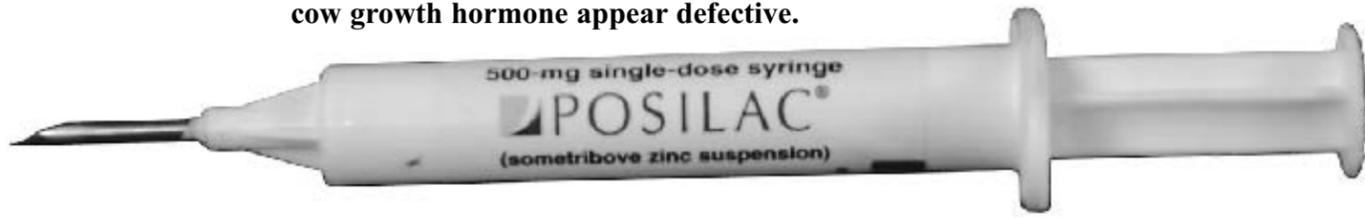


# “...because FDA says it’s safe?”

FDA’s long-ago “human safety” precepts for Monsanto’s biotech cow growth hormone appear defective.



rbGH  
&  
Human Safety

by Pete Hardin

**“Activists’ purely speculative concerns about rBST – ranging from the destruction of small family farms to the risk of cancer – have proven baseless. Before approval by the Food and Drug Administration, rBST underwent the longest and most comprehensive regulatory review of any veterinary product in history. Three years before the F.D.A. approved the marketing of milk from supplemented cows, its scientists, in an article published in the journal *Science*, summarized more than 120 studies showing that rBST poses no risk to human health.”**

—Excerpt from an article by Henry I. Miller on the “op-ed” page of *The New York Times* on June 29, 2007. Miller is identified as “a doctor and fellow at the Hoover Institution, headed the Food and Drug Administration’s Office of Biotechnology from 1989 to 1993. He is co-author, most recently, of “The Frankenfood Myth.”

## More and more U.S. dairy processors rejecting rbGH milk

The U.S. dairy industry is witnessing a rush to the exits. More and more dairy processors and food marketers are announcing policies to avoid milk coming from dairy farms where milk cows are injected with Monsanto’s synthetic, milk-stimulating cow hormone drug: Posilac.

[Posilac is the trade name of Monsanto’s patented biotech hormone, known as recombinant bovine growth hormone (rbGH), or, as Monsanto and its allies prefer, recombinant bovine somatotrophin. More on the nomenclature later.]

Dairy’s farm-to-consumer supply chain is being jerked hard by perceived consumer desires to avoid milk products from rbGH-injected dairy cows. Huge, national vendors have declared “rbGH-free” intentions. Dairy farmers, raw milk marketers, and processors now face major national food firms changing milk buying practices, due to fast-growing consumer resistance. Pure and simple: consumers don’t want their milk supplies sourced from dairy herds where the cows are poked with Monsanto’s needle.

Recently, two major national food vendors have announced they will convert to “rbGH-free” milk supplies in early 2008: the Kroger Company (with thousands of supermarkets nationwide), and Starbucks (the ubiquitous high-end coffee emporium).

What’s behind the furor in the dairy market place that’s propelling “rbGH-free” dairy demand? Why is this issue literally “boiling over” thirteen and a half years after Monsanto first started marketing this FDA-approved veterinary drug to dairy farmers? What are the bases for human health/safety concerns?

**Writer’s note:** For more than 20 years, as a journalist and activist, I have been enmeshed in the most controversial food safety battle in this nation’s history: biotech-produced bovine growth hormone injections to boost cows’ milk output. Monsanto—the global corporate food biotech giant—produces and markets that drug under the trademark “Posilac.” The biotech hormone’s trade name, along with the fact that the drug is delivered by a hypodermic needle, are perhaps the only points of agreement between proponents and opponents in this epic food safety battle.

Throughout this decades-long, food safety battle, this nation’s consumers’ inherent skepticism about injecting U.S. dairy cows with powerful, synthetic growth hormones to boost daily milk flow stands as wise testament to the common person’s human health concerns involving rbGH. Monsanto and its allies have plastered rbGH opponents with many names: “Luddites,” “food terrorists,” “anti-science.” But actual abuse of scientific procedures and human safety cautions is the domain of those responsible for developing and overseeing the human safety aspects of this potent, synthetic hormone.

The two sides cannot even agree upon a name for the drug. Opponents refer to Posilac as “rbGH”—recombinant bovine growth hormone. That was the original moniker, before Monsanto and friends realized that the word “hormone,” in reference to the public milk supply, was a red flag. So in the late 1980s, Monsanto renamed the product “recombinant bovine somatotropin, or “rbST”. (Note: All milk contains various naturally-occurring hormones.) In this report, Posilac will be referred to as “rbGH”—except when directly quoting citations that use other references to Monsanto’s diabolical, synthetic cow hormone.

Consumer fears about “synthetic hormones in milk” preceded the commercial use of rbGH by several years. Despite the best efforts of the federal Food and Drug Administration, Monsanto, and their biotechnology-worshipping allies to try to convince the American public that Posilac poses no human safety concerns, the public isn’t buying.

The U.S. dairy industry—from farm to consumer—is being dragged deeper, towards an Armageddon-like conflict over the safety of milk from cows injected with Posilac. This special report in *The Milkweed* is intended to depict the bedrock facts of this deep conflict that is rapidly coming to a boil.

—Pete Hardin

## FDA’s long-ago rbGH human safety precepts were faulty

The central thesis of this report is that the FDA’s basic rbGH human safety presumptions are faulty. Rather than perform the legally mandated role as the overseer of the safety of veterinary drugs and the nation’s food supply, FDA employees have served as “pom-pom girls”—cheering on the approval and marketing of this powerful synthetic hormone drug.

Failed oversight of human and veterinary drugs has, unfortunately, become “business as usual” at FDA. Public confidence is at an all-time low, following repeated revelations of inadequate safety-testing of drugs by the agency.

Let’s summarize some of the “worst of the worst” failures in FDA’s human safety oversight for Monsanto’s rbGH:

**\* No mandatory residue assay required.** FDA specifically violated its own rules by failing to require Monsanto to develop a mandatory detection test for drug residues in the milk and meat of treated dairy cows. Failure to require a rbGH residue detection test—which dates back to roughly 1987—has broad implications even today. There is no test to verify the accuracy of dairy processors’ claims milk labeled “rbGH-Free” is in fact from dairy herds that have not been injected with Posilac.

FDA’s failure to require drug companies developing rbGH mandatory drug residue test for rbGH is a violation of Section 512 of the 1968 Animal Drug Amendments of the 1938 Federal Food, Drug and Cosmetic Act.

Without a residue assay, the myth, indeed the fabrication, that milk from rbGH-injected cows is “the same” as normal cows’ milk is perpetuated. Specifically, FDA’s rules mandate that the developer of an “investigative new animal drug” must create a test to measure for drug residues, before any products from animals receiving the research drug may be used in the human food chain. But FDA never required that test for rbGH. Rather, based on limited rat-feeding tests, in 1987, FDA officials approved human consumption of milk/meat from rbGH-treated cows in experiments conducted at Monsanto’s research facility in Missouri, at many university dairy herds, and numerous private dairy farms.

Lack of a mandatory, drug residue test has created the most problematic headache for the dairy industry: no test to verify claims by an increasing number of firms (like Kroger and Starbucks) that their products are “rbGH-free.” Thus, the trust of the public in its dairy product supply is without any verification. Europe uses at least two different tests for determining whether dairy products have been processed from rbGH-treated cows’ milk. A Cornell University scientist, Dr. Ron Gorewit, patented an rbGH-detection assay with a colleague, but FDA has refused to acknowledge the validity of that test. FDA recognizes no test for the presence of rbGH residues in milk, period.

Thus, when Monsanto (and others), contend that milk from rbGH-treated cows is “the same” as normal cows’ milk, as far as actual drug residues goes, that claim must be considered without scientific substantiation.

## \* 1990 *Science* article on rbGH “human safety”—flawed

The above-cited quotation from Henry I. Miller in the June 29, 2007 issue of *The New York Times* is instructive. Miller headed FDA’s Office of Biotechnology from 1989 to 1993—a key period when FDA was finalizing its rbGH human safety review. Miller refers to FDA-written article that appeared in the journal *Science* on August 24, 1990 as having “... summarized more than 120 studies showing that rBST poses no risk to human health.”

*Science* graced its pages with a ten-page article titled, “Bovine Growth Hormone: Human Food Safety Evaluation.” This article represented a response to the white-hot public safety issue for FDA. Never before had the agency addressed human safety concerns of an animal drug still under review. Commercial sale of rbGH was still three and a half years into the future.

Miller’s recent assertions, to the benefit of rbGH critics, show that Monsanto, FDA and the supporters of rbGH truly have almost nothing new to say in the past 17 years, except to regurgitate the standard party line, “rbGH is safe because FDA says it’s safe.”

When scrutinized in detail, that long-ago article in *Science*—FDA’s “all clear” prognosis for human safety issues—fails miserably in efforts to assuage human safety concerns regarding rbGH. Here’s why:

—FDA’s *Science* article cited, as proof of “human safety” of the biotech-derived cow hormone, research conducted many years earlier, in which human dwarfs were injected with *natural* cow growth hormones. FDA noted that the dwarfs did not grow, in response to receiving the injections, which were extracted from the pituitary glands of dead cows.

Trouble is: that research article noted that a large percentage of the dwarfs in the experiment died of Creutzfeld-Jakobs Disease—the human equivalent of “mad cow disease.”

The experience of those dwarfs who died following injections of natural cow growth hormones has a chilling parallel. In the early 1980s, French youths injected with synthetic *human* growth hormones also developed degenerative brain-wasting diseases.

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—FDA cites a study which demonstrated that commercial pasteurization temperatures break down cow growth hormones in milk from rbGH-treated dairy cows.

That research citation was attributed in the *Science* article to P. P. Gronewegen and others.

Truth is: This seemingly prestigious researcher, Gronewegen, was at that time an *undergraduate* student at the University of Guelph in Ontario, Canada. The pasteurization study attributed to him actually involved processing of milk from a very few cows for the feeding to calves.

Worse yet: Gronewegen's research dramatically "overcooked" the batches of milk. Instead of pasteurizing his batches of raw milk at the standard, 15-second time, Gronewegen pasteurized that milk for 25-30 minutes—100-120 times longer than the recommended heat treatment.

[Editor's note: Credit for unveiling digging out these unsavory details of FDA's rbGH approval process goes to Robert Cohen, a resident of Oradell, New Jersey. Cohen's curiosity about rbGH was first sparked by the thought of his daughters drinking rbGH milk in their school. Cohen, perhaps more than any other person operating without monetary compensation, dug deep into rbGH. He studied every scientific document cited by FDA in the *Science* article. Cohen even brought a *pro se* lawsuit against FDA, when the agency denied him access to research documents used in the rbGH approval. (He lost.) Cohen's search for answers are detailed in his unorthodox book: "Milk—The Deadly Poison." Cohen is a vegan.]

—A major portion of FDA's *Science* article attempted to rebut concerns about Insulin-like Growth Factor-1 (IGF-1). IGF-1 is a secondary hormone produced by mammals in response to levels of natural (and synthetic) growth hormones. IGF-1 circulates in the blood of mammals, miraculously coordinating cellular growth and function. IGF-1 is structurally identical in both cows and humans. Injections of rbGH dramatically boost the IGF-1 content in cows' blood. FDA's *Science* article admitted such. The reason rbGH works is because the added synthetic growth hormone's presence spurs more production of IGF-1, which circulates to the milk duct tissues, where a tremendous concentration of IGF-1 receptors exist.

FDA's *Science* article acknowledges that IGF-1 is not destroyed by normal pasteurization. Indeed, FDA admitted in the *Science* article that if cow's milk-sourced IGF-1 entered the human blood stream, the IGF-1 would be active in humans. That same article also included an admission by FDA that rbGH injections boost the levels of IGF-1 in cow's milk. But FDA scientists argued in the *Science* article, that digestive acids in the human gut would break down any IGF-1 consumed through milk. Subsequent research has widely discounted FDA's mistaken notion that stomach acids denature milk-borne IGF-1.

FDA's stance, taken back in 1990, that IGF-1 in milk is destroyed by human stomach acids, is one of the agency's shakiest cornerstones of logic in the rbGH "safety" fray. In 1995, the *Journal of Endocrinology* cited work by researchers in Australia who demonstrated that milk proteins protect IGF-1 from digestion. The footnotes from this particular work cited studies published *prior to 1990* with similar conclusions.

What's the significance? IGF-1 is one of the leading suspects involved in the development and spread of cancers. Many thousands of articles reported in scientific and medical journals have explored the possible relationships between IGF-1 and human cancer development and growth.

In the rbGH human safety debate, IGF-1 is, far and away, the key issue.

### rbGH "lead-off batter" for vast array of food biotech products

Unfortunately for the best interests of the U.S. dairy industry, the biotech cow growth hormone drug was the first major research and commercial application of genetic modification in the food industry. Commercializing food biotechnologies have required aggregate investments of tens, if not hundreds, of billions of dollars invested in the development process ... with FDA conspiring in the process to bring these research projects to commercial fruition and profit.

Why did Monsanto (and other companies) decide to initially replicate bovine growth hormone? From the late 1940s into roughly the mid-1960s, mammalian growth hormone research was a hot research topic. Scientists tinkered with some of the rudiments of life. But high costs of obtaining samples (from dead mammals' pituitary glands), coupled with poor quality of those samples, ultimately put that research into mothballs. But when early scientists attained ability to splice genes, continuing prior decades' growth hormone research seemed like an easy leap. Biotechnology allowed vat production of large volumes of relatively cheap growth hormone of presumed consistent quality.

Monsanto's rbGH product replicates dairy cow growth hormone, but Monsanto scientists added a methionine marker to the DNA sequence, which presumably increases the potency of the product. Originally, four biotech firms attempted to develop patented cow growth hormone drugs. Besides Monsanto, Eli Lilly, American Cyanamid and UpJohn entered the "rbGH sweepstakes." But only Monsanto's product was approved for commercial sale and use.

### Monsanto changes the name: "hormone" out!

Initial consumer reaction to rbGH was decidedly negative. Much of that negative response was due to the single word, "hormone." A significant number of U.S. consumers held serious fears about the use of synthetic hormones in the production of their foods. Why did U.S. consumers react negatively to early news about rbGH?

Back in the 1940s, the FDA had approved a steroid hormone—Diethylstilbestrol (DES)—as a growth promoter for livestock in the U.S. DES was also approved as a human drug—a fertility enhancer for women. That use became a

separate debacle.

But in 1979, the FDA banned DES as an animal growth promoter. Subsequent laboratory tests indicated DES was a serious carcinogen.

U.S. drug companies were stuck with carry-over inventories of DES animal drugs. Rather than take a loss destroying those inventories, manufacturers "dumped" products on farmers in less developed countries, promoting that DES would help livestock and poultry grow faster. The DES-related human health debacle in Puerto Rico helped hone skepticism in the U.S. about synthetic hormones in the food supply.

Many Puerto Rican farmers supplemented their cattle, swine and poultry feed liberally with DES ... with readily visible results—bigger swine and chickens.

But Puerto Rican health authorities soon uncovered a horrid public health debacle: THOUSANDS of infants and children were showing full sexual maturity. Girls as young as two or three years old showed fully developed sexual glands, public hair, and were menstruating! Medical sleuthing traced back this epidemic of widespread, premature sexual development to the massive infusion of DES in livestock and poultry being consumed by Puerto Ricans. Publicity of these events helped anneal public attitudes against use of synthetic hormones in the food supply—just as rbGH was gaining publicity.

Sadly, DES—a synthetic steroid hormone—also left an unusual, cruel legacy of cancers—in humans.

Starting in the late 1940s, FDA approved DES as a fertility enhancer for women. But in the 1960s and 1970s, medical researchers linked mothers having taken DES to horrid cancers in the reproductive glands of both female and male offspring. Even worse, as time evolved, it became clear that DES treatments passed on similar cancers even to the *grandchildren* of women who'd received the drug.

DES helped steel attitudes for many consumers in the 1980s, when Monsanto began touting the wonders of synthetic growth hormones injections for boosting cows' milk volume. As consumer opinions reflected serious discomfort about the use of rbGH, Monsanto changed the generic name from recombinant bovine growth hormone (rbGH) to recombinant bovine somatotropin (rbST).

### Samuel S. Epstein, M.D.—warned of IGF-1 & cancers

The first rbGH critic with solid medical credentials to emerge with dire warnings of potential human health dangers, including cancers, was Samuel S. Epstein, M.D.—world-class environmental toxicologist from the University of Illinois-Chicago. Epstein enjoyed an long-standing, adversarial relationship with Monsanto.

Epstein's warnings about potential human health problems and rbGH circulated widely in scientific journal articles, op-ed columns written for newspapers, and testimony before a state legislative hearing in Wisconsin. Epstein's warnings focused on potential cancer dangers from increased amounts of a secondary hormone, Insulin-like Growth Factor-1 (IGF-1). Back in the late 1980s, scientific understanding of IGF-1's function was in its relative infancy.

Here's one sample of Epstein's numerous IGF-1/cancer warnings—an op-ed article to *The Los Angeles Times* printed on March 20, 1994—in which he warned, in part:

“IGF-1 induces rapid division and multiplication of normal human breast epithelial cells in tissue cultures.

“It is highly likely that IGF-1 promotes transformation of normal breast epithelium to breast cancer.

“IGF-1 maintains the malignancy of human breast-cancer cells, including their invasiveness and ability to spread to distant organs.”

Over the past two decades, Epstein has published a series of human health warnings about potential dangers from drinking milk from cows injected with rbGH ... culminating with a book published in 2006, "What's In Your Milk"—described as "An Expose of Industry and Government Cover-Up on the DANGERS of the Genetically-Engineered Milk You're Drinking."

### rbGH "biggest human health issue in FDA's history"

In December 1986, the National Dairy Board (a promotion entity paid for by dairy farmers' moneys) received a report from Fine, Travis and Associates that detailed a communications strategy to try to counter widespread public fears about "hormones in their milk." That report recommended, in part:

#### "The Solution

“Concern, as well as attack, lies in the assumption that the milk ingested is somehow different from non-BST milk. Communications should be concentrated in persuading the consumer, through credible authorities, that milk from BST-treated cows is identical in regard to milk from non-treated cows.”

Fine, Travis recommended avoiding technical details of rbGH.

In early 1990, the National Dairy Board commissioned a study of consumer attitudes about rbGH. The results were shocking: the word "hormone" was a glaring red flag, with a significant number of consumers interviewed stating that they would reduce milk consumption, if rbGH use became common on dairy farms.

Here's a summary of consumer concerns determined by that study:

“Negative reactions to BST are based primarily upon concern about its safety and the feeling that it is not natural.

“While consumers are willing to accept that BST is naturally found in milk, most do not believe that milk from cows treated with BST is just like milk from untreated cows.

“The majority of respondents feel that:

—the long run health implications of BST aren't known (84%)

—Milk from cows treated with BST may be harmful to humans (62%)

—Respondents do not feel that milk from cows treated with BST is completely safe (59%).

The leadership of any normal, food-marketing industry, upon learning that 84% of its consumers had safety reservations about a new technology, would not have embraced rbGH. But dairy producers' and processors' national organizations were clueless.

In that same survey, 25% of all consumers indicated that they would decrease milk purchases, and another 16% stated they would cease milk purchases.

Dairy producer groups, in tandem with dairy processor groups, started meeting secretly with Monsanto and other firms in the race to develop rbGH commercially. Monsanto and its competitors actually funded an innocuous-sounding organization, the Animal Health Institute (AHI), to spread the good word about rbGH and coordinate responses to the growing public uproar over hormones in their milk.

But public concerns about rbGH and "hormones in the milk" human safety concerns continued to grow. It seemed that the more that FDA officials, Monsanto, and dairy industry's leadership trumpeted how "safe" rbGH derived milk was, consumers became more scared. These concerns helped launch untold tens of millions of dollars in a massive public relations campaign aimed at overriding the public's gut-level fears that milk from dairy cows injected with rbGH were potentially dangerous.

Groups such as the American Medical Association, the American Dietetic Association, and the National Dairy Board were pulled into the effort to promote rbGH as safe. Indeed, a cassette tape was distributed, with the blessing of the American Medical Association, to medical doctors about "rbGH safety." Doctors could listen to that cassette tape and qualify for part of their continuing medical education.

Former U.S. Surgeon General, C. Everett Koop became a well-remunerated spokesperson touting the safety of the biotech cow hormone drug.

On February 6, 1994—just as Monsanto started marketing Posilac—Dr. Koop issued the following statement (for pay):

"Milk from cows given supplemental bovine somatotropin is the same as any other milk. So there should be no doubt in the minds of consumers that the milk they drink is just as safe, nutritious and wholesome as it has always been.

"Unfortunately, a few fringe groups are using misleading statements and blatant falsehoods as part of a long-running campaign to scare consumers about a perfectly safe food ...

"Even worse are attempts by some persons to use school children as pawns in their opposition to BST. Any suggestion that milk from BST-supplemented cows is unsafe for children to consume at school, or at home, is a potential threat to their health and well-being."

During the 1980s, the four companies attempting to develop rbGH threw in together to fund the "Animal Health Institute" (AHI)—a front organization that coordinated both offensive and defensive efforts on behalf of the as yet unmarked biotech cow growth hormone.

In December 1989, Dr. Richard Teske, a high-level official at FDA's Center for Veterinary Medicine, told a Wisconsin farm paper that rbGH was the greatest human food safety furor in the agency's history."

### Monsanto files—stolen from FDA—prove troublesome

In early 1990, Monsanto and FDA were blistered when a two-part series appeared in *The Milkweed*, which published wide-ranging information gleaned from stolen, "confidential" files compiled by Monsanto and submitted to FDA as part of the rbGH drug approval process. The articles were co-authored by Dr. Epstein and Pete Hardin.

\*The health of first lactation dairy cows subjected to injections of Posilac was adversely affected. Data collected from post-slaughter analyses detailed how key glands and organs of rbGH-injected animals, on average, were often-times much larger than similar glands and organs from "control" animals in the 1985-86 study of 80 cows at Monsanto's research farm in Dardennes, Missouri. Hearts, livers, ovaries, pituitaries and lungs ... were all dramatically larger in rbGH-treated animals. Such data should have clued FDA to inherent health problems for rbGH-injected dairy cows.

\* Tables detailed daily levels of amounts of hormones in blood of rbGH-treated animals during several 14-day injection cycles. These tables incorporated data from seven different versions of rbGH that Monsanto had been testing in the 1980s. Wild swings in the blood-borne hormones showed tremendous variation in hormone levels within the 14-day injection cycle. Some of these blood hormone level swings registered as high as nearly 1000X above pre-injection levels! With some such hormones transferring from blood to milk, these wild swings in daily blood hormone levels ought to have keyed FDA officials to likely surges in hormone levels in milk. If blood hormone levels rose during injection cycles, some of those hormones would have transferred to the milk of injected cows.

\* The stolen Monsanto rbGH files available to Epstein and Hardin contained far fewer documents about human safety testing. However one memorandum from that limited trove of documents, written by FDA's Dr. Judith Juskevich to Monsanto on February 20, 1987, revealed chilling details of the limited human safety oversight for rbGH demanded of Monsanto. That letter, in part, stated:

"The firm has submitted a 28-day oral feeding study in rats that demonstrates no oral activity of MBS at doses up to 6 mg/kg/day (cf. HFV-156 memorandum dated February 18, 1985). Based on the results of this study, the sponsor was granted a zero withdrawal and milk discard period for cows treated with daily injections of up to 40/mg/head/day (cf. HFV-144 memorandum dated September 20, 1986; this INAD) ...

"Based on the results of the oral feeding study and our knowledge of the

characteristics and biological activity of bovine somatotropin, we have no objections to granting the sponsor's requests ..."

"... Dairy cows and beef cows treated with up to 75 mg of MBS/head/day may be slaughtered with no withdrawal period. No milk discard period will be recognized for milk from treated dairy cows."

Only a few dozen rats were actually studied in this 28-day study. Subsequent information detailed how the rats were fed rbGH for a total of only 14 days.

In early 1990, publishing details from Monsanto's stolen rbGH documents helped throw gasoline on the already hot-burning flames of the synthetic cow hormone controversy.

### 8/22/90 Science article attempts to quell public concerns

The "rbGH is safe" public relations offensive was in full concert, engineered by Monsanto, FDA, AHI, and many leading organizations of dairy producers and processors.

On August 24, 1990, FDA's long-awaited, unprecedented article detailing the human safety considerations for rbGH was printed in the journal *Science*. "Bovine Growth Hormone: Human Food Safety Evaluation" was co-authored by Judith C. Juskevich and C. Greg Guyer. Co-author Juskevich (she had written the February 20, 1987 memo okaying consumption milk/meat from cows in rbGH experiments), had retired from FDA and worked as a contractee. Guyer worked at FDA's Center for Veterinary Medicine in the New Animal Drug Evaluation unit. (Simultaneously, another "all safe" rbGH article appeared in the *Journal of the American Medical Association*.)

Most of the "worst of the worst" human safety presumptions contained in FDA's article in *Science* have been delineated, but merit repeating:

\* Decades-old human dwarf experiments in which many of the participants fed growth hormones extracted from dead cows died of brain-wasting diseases akin to "Mad Cow Disease."

\* A bogus experiment, whose lead author was at the time a Canadian undergraduate student, that cooked milk for 100-120X the normal time, in order to prove that "pasteurization" broke down cow growth hormones in milk.

\* Although admitting that rbGH-injected cows' milk contained far higher levels of IGF-1, and that IGF-1 contained in bovine milk would be active if it entered the human bloodstream, FDA claimed that human stomach acids broke down IGF-1 ... so there were no human health concerns about drinking such milk!

Another, seemingly trivial data table included in the *Science* article was also quickly recognized as dynamite by rbGH critics. FDA claimed that in experiments involving both injections and feedings of recombinant IGF-1 (rIGF-1) to laboratory rats, no important differences were observed in various sizes of organs and bones. FDA's reviewers determined: "Therefore, it was concluded that rIGF-1 is orally inactive at doses up to 2 mg/kg per day."

One problem: male rats orally dosed with rIGF-1 at the rate of only 0.02 mg/kg per day showed significant growth in their tibia (foreleg) bones. Tibia growth is critical. Tibia length in mammals is directly linked to the levels of naturally-occurring growth hormone. Synthetic growth hormone injections/oral doses in the bloodstream spur additional IGF-1 production, which leads to further tibia growth.

Tibia growth in rats parallels a veterinary advisory issued by Monsanto for dairy farmers using Posilac. One side-effect for cows injected with rbGH is "lameness"—caused by the additional IGF-1 in their bodies spurring further growth of their foreleg bones.

The fact that the rats treated with low doses of rIGF-1 showed tibia growth was a warning that FDA overseers should have caught.

In summary: the FDA article which appeared in the *Science* issue of August 24, 1990 stands as the Rock of Gibraltar for all presumptions of human safety. The synthetic cow growth hormone was deemed safe for humans drinking the milk from rbGH-injected dairy cows ... and since that time, FDA, Monsanto, and all their biotech allies have simply repeated the mantra: "rbGH milk is safe because FDA says it's safe." Repeating that mantra continues to the present, as evidenced by Henry I. Miller's op-ed piece in *The New York Times* in late June 2007.

### Fast-forwarding through the years ... 1990 to present

This report is not a book. It is impossible in this limited space to detail all the major events in this human safety controversy that has spanned more than two decades. Let's fast-forward through key events from mid-1990 to the present ...

**1992:** FDA ruled that biotech variants of foods were "the same" as their natural counterparts and needed no special human safety testing. That policy was engineered by a White House task force, headed by then-Vice President Dan Quayle. Quayle—the newspaper publisher-turned U.S. Senator-turned Vice President—couldn't even spell the word "potato." But his task force, aimed at boosting the nation's economic competitiveness, determined that biotech foods were the same as natural foods. FDA followed suit.

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# rbGH & Human Safety

**Summer 1993:** Confidential documents leaked from inside Monsanto show that massive quantities of rbGH produced by the Sandoz firm in Austria had been contaminated during manufacture. This revelation caused financial losses for Monsanto, and gave clue to similar batch contamination problems that would plague the company eleven years later.

In late 2003, Monsanto announced a cut-back in sales of Posilac, due to unspecified reasons. In January 2004, the company cut back sales of Posilac by 50% to dairy farmer customers. What happened? FDA inspection of the rbGH production facilities in Austria found widespread contamination and quality control problems. Making biotech cow hormones is not like making Jell-O.

**Fall 1993:** FDA approved commercial sale of Monsanto's rbGH, with sales to commence on February 4, 1994.

**December 1993-January 1994:** A powerful Washington, D.C. law firm, Covington & Burling, sent letters to virtually all U.S. dairy processors, warning that they faced potential legal consequences if they labeled their consumer products as "rbGH-Free."

Michael Taylor, a lawyer who formerly represented Monsanto in biotechnology food matters, from his recently-created post at FDA, issues labeling rules for dairy firms marketing "rbGH-Free" dairy products. Taylor's edict required that dairy products so-labeled must also include accompanying language that FDA finds "no difference" between milk from rbGH-injected cows and normal cow's milk.

Monsanto also commenced selective lawsuits against two milk processors that were advertising their products as "rbGH-Free."

**February 4, 1994:** Monsanto began selling Posilac to U.S. dairy farmers. Milk production in some regions of the country, such as Texas, skyrockets.

**February 10, 1994:** Monsanto growth hormone researcher, Dr. Bernard Violand, submitted an article to *Protein Science*, titled "Isolation of Escherichia coli synthesized recombinant proteins that contain e-N-acetyllysine." That article, published in July 1994, detailed how unrecognized additional amino acid sequences had occurred in both recombinant bovine and porcine growth hormones manufactured by his firm. Questions should have been raised about whether the biotech hormone Monsanto had just started selling was in fact identical to rbGH that had been "safety tested" by the company. What's a single amino acid sequence change worth? Persons suffering from "sickle cell anemia" have a genetic variant of but a single amino acid sequence difference.

Violand's revelation about unintended consequences in genetic engineering opened a Pandora's Box. In recent years, some scientists have become highly concerned about biotechnology, due to the realization that splicing a single gene (or two) into a DNA sequence is not an isolated event. Other, unforeseen changes, are also being documented.

**1995:** *The Journal of Endocrinology* [(1995): 146. Pages 215-225] reported an article written by Australian researchers titled, "Degradation of IGF-1 in the adult rat gastrointestinal tract is limited by a specific antiserum or the dietary protein casein." WOW! Just as rbGH-critic Robert Cohen had theorized earlier, presence of casein (a milk protein) protects IGF-1 as it courses through the gut to the bloodstream. This research unveiled the fallacy of FDA's presumption that milk-borne IGF-1s would be destroyed by stomach acids. Much similar research has followed, replicating findings that IGF-1 passes through the human gut into the bloodstream

**March 1996:** *The New York Times* reported that scientists are shocked to learn that persons with allergies to nuts are affected when fed biotech soybeans that have a single gene inserted from Brazil nuts! This event proved that biotech-derived foods are NOT the same as their natural counterparts!

**STOP! ENOUGH!** During the next ten years, the rbGH issue always smoldered, and sometimes flared. FDA and Monsanto steadfastly held true to the original contentions that rbGH milk was the same as "normal" cows' milk and, thus, safe for human consumption.

## May 2006: Research links rbGH/higher human "twinning"

In the May 2006 issue of *The Journal of Reproductive Medicine*, an obstetrician at the Albert Einstein College of Medicine in New York City, Dr. Gary Steinman, published an article that theorized higher rates of human "twinning" (multiple births) in the U.S. were due to higher levels of IGF-1 in cows' milk.

According to a report of Dr. Steinman's research in *The New York Times* that appeared on May 30, 2006, "Eating dairy products increases blood levels of insulinlike growth factor, or I.G.F., and it is this increased hormone level that is associated with increased rates of multiple ovulation."

Steinman qualified his findings, stating to that newspaper: "Since this is the first time diet has been implicated in an important role for determining twinning rate, it must be confirmed by others before rigid recommendations can be made concerning health care."

"The more I.G.F., the more the ovary is stimulated to release additional eggs at ovulation."

*The NYT* continued:

"All cow's milk has bovine growth hormone in it, naturally produced by the animal's pituitary gland. Many dairy farmers inject their cattle with recombinant bovine somatotropin, a synthetic version of the naturally occurring hormone. This increases size and milk production, but it has another effect: cows

with higher growth hormone levels produce more twins."

FDA and Monsanto, in tandem with the U.S. dairy industry, have basically ignored the potential impact of Dr. Steinman's report. Steinman contrasted human "twinning" in the U.S. with rates of multiple births in the United Kingdom--where no rbGH use is allowed. U.S. rates are higher.

(There's an ironic bovine parallel to Dr. Steinman's research suggesting rbGH-derived hormones in the public milk supply may be responsible for increased rates of human "twinning" in the U.S. One of the side-effects upon dairy cows receiving Posilac injections is a dramatic increase in the number of twin calves produced. However, the physiological mechanisms at work for bovines and humans may be different.)

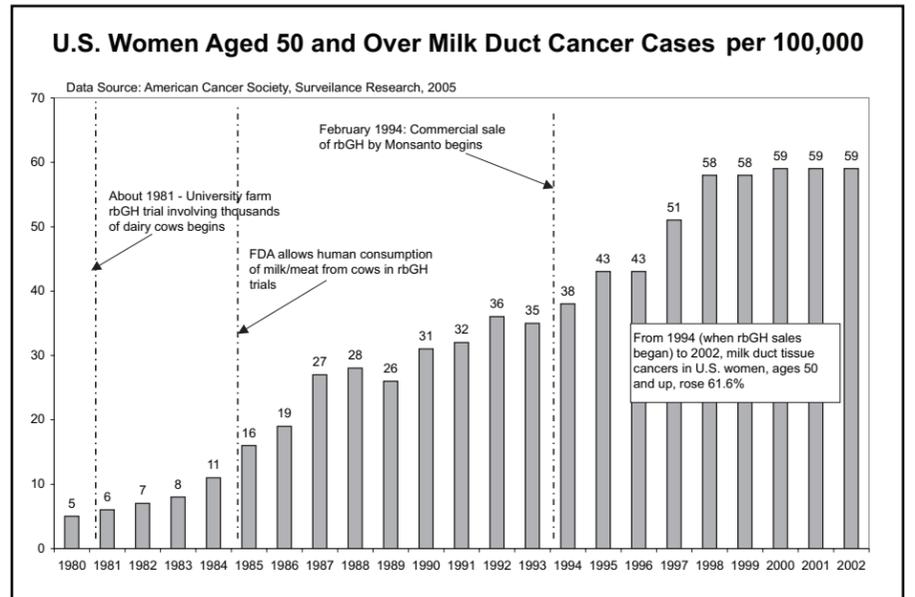
## August 2006: rbGH tied to increased breast cancers in U.S.

In August 2006, *The Milkweed* published an article by writer Paris Reidhead, titled: "Milk Duct Tissue Cancers Rose 55.3% in U.S. Following rbGH Approval." Reidhead utilized annual data on milk duct tissue cancers in post-menopausal woman, ages 50 and older, in the U.S., tracking the annual figures in a bar graph that also delineated when rbGH commercial use started in this country.

The details are contained in the headline: a rapid rise in milk duct tissue cancers in post menopausal women in the U.S. spiked dramatically in the four years following FDA's approval of rbGH commercial sale and use.

A chart of those milk duct tissue cancers is reprinted here.

In December 2006, Reidhead detailed similar data on prostate cancers. However, to the untrained analyst, the trend lines for prostate cancers in U.S. males since the commercialization of Posilac, were far less dramatic.



## Years later, critics' warnings & consumers' fears materialize

The irony of the rbGH human health fray, now more than 20 years running, is that the gut-level instincts of U.S. consumers and the warnings of potential cancer dangers from a limited number of critics ... now appear more valid than ever before.

Over the past several years, concerns about the quality and safety of their foods have compelled many U.S. consumers to ask deeper questions about how and where their food products—including milk—are produced and processed. Once such questioning begins, it logically only increases. The U.S. dairy industry is now being torn, as dairy processors are increasingly rejecting milk from rbGH-treated dairy herds. But without actual tests to prove claims that milk and dairy products are "rbGH-free," the claims must be taken on faith.

Faith? After an array of food and drug safety scandals that have plagued the FDA for decades, there is little public credence to when a product is blessed with FDA's words of "safety." The march of time, science, and consumer attitudes have all coalesced to force a market-place rejection of rbGH.

And the best FDA and Monsanto can do is reiterate: "rbGH is safe because FDA says it's safe." And those "safety" claims owe their foundation to the mistaken presumptions that FDA laid out in the August 24, 1999 article in *Science*.

FDA laid the foundations of the rbGH human "safety" debate long ago. Consumers' fears that injecting dairy cows with synthetic growth hormones was not a good idea will likely prove far wiser than the oversight of human health/safety exercised by FDA. Then and now, the human "safety" precepts that FDA used in allowing commercial sale and use of rbGH do not stand up well under scrutiny. Now 13-plus years after FDA originally okayed commercial sale of Posilac, human health data collected and analyzed by various sources shows troubling trends in certain areas--increased rates of multiple births among mothers in the U.S, and milk duct tissue cancers in post-menopausal women over 50 years of age, are two areas of concern discussed here.

The American public deserves a complete review of the human safety aspects of rbGH. Current rejection of the FDA-approved technology by an increasing number of consumers and dairy product marketers is leading in the right direction ... belatedly the marketplace is showing greater wisdom than those mandated to oversee safety of the public milk supply.

### ADDITIONAL COPIES AVAILABLE

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