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DRUG COMPANY PROFITS & POLITICS VERSUS PROTECTING THE PUBLIC

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Previous Newsletters have detailed alarming examples of how powerful pharmaceutical manufacturers have gained permission to promote products that they knew posed potential health hazards. In some instances, negative information was withheld from regulatory authorities. In others, approval was granted over the objections of members of the FDA's own review panel because of political pressure and the promise of significant financial rewards for involved officials who could insure the desired results.

As indicated in the last issue, one of the most outrageous and scandalous illustrations of all the above is aspartame, a deadly drug that is marketed as a food additive. It was discovered in 1956 when a Searle researcher working on a new ulcer drug accidentally spilled some aspartame on his fingers and noted that it tasted very sweet. Further investigation revealed that it was almost 200 times sweeter than sugar but had no calories.

Searle started safety studies to obtain FDA approval as a food additive but in the first trial of seven monkeys fed aspartame, one died and five others had grand mal seizures. A distinguished food additive researcher subsequently reported that aspartame had caused "holes in the brains of mice". Searle scientists repeated his study and obtained the same results. Additional research revealed that aspartame was converted in the body into dangerous substances that could cause severe damage to brain cells, epilepsy, brain tumors and other cancers, as well as death due to methanol or formaldehyde poisoning.

ALSO INCLUDED IN THIS ISSUE

Since the aspartame saga was too complex and convoluted to cover completely in our last Newsletter, this issue will include the rest of this incredible story of fraud and deceit.

FDA Fiascoes Due To Political And Pharmaceutical Company Pressures

As previously indicated, restricted approval for aspartame to be used as an artificial sweetener for dried foods was obtained in July 1974. This was predicated on Searle's reassurance that over 100

studies "raised no health problems" but the company had concealed negative and damaging information that was in their files. Even without this, an FDA reviewer warned that the documents submitted were not adequate to evaluate potential toxicity and that further clinical testing was necessary. The following month, the first of several formal objections by concerned and knowledgeable authorities detailing numerous reasons why aspartame should not be approved were filed and FDA approval was put on hold in December pending additional information. Over the next two years there were so many complaints that the agency ordered an extensive examination of Searle's aspartame testing and reporting procedures. Investigators described these as being so shoddy, full of inaccuracies and manipulated data, that an unprecedented Grand Jury inquiry was requested in January 1977 to determine whether criminal charges should be filed against Searle for knowingly misrepresenting or concealing findings and making false statements about aspartame's safety. In March, Searle hired Donald Rumsfeld, who had powerful political connections, as CEO and Searle's problems suddenly started to disappear. In August, another study commissioned by the FDA revealed numerous additional serious deficiencies and deceptions, such as Searle's failure to report malignancies and deaths in aspartame treated animals. Nothing was done and one of the senior FDA scientists on the team that reviewed the report later said that it was obvious that top agency officials were "working up to a whitewash".

There was other evidence that powerful forces were working to get Searle off the hook because the Searle Grand Jury probe was called off in 1979. Mounting public pressure and outrage over this eventually forced the FDA commissioner to establish a Public Board of Inquiry composed of three scientists to rule on the questionable safety issues. Their September 1980 report concluded that there was "**no proof of reasonable certainty that aspartame was safe for use as a food additive" and that it should not be approved until the issue of brain tumors in animals had been thoroughly resolved**. This appeared to be the final blow, but Rumsfeld bragged to subordinates that he would use his political pull to guarantee approval for aspartame (NutraSweet). Ronald Reagan was sworn in as President on January 21, 1981 and immediately suspended the FDA commissioner. The next day, Searle re-applied to the FDA for approval of aspartame as a food sweetener based on "ten new studies". Rumsfeld, who was on Reagan's transition team, hand picked Dr. Arthur Hull Hayes Jr. to be the new FDA Commissioner. Armed with the highly suspect "new tests", Hayes appointed a five member Scientific Commission to review the Public Board of Inquiry's decision. When it became obvious that they would also uphold the ban by a 3-2 decision, Hayes arbitrarily installed a sixth member he knew would cause a deadlock. In one of his first official acts as the new FDA commissioner, Hayes then overruled the Public Board of Inquiry, ignored the recommendations of his own FDA review team and approved NutraSweet for use in dry foods and as a tabletop sweetener. The next year Searle filed a petition for aspartame to be approved for use in carbonated beverages and other liquids.

The above is a brief summary of some of the appalling abuses cited in our last Newsletter. As will be seen, subsequent developments proved to be even more horrendous.

The White House - FDA - Searle And Monsanto Revolving Doors

To pick up where we left off, the National Soft Drink Association requested a hearing in July 1983 to delay approval of NutraSweet in beverages because liquid aspartame is very unstable and, when subjected to temperatures above 85 degrees, it breaks down into formaldehyde and another deadly carcinogen. **This represented a clear violation of The Delaney Amendment, which makes it illegal to allow any residues of cancer causing chemicals in foods.** Petitions were also filed the following month by Attorney Jim Turner and Dr. Woodrow Monte to halt approval based on other unresolved safety issues. No action was taken and 6 weeks later, carbonated drinks containing NutraSweet were already on store shelves. Because of continued complaints and criticisms, the FDA asked the Centers for Disease Control (CDC) to investigate NutraSweet's alleged adverse health

effects, although it seems clear that they had already reached a decision. Federal health officials said at the outset that they doubted anything would emerge from the data to indict aspartame and the National Soft Drink Association also predicted that the study would "provide further evidence that aspartame is a safe ingredient." Sure enough, CDC announced in 1984 that no "serious, widespread" side effects had been found and that "it was unlikely" that a link between NutraSweet and various complaints could be proved because there was no consistent reaction pattern. This was not true since side effects fell into two distinct categories: central nervous system (65%) and gastrointestinal disorders (24%). In addition, **CDC also found that the symptoms in approximately 25% of the complainants had stopped and then resumed, corresponding with their having stopped aspartame and then restarting consumption either purposely or by accident**. The FDA did not mention this when they released the CDC report and lawyer Robert Shapiro, NutraSweet's head, used the report to proclaim that the CDC survey "clearly established the safety" of aspartame. The day the report was released, Pepsi Cola, which had obtained an advance copy of the notice, announced its switch to NutraSweet with a worldwide media blitz and aggressive marketing that soon made NutraSweet a household name. It is no accident that Rumsfield's close friend was Donald Kendall, Pepsi's Chairman, who also had considerable political pull, since Richard Nixon had previously been Pepsico's lawyer.

From 1985 to 1995, aspartame consumption skyrocketed and reports of bad side effects increased proportionally. During this period, some 400 aspartame studies were performed, half of which raised significant safety questions while half found no problems. **Every study paid for by impartial sources raised serious questions and 100% of those finding no problems had been funded by Searle and its successor, Monsanto.** The FDA continued to ignore negative findings and in 1992 approved aspartame for use in malt beverages, breakfast cereals, and refrigerated puddings and fillings. The following year it was also approved for use in hard and soft candies, non-alcoholic favored beverages, tea beverages, fruit juices and concentrates, baked goods and baking mixes, and frostings, toppings and fillings for baked goods. **In 1996, FDA Commissioner Dr. David Kessler lifted all restrictions on the use of aspartame and granted it blanket approval to be used as freely as sugar. He did this without public notification despite the fact that this food additive had been shown to be a neurotoxic drug that affected the brain and interacted with several medications.** He also ignored a request by Senator Metzenbaum to initiate additional safety testing. This was not surprising, given that Kessler had previously served on Sen. Orrin Hatch's Labor and Human Resources Committee which had successfully stonewalled Metzenbaum's prior attempts to hold hearings on aspartame safety. A *Wall Street Journal* article commented on Hatch's "strong support of the pharmaceutical industries" and his former campaign manager, C. McClain Haddow, was sentenced to prison for conflict-of-interest charges arising from his work as a Reagan administration health official. Thomas Parry, Hatch's former chief of staff, has made a fortune as a lobbyist for 30 clients including several large drug companies and defense firms, who have contributed heavily to Hatch's campaigns in return for various favors.

Kessler's abrupt announcement in November 1996 that he was resigning caught many by surprise. Some critics claimed that it was because of lying under oath before a Senate oversight committee and padding expenses. However, two weeks previously, Dr. Robert Moser, NutraSweet spokesman, had declared that no scientific evidence was ever found to implicate aspartame as the cause of seizures based on the 15 "Pivotal Studies" Kessler had relied on in granting blank approval. A few days later an activist group announced it had proof that Kessler had conclusive negative evidence from at least one of these studies. Kessler had also been accused of protecting Monsanto (which had acquired Searle) by ignoring the FDA register of 10,000 complaints and their published list of 92 aspartame reactions ranging from coma and blindness to seizures and death. An independent laboratory confirmed that Diet Coke stored in a refrigerator for 10 weeks contained two

carcinogens among other breakdown products. These findings were published in *Food Chemical News* and sent to the FDA but the Agency replied that they were already well aware of this. Yet, Kessler repeatedly refused to allow FDA to conduct its own chemical breakdown tests of aspartame.

Kessler's predecessor, Arthur Hull Hayes, a Defense Department contract researcher who had been appointed Commissioner for the express purpose of approving aspartame claimed that NutraSweet had been shown to be safe for its proposed uses and that few compounds had withstood such detailed testing and repeated close scrutiny. However, when later questioned about this, he admitted that he had relied on a preliminary report of a study he "skimmed through" conducted by Japan's Ajinomoto, Inc. - a licensee of G.D. Searle. He explained that his approval was meant to serve as an example of the Reagan administration's new reforms that were designed to eliminate "treasonous liberal constraints on free enterprise." However, **by basing his approval on this admitted tentative and obviously biased report he violated federal law since it had not been reviewed by the FDA board. Despite numerous protests, nothing was done**. Hayes also resigned under a cloud of controversy, corruption, and the threat of criminal prosecution for padding travel expenses. There was the additional matter of a jet that had been placed at his disposal for personal use by General Foods, a huge NutraSweet customer. He was promptly hired at $1,000.00/day for ten years as "senior scientific consultant" by Searle's public relation firm Burson-Marsteller. Although many are not familiar with this name, Burson-Marsteller was the world's largest PR firm in 1994 (63 offices in 32 countries and almost $200 million in annual revenues) and also represented several of NutraSweet's other major users. Hayes has refused to talk about his relationship with them ever since.

FDA's chief counsel, Richard Merrill, petitioned Samuel Skinner, U.S. Attorney for the northern district of Illinois, to conduct an unprecedented Grand Jury investigation of Searle's aspartame safety studies. Skinner, a protégé of the Republican Governor of Illinois, was appointed Federal Prosecutor in Chicago by President Ford in 1975. Merrill's 33-page letter to Skinner charged Searle with criminal fraud for knowingly supplying false information and was supported by detailed documentation. The probe began in January 1977 and a few weeks later, Skinner met with Sidley & Austin, Searle's law firm, but the topic of conversation was apparently not the investigation but rather a job offer. The following month, Jimmy Carter, the new President, announced that Skinner would not be asked to remain in office. That may have been anticipated since Skinner informed reporters that he had already begun "preliminary discussions" with Sidley & Austin. On July 1, 1977, Skinner left the U.S. Attorney's office to take a top position with the firm that included a senior partnership. Four months prior to leaving, Skinner himself from the Searle prosecution but told subordinates to keep this "confidential to avoid any undue embarrassment" and the investigation was not pursued during this period. William Conlon, a senior U.S. Attorney, eventually inherited the case. Conlon dragged his feet citing case load pressures and gave a "deaf ear" to complaints of delays from the Justice Department. On December 8, 1977, Skinner's withdrawal and resignation and Conlon's failure to pursue the investigation had stalled the Searle Grand Jury probe long enough for the statute of limitations on the aspartame charges to expire.

In January 1979, Conlon also joined Sidley & Austin and ironically was appointed to the Illinois State Board of Ethics in 1982. In 1984, when Common Cause, a citizen's group opposed to special interest politics asked Dan Reidy of the U.S. attorney's office why the investigation had been called off, he replied that because it was a Grand Jury investigation, he was "bound by law to secrecy." FDA officials had described Searle's testing procedures as "bizarre" and expressed little doubt that if Skinner had pursued the probe the company would have been convicted because of fabricated laboratory tests and illegal dealings with federal regulators. A Searle spokesman exploited the demise of the investigation to claim

that there was "no validity to the charges" and that the company had been completely "exonerated." Skinner later went on to direct George H. W. Bush's presidential campaign in Illinois and Bush subsequently appointed him head of the Dept. of Transportation. This gave him jurisdiction over the FAA, which had received several complaints about accidents resulting from confusion and aberrant pilot behavior due to drinking soft drinks containing aspartame. Skinner became Bush's Chief of Staff during the Gulf War, where he was also in a position to head off any aspartame complaints to the FDA, FAA, or Department of Defense. Skinner's wife continued to work for Sidley & Austin at a handsome salary, while he was in the White House.

G.D. Searle and Sidley & Austin have been described as "Siamese Twins." Edwin Austin, a senior partner in the law firm, taught Sunday school in Wilmette, a Chicago suburb, as did Dr. Claude Howard Searle, whose father was a founder of the drug company. Austin was appointed to the Illinois Supreme Court in 1969 and the Searle family took extensive advantage of their friendship. Morris Leibman of Sidley & Austin was for many years Chairman of the American Bar Association's "Standing Committee on Law and National Security," a position that won him Reagan's Medal of Freedom in 1981. Howard Trienens, a law clerk to the late chief Justice Vinson in the early 1950s, was a Searle director and had also worked for Sidley & Austin until 1949. California Governor George Deukmejian joined Sidley & Austin's Los Angeles branch upon leaving office and reportedly made a "very comfortable" living for bringing in corporate clients that had profited from being past contributors to his campaign fund. John E. Robson, head of Sidley & Austin's Washington office, was appointed executive vice-president of Searle & Co. in 1977, the same year Skinner was named a partner in the law firm. Robson was also active in Republican politics, serving as the first General Counsel of the Department of Transportation and was appointed chairman of the Civil Aeronautics Board in 1975 by Gerald Ford. He then moved on to Searle, and stayed with the company until it was bought by Monsanto in 1985.

The acquisition by Monsanto Chemical was most likely engineered by Donald Rumsfeld. Searle had lost $28 million in 1984 because of litigation centering around complications from its copper intrauterine device and more suits were pending. Monsanto quickly split off the NutraSweet Company as a separate division with lawyer Robert Shapiro as president. Shapiro later became CEO of Monsanto and Rumsfeld received a $12 million bonus in addition to his hefty salary as Searle's CEO and appointment to the Monsanto Board of Directors. Rumsfeld started out in Washington in 1957 during the Eisenhower Administration as Administrative Assistant to an Ohio Congressman. He was elected to the House of Representatives from Illinois in 1962 at the age of 30 but resigned in 1969 during his fourth term to serve in the Nixon Administration as Director of the United States Office of Economic Opportunity and Assistant to the President. He left to serve as U.S. ambassador to NATO in 1973 but was called back the following year to serve as Chairman of the transition to the Presidency of Gerald R. Ford after Nixon's sudden resignation. He became Ford's Chief of Staff and in 1976 was responsible for transferring George H. W. Bush from envoy to China to Director of the CIA. "Rummy", as his friends call him, had earned a reputation as a "fixer", so it is not surprising that he was brought in to save Searle from sinking in 1977. He quickly hired some of his cronies who also had powerful political connections and lived up to his title by getting aspartame approved. Not much could be done about the intrauterine device lawsuits and selling out to Monsanto in 1985 was a brilliant move for which he was handsomely rewarded. Rumsfeld also served as chairman of the RAND Corporation, an American Think Tank formed to offer research advice to the U.S. military and he is now Secretary of Defense.

There are numerous other examples of the "revolving door" between government officials and Monsanto, including the present administration. Jack Watson, Jimmy Carter's Chief of Staff, joined Monsanto's Washington legal department. Clarence Thomas was a Monsanto

attorney before being appointed to the Supreme Court by George H. W. Bush and may have played a key role in the Court's "gift" of the nomination to George W. Bush during the Florida election result controversy. In that 2000 election, Monsanto donated hundreds of thousands of dollars in PAC money and soft money to political candidates. John Ashcroft received 5 times as much from Monsanto during his Senate election campaign than the second highest recipient, Larry Combest (R-TX) the powerful Chairman of the House Agriculture Committee. When Ashcroft became Attorney General he quickly brought in Larry Thompson, an attorney from Monsanto's Spalding and King law firm and an old friend of Clarence Thomas to serve as Deputy Attorney General. Tommy Thompson, who was appointed head of Health and Human Services, and former Governor of Wisconsin had also helped Monsanto by getting Wisconsin to set up a $317 million biotech zone there using state funds. He received $50,000 from Monsanto and the biotech industry for his reelection campaign. Ann Veneman, Bush's Secretary of Agriculture, was previously on the Board of Directors of Calgene Pharmaceuticals, a Monsanto affiliate that developed the first bio-engineered tomato. She also served on the International Policy Council on Agriculture, Food and Trade, a group funded in part by Cargill, another Monsanto affiliate. Attorney Linda J. Fisher, who had been Assistant Administrator of the United States Environmental Protection Agency became Vice President of Government and Public Affairs for Monsanto in Washington, where she coordinated the company's strategy to blunt resistance to genetically modified food from 1995 to 2000. She was appointed by Bush in 2001 to be deputy administrator of the Environmental Protection Agency and joined DuPont in June 2004 as vice president to promote their genetically engineered seeds and other biotech products that require EPA approval. Lidia Watrud, who had been a Monsanto microbial biotechnology researcher for 15 years, is now with the Environmental Protection Agency overseeing genetically modified foods. Margaret Miller, a former laboratory supervisor for Monsanto, became FDA Deputy Director of Human Food Safety and Consultative Services.

Mickey Kantor, former U. S. Trade Representative, Clinton's Secretary of Commerce and one his closest advisers, later joined the law firm of Mayer, Brown & Platt, which protects Monsanto's interests in matters of international trade, food safety and product labeling. During the 1996 US election, Monsanto donated thousands of dollars to Clinton in "soft money" (funds not included in the ban on corporate donations). Prior to Kantor's arrival at the firm in 1997, one of their top lobbyists had been William Daley, whom Clinton promptly chose to replace Kantor as Commerce Secretary, which enabled Monsanto to be heavily promoted on several continents. Kantor was also appointed to the Monsanto Board in 1997 (at $100,000/year), where he joined two other Washington insiders, William Ruckleshaus, former director of the EPA, and Gwendolyn King, former head of the Social Security Administration. Rufus Yerxa, Monsanto's chief counsel, was appointed as U. S. deputy to the World Trade Organization. Carol T. Foreman, former Monsanto lobbyist, was appointed as U. S. "Consumer Advocate" on the U. S. Biotech Consultative Forum Delegation. Marcia Hale, Assistant to President Clinton for Intergovernmental Relations left to become Director of International Government Affairs for Monsanto Corporation in order to coordinate public affairs and corporate strategy in the United Kingdom and Ireland and then returned to Monsanto's Washington office to handle international and "other matters." Josh King, Clinton's Director of Production for White House events, is now Director of Global Communication in Monsanto's Washington office.

More Monsanto Machinations, Manipulations And Malfeasance

The Edmonds Institute lists the names of hundreds of people who move in and out of positions as Federal regulators and directors, commissioners and scientists at the companies they are supposed to regulate (www.edmonds-institute.org/door.html). Monsanto was so well represented that one authority stated "The FDA no longer needed a revolving door, they could build a bridge to take care of the traffic." Another described the FDA as "Monsanto's Washington Branch Office". Michael Taylor, Tipper Gore's cousin, started out as an FDA

staff lawyer in 1976 and rose through the ranks to become Executive Assistant to the FDA Commissioner. He left in 1981 to join the Washington law firm King & Spalding to serve as their Searle and Monsanto's "FDA specialist". Monsanto was developing Posilac, their recombinant bovine growth hormone (rBGH) to enhance dairy cow productivity. While working for Monsanto, Taylor had prepared a memo to determine whether Monsanto could sue states or companies that wanted to tell the public that their products were free of Monsanto's drug. In 1991 the FDA created a new position of Deputy Commissioner for Policy to supervise the formulation of its policy on genetically engineered food and Taylor was appointed to the post.

During his tenure, warnings from FDA and other scientists were persistently overridden and drafts of the policy statement dealing with use, marketing and labeling guidelines that Taylor developed increasingly contradicted assertions that milk from cows injected with Posilac contained contaminants and a potent carcinogen. **When Posilac was approved in 1993, the FDA guidelines exempted milk producers from labeling dairy products from cows that had been treated with rBGH and ruled that non-rBGH product labels must state that there is no difference between rBGH and the natural hormone.** Ten days after Taylor's policy was finalized, his old law firm filed suits on behalf of Monsanto against two dairy farms offering rBGH-free milk. In response to consumer demand, Maine's Oakhurst Dairy had labeled their milk "Our Farmers' Pledge: No Artificial Growth Hormones" for four years, but Monsanto claimed it could no longer let customers know whether its milk contained genetically engineered hormones. Assisting Taylor in drafting the policy was Margaret Miller, deputy director of the FDA's Office of New Animal Drugs, a research scientist who had worked on rBGH safety studies for Monsanto prior to joining the FDA in 1989. Suzanne Sechen, a primary reviewer for rBGH in this division had also done research for several Monsanto-funded rBGH studies as a Cornell graduate student under one of Monsanto's university consultants who was a staunch rBGH advocate.

Prior to FDA approval, Monsanto had admitted that Posilac could raise the incidence of mastitis in cows by up to 80%, resulting in increased amounts of bacteria and pus in milk. Although the Posilac warning insert was forced to acknowledge "an increase" in mastitis (as well as some 20 other veterinary health problems), these contaminants in milk were disguised as "an increase in somatic cell counts in some herds". Robert Cohen, author of *Milk: The Deadly Poison*, and *Milk A-Z* noted, "In ten drops of milk, a million cells of pus. All of this in your morning cereal, but it [milk] still appears white and pure." He also stated that approval of Posilac was denied in 1992 until the "mastitis issue" had been resolved because this could lead to increased antibiotic residues in milk. Miller and Taylor addressed this concern by allowing a 100-fold increase in the amount of antibiotics Americans could consume in milk. The *Wall Street Journal* reported that 38% of 50 retail milk samples examined from ten major cities were contaminated with sulfamethazine (a known carcinogen linked with thyroid cancer), other sulfa drugs, and antibiotics. Ten percent contained streptomycin derived antibiotics at levels over 100 parts per billion although the FDA tolerance level is zero. Another analysis of 50 retail milk samples in New York City found that 80% contained traces of tetracycline and 25% were tainted with sulfamethazine. The FDA's own survey of 70 milk samples collected from 14 U.S. cities also found sulfa drugs as well as other antibiotics in over half the samples.

Experts have become alarmed because bacteria exposed to the antibiotics given to dairy cows have become increasingly resistant to drug treatment and are passed on to humans. There are well over 10,000 deaths in the U. S. annually from antibiotic resistant infections and the number is steadily increasing. Posilac contains bovine genetic material that is spliced with genetic material from *E. Coli* and there are fears that this may have contributed to the emergence of new resistant coliform strains that can cause fatal hemorrhagic colitis. Posilac injected cows also produce milk with exceedingly high levels of Insulin Growth

Factor-1 (IGF-1), which is known to promote cancer. Some studies have found that rBGH milk has ten times as much IGF-1 as non-rBGH milk and such levels are associated with significantly increased rates of cancer of the breast and colon and an eight-fold increase in prostate cancer. Adding Posilac and other growth hormones to milk also causes secondary sex characteristics to appear earlier in young children, particularly girls. The Cancer Prevention Coalition states that some girls are now experiencing puberty effects as young as three years of age. Fifty years ago the incidence of breast cancer risk in U.S. women was one in twenty; it has now risen to one in eight.

Vice-President Dan Quayle referred to Taylor's FDA's policy as "regulatory relief" for the industry but because of the above concerns and claims of collusion with Monsanto, a General Accounting Office investigation into the approval was initiated in 1994. It revealed that **Miller had violated the FDA ethics rules eight times, including publishing eight articles for Monsanto while she was at the FDA, drafting the rBGH labeling laws and regulations that Taylor, a former Monsanto lawyer, approved**. **Nothing was done** since the official report found "no conflicting financial interests with respect to the drug's approval" and only "one minor deviation from now superseded FDA regulations". However, after the investigation, Taylor was transferred to the U.S. Department of Agriculture where he served as Administrator of the Food Safety and Inspection Service from 1994 to 1996, when he returned to head Monsanto's Washington law firm as the corporation's Vice President of Public Policy. Every other industrialized country in the world has banned rBGH milk and the United Nations Food Standards Body he refused to certify it as safe. Since rBGH was approved, almost half of the small and medium-sized dairy farmers have gone out of business leaving production to large industrial-sized dairies that churn out as much total rBGH milk as possible to take advantage of government subsidies. In one such facility, **mortality rates for rBGH injected cows was 40%/year, meaning that most were dead after 30 months compared to the typical lifespan of 15 to 20 years**. We hardly need more milk since the USDA is stuck with well over a $1 billion worth of surplus milk powder, some of which is so old it may be unusable. It costs over $20 million/year to store and 20 – 25 million pounds come in weekly as a result of subsidies to farmers that were renewed a few years ago and there are no foreign markets.

Dr. Michael Friedman, former head of the FDA also has strong ties to Monsanto and the pharmaceutical industry. A 1996 *60 Minutes* television program pointed out that the alarming rise in brain tumors in the United States during the previous ten years was directly proportional to the increased use of aspartame since NutraSweet had been approved. Searle and acting FDA Commissioner Michael Friedman had previously claimed the data posed no problem. In 1999, Friedman left the FDA to become Vice President of Clinical Research for the Searle pharmaceutical division of Monsanto and was subsequently promoted to Senior Vice President for Clinical Affairs. According to the press, Dr. Virginia Weldon, Vice President for Public Policy at Monsanto who had appeared on the *60 Minutes* show to defend the company was the "top candidate" to replace him as FDA Commissioner. The following year Friedman became Senior Vice President of Research and Development, Medical and Public Policy for the Pharmacia Corporation, which had been created in April 2000 through the merger of Pharmacia & Upjohn with Monsanto Company and its Searle unit. **His salary was not revealed but records show that compensation for other executives for the year 2000 included $7 million for Goran Ando, Executive VP, over $9 million and stock options of $35 million for Philip Needleman, Senior Executive VP and Fred Hassan, President and CEO, received $11 million and stock options of $71 million.** The following year, Friedman was also appointed Chief Medical Officer for Biomedical Preparedness for The Pharmaceutical Research and Manufacturers of America (PhRMA) which represents over 60 leading pharmaceutical and biotechnology companies.

Although much of the "revolving door" activity has been done without fanfare, in 2002 a new and more formal and open partnership was formed with the web site announcement of the creation of "Homeland Health." This was described as a "partnership of: U.S. Department of Health and Human Services America's Pharmaceutical Companies". As one critic noted, "It is not clear whether their lack of punctuation separating what presumably used to be a government branch, from "America's Pharmaceutical Companies," is a coincidental oversight, or is a phrase that is actually pointing to truth - a truth that is frightening, to say the least. Among the services this new Homeland partnership will be providing to the citizens of America - whether we like it or not - is protection from bio-terrorists in a "combined effort to do whatever it takes - for as long as it takes - to win the war against bioterrorism." PhRMA's president announced that Dr. Michael Friedman would also be the association's Chief Medical Officer for Biomedical Preparedness and lead the initiative by interfacing with a number of government agencies including HHS, The Dept. of Defense, FDA, NIH, CDC and Homeland Security. This is significant since Pharmacia will likely have the most influence on PhRMA's involvement in bioterrorism. In addition to Friedman, others on Pharmacia's Board include William Ruckelshaus, former EPA head; Mickey Kantor, former Secretary of Commerce, Monsanto lawyer and on Monsanto's Board of Directors; and Frank Carlucci, former Deputy Director of the CIA and Reagan's Deputy Secretary of Defense and National Security Advisor.

The Carlyle Connection

Frank Carlucci is also Chairman of the Board and CEO of the Carlyle Group, which describes itself as a "merchant bank" but is actually one of the major U.S. defense contractors. Its Pennsylvania offices, midway between the White House and the Capitol building and within a stone's throw of FBI headquarters and other important government departments, accurately reflects its position at the very center of the Washington establishment. Since its start in 1987 in a room in New York's Carlyle Hotel, the group has grown from four investors with $5 million in capital to a globe-spanning private equity fund that is now estimated to manage close to $15 billion that have provided a 35% return on investments. Carlucci, a close friend of Donald Rumsfeld ever since they were college roommates at Princeton, joined Carlyle in 1989, and soon brought in over $1 billion annually from Pentagon contracts. Other officers include Senior Counselor James Baker III, Chief of Staff and Treasury Secretary under Reagan and George H. W. Bush's Secretary of State, and ex-president Bush, whose title is "Broker". Bush, who had been CIA director for Ford and had strong Saudi ties, brokered the deal for the Bin Laden family to invest millions in Carlyle. Because it is privately held, Carlyle doesn't have to reveal information about its partners or investments to the SEC or to anyone else, but others known to be involved with the company include: Arthur Levitt, Chairman of the SEC from 1993 to 2001; William Kennard, former FCC Chairman; Saudi Arabia's Prince Alwaleed and Bin Laden family members; former U.K. Prime Minister John Major; former Philippines President Fidel Ramos; and billionaire George Soros, who invested over $100 million. Various Carlyle subsidiaries have also hired retired four star generals at six figure salaries, including John M. Shalikashvili, former chairman of the Joint Chiefs of Staff. President George W. Bush was on the payroll for three years in the early 1990's.

Carlyle stands to profit tremendously from the war on bioterrorism through its control of the only U.S. company approved to make anthrax vaccine and one of the three that have approval for over-the-counter potassium iodide pills used to help protect against thyroid cancer in the event of exposure to large amounts of radiation. In June 2002, President Bush signed into law the Public Health Security and Bioterrorism Preparedness and Response Act that requires state and local officials to "provide adequate protection" by distributing potassium iodide to all public facilities within a few miles of a nuclear power plant. Carlyle and Homeland Health, headed by Pharmacia's VP Michael Friedman, also stand to reap huge profits from Project BioShield, which Bush signed into law last July. It is designed to provide

new tools to improve medical countermeasures that would protect Americans against a chemical, biological, radiological, or nuclear attack. The fiscal year 2004 appropriation for the Department of Homeland Security included $5.6 billion over 10 years for the purchase of next generation countermeasures against anthrax and smallpox as well as other harmful agents.

Are Monsanto's And NutraSweet's Days Numbered?

In trying to peer into the future it is often helpful to review pertinent past events. Monsanto's first product was saccharin, which it brought out in 1902. From 1903 to 1905, their entire saccharin output was shipped to a growing soft drink company in Georgia called Coca-Cola and by 1915 annual sales were over $1 million. Because of animal studies suggesting it could cause cancer the government filed a suit questioning the safety of saccharine in 1917 but it was dismissed in 1925 for lack of proof and sales steadily increased. Saccharin's safety was again challenged in 1977 when the FDA proposed a ban following an animal study showing that saccharin (Sweet and Low) was a carcinogen. Congressmen were flooded with letters supporting saccharin from the public and scientists and there was also strong pressure from Monsanto. Congress passed a two year moratorium on the ban to allow time for more research but did mandate that that all food containing saccharin bear the following warning label: "Use of this product may be hazardous to your health. This product contains saccharin, which has been determined to cause cancer in laboratory animals." The moratorium was extended seven times and in 1991 the FDA withdrew its proposal to ban saccharin. The pressure from Monsanto continued and President Clinton signed a bill in 2000 that also removed the warning label.

Monsanto has a long history of poisoning people as well as the environment. From 1935 to 1972, it manufactured polychlorinated biphenyls (PCBs) at its plant in Anniston, a picturesque town in rural Alabama. Documents show that Monsanto knew in 1950 that PCBs, widely used as industrial coolants and electrical insulators, were a toxic danger but continued to dump large amounts of these as well as lead and mercury into landfills where they leached into local streams and soil around houses whenever it rained. In February 1966, after State conservationists reported that Monsanto waste was killing massive numbers of fish the company hired an aquatic biologist to conduct its own testing. He arrived seven months later with tanks of bluegill fish caged in cloth containers that were submerged at various points along nearby Snow Creek. He reported that all fish turned belly-up within 10 seconds, spurting blood and shedding skin as if dunked into boiling water and that "all were dead in 3 1/2 minutes". He told Monsanto that the deaths were due to "extremely toxic" wastewater and calculated that the outflow would probably kill fish even if diluted 1000 times and warned, "Since this is a surface stream that passes through residential areas, it may represent a potential source of danger to children" and urged the company to clean up Snow Creek, and stop dumping untreated waste there. Monsanto did not release these findings and did nothing to stop the leaking of 50,000 pounds of PCBs into Snow Creek annually and burying more than 1 million pounds of PCB-laced waste in unlined, uncapped landfills.

What followed is an incredible tale of corruption, conflict of interest and deceit involving State and Federal officials much too lengthy to detail here. Although PCB production had been banned in 1977, fish continued to die over the next two decades because Monsanto failed to comply with orders to conduct proper cleanup activities. Anniston residents who were experiencing increased rates of cancer, birth defects and other serious health problems filed a class action suit in 1996 against Monsanto in state court for polluting people and other problems. Testing by Alabama officials and private firms had confirmed that astronomical PCB levels persisted in yard soils, dust inside homes and drainage ditches and almost one-third of those living near the plant were found to have elevated PCB blood concentrations. Monsanto could see the writing on the wall and in 1997, it created another

company, Solutia, to control its chemical operations, including the Anniston plant. Any liabilities would first be incurred by Solutia then Monsanto. In March 2000, Monsanto merged with Pharmacia and Upjohn, maintaining the name Pharmacia and the original Monsanto ceases to exist. Now, Solutia then Pharmacia is liable for any Anniston penalties. In October 2000, Pharmacia created an agricultural subsidiary called Monsanto Company so that now Solutia, then Monsanto, then Pharmacia becomes liable.

After various legal challenges, the trial finally began in January 2002 and several thousand pages of internal Monsanto documents revealed how the company had deliberately concealed the PCB hazards and exposure to Anniston residents. For example, a 1975 Monsanto study confirmed that PCBs cause tumors in rats but officials ordered its conclusion to be changed from "slightly tumorigenic" to "does not appear to be carcinogenic." In February 2002, the jury ruled against Monsanto and its corporate successors on all six counts it had considered: negligence, wantonness, suppression of the truth, nuisance, trespass and outrage. The last charge was unusual, since under Alabama law, the rare claim of outrage typically requires conduct "so outrageous in character and extreme in degree as to go beyond all possible bounds of decency so as to be regarded as atrocious and utterly intolerable in civilized society." In June 2003, Solutia and its parent company, Pharmacia Corp., filed suit against Halliburton, Phelps Dodge Industries, United States Pipe and 16 other companies for past and future cleanup costs stating that "government records show that many of these industrial facilities previously discharged PCBs and other hazardous metal wastes into the creeks in the area or disposed of waste on their properties or elsewhere in the community." In another delaying tactic, it attempted to add these companies as defendants to the class action and other suits filed against them by 18,000 Anniston residents who had been hurt or damaged. Solutia was finally forced to seek bankruptcy protection on December 17, 2003 stating that it expected to pay $60 million for retiree benefits and $40 million for environmental mitigation annually for the next five years and that those liabilities should either should be terminated as part of its bankruptcy or be transferred to Monsanto or Pharmacia. Solutia also sued Pharmacia to force it to take on some of the retiree health insurance, life insurance and disability payments. Talks between the two parties over who should be responsible to pay the over $500 million in employee benefits for former Monsanto employees, environmental clean-up costs as well as expenses in some 600 lawsuits over the next five years had fallen apart a few weeks earlier after Solutia refused to pay a $3 million settlement of two Texas court cases. The defendant named in those cases was Pharmacia, which had merged with Monsanto in April 2000, but was now an unrelated unit of Pfizer, which had acquired Pharmacia three years later through a reverse triple merger that included the potential billions of dollars in Anniston toxic tort liability. Solutia said it had no involvement in the case other than helping settle it on behalf of Pharmacia and Monsanto. Pfizer contended it had no legal exposure connected to either Solutia or Monsanto, and Monsanto said Solutia was contractually bound to cover the costs. None of the above cases have been settled and will likely remain in legal limbo for years.

Monsanto has also given us such environmental poisons as Agent Orange, Roundup and other herbicides as well as Cycle-Safe, the world's first plastic soft-drink bottle, all of which have been linked to cancer and other health hazards. As with aspartame, Monsanto vigorously denied such charges although the FDA banned Cycle-Safe a year after it was approved because it posed a cancer risk. With respect to aspartame, the Delaney law bans any food additive that is carcinogenic in animals or can be shown to cause cancer. Because aspartame clearly falls into this category, Monsanto layer Michael Taylor had written over a dozen articles critical of Delaney and continued trying to have this regulation removed when he was subsequently appointed FDA Deputy Commissioner for Policy in 1991. Nevertheless, the writing was again on the wall and in May 2000, Monsanto, now a wholly owned subsidiary of Pharmacia Corporation, sold the NutraSweet Company and the rights to Equal and Neotame, a more potent aspartame product. Sucralose (Splenda) which was approved

in 1998 had been taking an increasing share of the sweetener market and stevia loomed on the horizon.

Stevia is a calorie-free herb used as a sweetener in South America for centuries and popular all over the world, especially in Japan, where it has 41% of the sweetener market, including sugar. Stevia was promoted in the U. S. in the 1980's as a flavoring agent by Lipton and Celestial Seasonings, one of the world's largest herbal tea companies. Health food stores also sold stevia as a natural sugar substitute. In 1986, the FDA came into Celestial's warehouse without warning and seized their stock of stevia. No reason was given for the seizure; the company was simply told they could not use it in their teas. In 1991, the same year that Monsanto lawyer Taylor became Deputy Commissioner for Policy, the FDA banned all imports and sales of stevia, claiming that it was an "unsafe food additive", although there was no evidence for this. Because of pressure from consumers and supplement manufacturers, Congress passed the Dietary Supplement & Health Education Act (DSHEA) in 1994, which obviously permitted stevia to be sold as a dietary supplement. Monsanto interests had anticipated this and the Act's guidelines for labeling and marketing were so strict that the slightest implication that stevia had sweetening qualities or simply suggesting that it could be mixed with water could cause it to be recalled. Many consumers were again using it as a sweetener and based on an anonymous tip, the FDA embargoed stevia shipments to the small Stevita Company in Arlington Texas. **In 1998, in a decree reminiscent of Nazi Germany, the FDA further demanded that Stevita destroy a warehouse full of "cookbooks, literature, and other publications" and promised to be on hand to "'witness the destruction" of the offending materials. The FDA subsequently told Stevita to recall the more than 6,500 books already in distribution to stores and private individuals so they could also be destroyed.**

Monsanto's fears about the future of aspartame seem well founded. The FDA has received more complaints about aspartame than for all other food additives combined and numerous suits are likely. The FDA had previously been sued several times for collusion with Monsanto and failure to recall aspartame to no avail. However, over the last six months, the National Justice League filed several suits in California alone accusing Coca-Cola, PepsiCo, Bayer, Dannon, Wrigley, ConAgra Foods, Wyeth, Pfizer, Slimfast, The NutraSweet Company, Kraft Foods and Philip Morris of exposing the public to a substance they knew was toxic to humans. Legal scholars who have reviewed the detailed documents submitted believe that the defendants cannot present a case that will justify their use of aspartame. Pepsi and Coke have already switched to other sweeteners and although this is like locking the barn after the horses have been stolen, it seems likely that others will make similar changes. Lengthy legal battles are looming - so Stay Tuned!

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