC recommends that a milk-discard period of 5 days and a withdrawal period of 15 days prior to slaughter be observed, as requested by the sponsor."

Elevated serum hormone levels in bGH-treated cows' blood was one reason FDA required a 15-day withdrawal period for meat, in the early 1980s. About 1986, the agency removed withdrawal restrictions for milk and meat. Just why FDA altered these policies is not clarified in documents available.

Further evidence of bGH manufacturers' ignoring human health considerations of elevated hormone levels is found in an October 4, 1988 letter from FDA's Dr. Susan Sechen to the industry. Sechen's letter noted that blood hormone levels are highest immediately following bGH injections. Sechen asked the industry to measure blood serum hormone levels.

The industry replied negatively to Sechen's request for blood hormone sampling. Replies indicate that the industry believed testing blood of treated cows for added hormones would raise public health/safety issues.

Sechen did not press for those blood hormone tests to be conducted. She did note that: "It would be nice to have information (if bGH is approved) and if the public should inquire."

Attacking critics

bGH manufacturers and FDA officials have savagely attacked critics.

A one-time leading researcher in the bovine growth hormone field, Dr. David Kronfeld, has since turned gadfly. Back in the 1960s, Kronfeld warned that companies should further research bGH fragments believed active in humans. Kronfeld's knack for posing "inappropriate" questions has helped him be "frozen out" of bGH research funds. He is now doing equine research at Virginia Polytechnic Institute (VPI).

As early as the late 1950s, Kronfeld warned that selecting dairy cattle merely for production would lead to a lack of ruggedness in dairy stock. That was because, he theorized, high-producing dairy cows naturally produce larger quantities of somatotropin. And those larger somatotropin levels in cows induce more physical problems.

In recent years, Kronfeld's letters and articles in veterinary journals have raised doubt about the design of animal health tests. Kronfeld has criticized manipulation of animal health data from field trials on reproduction and mastitis. For his "heresy," a Monsanto employee (Dr. Winston Samuel of Liverpool, NY) wrote three letters to VPI during 1989 implicitly threatening that Monsanto might cease all research grants to that university if Kronfeld didn't silence his criticisms of bGH research. Academic freedom?

A fired former FDA veterinarian, Dr. Richard Burroughs, headed oversight of bGH field trials at FDA until mid-1988. Burroughs has claimed that adverse health effects were being caused in bGH treated dairy cattle. In 1989, FDA fired Burroughs for alleged incompetence, after Burroughs shared his bGH research reservations with staffers on the Senate Agriculture Committee. Burroughs' charges have helped instigate an ongoing inquiry into FDA's bGH oversight by the General Accounting Office. Burroughs claims he was the only qualified veterinarian on FDA's bGH research review team. He's now practicing in Maryland.

1) Sonenberg, M., C. A. Free, J. M. Dellacha, G. Bonnadonna, A. Haymovits and A. C. Nadler (1965) The Metabolic Effects in Man of Bovine Growth Hormone Digested with Trypsin. Metabolism 14: 1189-1213.

2) Epstein, Samuel, M.D. (1990), Potential Public Health Hazards of Biosynthetic Milk Hormones. International Journal of Health Services 20: pages 73-84.

One of us (Epstein) has published articles documenting various adverse veterinary effects and associated with increased milk hormone levels following bGH treatment.

He documented detailed evidence concerning various adverse veterinary effects on treated cattle, as well as increased milk hormone levels following bGH treatment. He also theorized that bGH treatments could lead to additional illegal residue problems in the public milk supply.

Behind the blasts of second-grade name-calling at Drs. Kronfeld, Burroughs and Epstein ... a modest glimpse at the Monsanto bGH research fields substantiates charges by all three concerning research and potential public health wrongs.

Monsanto: Desperate for new money-makers

bGH is the "lead-off batter" for an expected wide range of applied agricultural biotechnologies. The biotech industry is desperate for commercial sales revenue generated by a major money-maker. Since the October 1987 stock market crash, biotech firm stocks have not rebounded with the rest of the market because biotechnology doesn't have many near-term projects ready to generate actual sales. Many of Biotech's promises to investors have far to go before fulfillment.

Symbolism of bGH as ag biotechnology's first major commercial project has caused firms to place greed before public safety. And top FDA officials are accomplices.

Some investment advisors are particularly critical of Monsanto's stock. For example, the March 15, 1990 Wall Street Journal noted the previous day's \$5.375 per share decline in Monsanto's stock, due to reports of lower first quarter earnings. Some investment advisors are strongly recommending sale of Monsanto stock, because the company's money-makers (such as Lasso -- a herbicide -- and Nutra-Sweet) have patents expiring in the next few years.

Via biotechnology the bGH manufacturers are trying to shift away from selling farm petroleum-based farm inputs that are widely associated with polluting the nation's soils and groundwater. From farmers to consumers, great skepticism in the past decade has grown over heavy use of pesticides, herbicides, etc.

Biotechnology's promise was "cleaner" ag production inputs. But bovine growth hormone fails that test, since indicated by Monsanto's research files, tremendously higher milk hormone levels result from bGH treatments.

Over the past decade, one of the strongest trends in consumer food marketing has been the shift towards "organic" foods; away from heavy use of pesticides and herbicides. The public wants a food supply free of chemicals and hormones. Given Monsanto data showing hormone levels as high as 1000 times greater in bGH-induced milk, it's sheer scandal for the company and FDA officials to assert hormone-derived milk is "the same" as natural cows' milk, let alone safe.

What is the track record of the bGH manufacturers? Monsanto has been a major manufacturer of 2, 4, 5-T (including Dioxin) and PCBs. Lilly counts Diethylstilbestrol (DES) among its achievements. DES, when used as a livestock growth promotant, is associated with hormonal damage to infants. DES, used as a human fertility treatment, is documented to have caused grotesque cancers in the daughters of treated women. One might have imagined the DES debacle would have shied off Lilly from another hormonally-based livestock product.

American Cyanamid designed a new research center in New Jersey a few years ago with an illegal drain running from the laboratory into a nearby river. Lab research wastes were conveniently (and illegally) dumped into the river.

Perpetuating lies

Very little actual research exists on the human safety aspects of bGH. FDA ostensibly bases its human safety determinations on the fact that human dwarfs did not respond to doses of natural cow growth hormone back in the 1950s. FDA's reliance on 1950s "dwarf data" is fallacious for several reasons. A major weak point in FDA's human safety logic is that natural cow growth hormone is less powerful and structurally different compared to companies' recombinant products. Scientific knowledge, research techniques and lab equipment have come a long time since those dwarfs received cow growth hormone nearly 40 years ago.

Why, if the manufacturers and FDA have misrepresented animal safety claims, should any credibility be given their assertions of human safety? Human safety questions concerning bGH remain void of modern research. The same sources of misrepresentation on animal health issues telling the public bGH milk is safe for humans, that bGH-milk is "the same" as regular cows' milk. But the Monsanto data on milk hormone levels shows clearly that bGH-milk is many, many times higher in hormone levels.

Rather than scrutinize milk and meat from bGH-treated cows, FDA has served as a cheerleader for this new technology. FDA is on the verge of publishing an article in *Science* magazine, in which the agency will detail its assertions of the "safety" of milk produced from bGH-treated cows.

Recommendations:

*All current bGH farm trial sites should be immediately identified. Milk and meat from ongoing bGH trials should be embargoed. No commercial sale of milk and meat from bGH farm trials should be allowed, pending extensive, independent investigation of human health issues.

*All files at FDA on bGH research much be made available immediately for public inspection.

*Appropriate Congressional committees -- Oversight, Agriculture, Health and Judiciary -- should review highly misleading, if not fraudulent conduct, of both the manufacturers and FDA in representing the safety of bGH to both humans and animals.

Want Extra Copies??

You may order additional copies of this bGH blockbuster from *The Milkweed*. We're reprinting the article as a separate item. Copies are available for \$1.00 each. Minimum order is five copies (\$5).

Copies will be mailed to you promptly by first class mail.

Send your order to:
The Milkweed
Box 713
Madison, WI 53701