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Killing Us Sweetly: How to Take Industry out of the FDA

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KILLING US SWEETLY: HOW TO TAKE INDUSTRY OUT OF THE FDA

*Jason Iuliano**

For more than a century, the Food and Drug Administration has claimed to protect the public health. During that time, it has actually been placing corporate profits above consumer safety. Nowhere is this corruption more evident than in the approval of artificial sweeteners. FDA leaders' close ties to the very industry they were supposed to be regulating present a startling picture. Ignoring warnings from both independent scientists and their own review panels, FDA decision makers let greed guide their actions. They approved carcinogenic sweeteners such as saccharin, aspartame, and sucralose while simultaneously banning the natural herb stevia because it would cut into industry profits. This Article proposes two reforms that can end these corrupt practices and take industry out of the FDA. By strengthening conflict of interest regulations and preventing companies from participating in safety trials, the FDA will be able to gain the independence it needs in order to regulate the food and drug industries.

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INTRODUCTION

It is a beautiful summer day. As you cruise down the highway, the sun shines through the windshield, warming your skin. A sign appears in the distance. It's too far away to read, but you know what it says anyway: "Beach 10 miles." You can already see the welcoming white sand and feel the refreshing ocean water. Today promises to be amazing. It's a shame that the next two hours will be the scariest moments of your life.

Just as you lean over to turn on your favorite radio station, everything flips 180 degrees. The ground and sky have traded places. Your vision indicates that your car is flying upside down through the air. You clench your eyes shut and brace for the expected impact with the ground. After a couple of terrifying, but uneventful, seconds, you risk a glance. Surprisingly, your car is gently coasting down the road. A thankful sigh escapes your lips. This relief, however, is short-lived as you notice an even more chilling problem. Although all the other cars are still in their lanes, they appear to be driving on the ceiling. Adding to the confusion, the sun is shining up from the floor. It takes a moment to come to this realization, but you know that, somehow, your vision has become inverted.

Panicked, you slam the brakes and turn the wheel towards the shoulder of the road. The car comes to a stop right next to the beach sign. Just another ten miles. You pull out your cell phone and dial 911. In the blink of an eye, your entire world has literally turned upside down.

Fifteen minutes later, the emergency room doctors are running a series of tests. An hour passes; the results come back negative. Your mother has arrived and is standing at the bedside sobbing. Seemingly, in defiance of gravity, a tear slips across her cheek and falls up.

Yet another doctor approaches. He asks an odd question. Do you drink diet soda? You grumble inwardly, thinking that there are more pressing matters at hand than your beverage preferences. Nonetheless, you tell the doctor that you enjoy diet soda from time to time and happened to drink a few cans this past week. The doctor nods knowingly and informs you that the aspartame in those diet

sodas is likely producing this frightening experience. He has had a number of other patients with similar symptoms, and, in those cases, artificial sweeteners have been linked as the cause. A short while later, your vision returns to normal, but you vow never to drink diet soda again.¹

Many people's first reaction is that artificial sweeteners could not be this dangerous. After all, they are FDA-approved, and the government would not let a harmful chemical enter the food supply. Unfortunately, their faith rests on a presumption that no longer holds true.

If only there were an impartial government administration that regulated the food and drug industries, that agency surely would have protected the American people from such a toxic substance. At one time, the Food and Drug Administration (FDA) filled this role, serving as the much needed corporate watchdog, but now, it is nothing more than a corporate lapdog. Today, any company with enough money can buy approval for even the most dangerous products.

There is also a disturbing corollary to this problem. These same powerful companies can prevent competing products from getting FDA approval.² Often, the products most easily targeted are safe, natural substances that cannot be patented. When a new, healthy product is submitted to the FDA without a large corporate backer, approval is anything but certain. If a wealthy corporation fears that this new product will cut into its profit margin, it can put

1. See JOSEPH MERCOLA, SWEET DECEPTION: WHY SPLENDA, NUTRASWEET, AND THE FDA MAY BE HAZARDOUS TO YOUR HEALTH 36 (2006) (describing a similar experience); see also HYMAN JACK ROBERTS, ASPARTAME DISEASE: AN IGNORED EPIDEMIC 68 (2001) (Roberts clinically observed 1200 patients who had adverse reactions to aspartame. More than 500 patients experienced vision problems, and 27 of those suffered blindness in one or both eyes.).

2. See *Delays in the FDA's Food Additive Petition Process and GRAS Affirmation Process: Hearings Before the Subcomm. on Human Resources and Intergovernmental Relations of the House Comm. on Gov't Reform and Oversight*, 104th Cong., at 78 (1995) (statement of Robert C. Gelardi, Executive Vice President, Calorie Control Council) (noting that "the careful timing of their submissions can hold up a review numerous times just short of approval"); *id.* at 90-91 (describing how anonymous submissions are often used to delay FDA approval for competitive reasons.); see H.R. REP. NO. 104-436, at 5, 9 (1995) (Parties have made anonymous submissions with the sole purpose of delaying agency decisions.); see *FDA Delay in Sucralose Approval Gets "Golden Grinch" Award from Sen. Mathews*, FOOD CHEM. NEWS, Aug. 29, 1994, at 46 (Sen. Harlan Mathews observed that "any third party could indefinitely delay approval of [a food] additive simply by repeatedly submitting their interpretation of data"); see also Lars Noah & Richard A. Merrill, *Starting From Scratch?: Reinventing the Food Additive Approval Process*, 78 B.U.L. REV. 329, 330 & 372.

up huge roadblocks and use its connections to cause the FDA to reject the application.³

Even many FDA employees are unsettled by their agency's actions.⁴ In a recent poll, more than one-third of FDA scientists believed that agency leadership is more concerned with rushing products to market than ensuring consumer safety.⁵ To guarantee that products are approved, FDA leaders often pressure scientists to unethically change data or alter their conclusions.⁶ Due to the close ties between upper management and the pharmaceutical industry, the FDA is willing to engage in these untoward practices. Unsurprisingly, sixty percent of researchers knew of instances in which industry had inappropriately influenced the FDA's decisions.⁷

The deception is not limited to internal documents. A full twenty percent of FDA scientists "have been asked explicitly by FDA decision makers to provide incomplete, inaccurate or misleading information to the public, regulated industry, media, or elected/senior government officials."⁸ This deceit directly subverts the FDA's mission statement, which lists "helping the public get the

3. See Lars Noah, *Sham Petitioning as a Threat to the Integrity of the Regulatory Process*, 74 N.C. L. REV. 1, 58 (allowing industry submissions "brings with it the possibility for strategic manipulation of the regulatory process in pursuit of anticompetitive ends"). We will see this process play out with respect to stevia in Part II.D.

4. Union of Concerned Scientists, Survey: FDA Scientists (2006), http://www.ucsusa.org/scientific_integrity/abuses_of_science/summary-of-the-fda-scientist.html (last visited Apr. 12, 2010) ("The results paint a picture of a troubled agency: hundreds of scientists reported significant interference with the FDA's scientific work, compromising the agency's ability to fulfill its mission of protecting public health and safety.").

5. Union of Concerned Scientists, *Voices of Scientists at FDA: Protecting the Public Health Depends on Independent Science* (2006), available at http://www.ucsusa.org/assets/documents/scientific_integrity/fda-survey-brochure.pdf.

6. *Id.* (Eighteen percent of FDA scientists responded, "I have been asked, for non-scientific reasons, to inappropriately exclude or alter technical information or my conclusions in an FDA scientific document."); see also Gardiner Harris, *F.D.A. Scientists Accuse Agency Officials of Misconduct*, N.Y. TIMES, Nov. 18, 2008, at A15. (According to a letter from FDA scientists to Congress, "Top federal health officials engaged in 'serious misconduct' by ignoring concerns of scientists at the Food and Drug Administration and approving for sale unsafe or ineffective medical devices . . . The letter says that the scientists have documentary evidence that senior agency managers 'corrupted the scientific review of medical devices' by ordering experts to change their opinions and conclusions in violation of the law.").

7. Union of Concerned Scientists, *supra* note 5.

8. *Id.*

accurate, science-based information they need to use medicines and foods to improve their health” as a primary goal.⁹

Unfortunately, nowadays, little things like facts and science are no longer relevant to agency leaders. Their main concern is speeding products through the approval process so pharmaceutical companies can earn more money at the expense of America’s health. One FDA scientist from the Center for Drug Evaluation and Research wrote that “[s]cientific discourse is strongly discouraged when it may jeopardize an approval. . . . Whenever safety or efficacy concerns are raised on scientific grounds . . . these concerns are not taken seriously.”¹⁰ Quite simply, FDA leaders have failed our nation, and the agency has been captured by the very industries it should be regulating.

On its own website, the FDA plainly states another urgent problem: “The Food and Drug Administration relies on data that sponsors submit to decide whether a drug should be approved.”¹¹ If the FDA hopes to promote public health, it cannot trust corporations to assess the safety and efficacy of their products. The desire to maximize profits all but guarantees that companies will distort their findings.

In fact, entire industries have thrived by “manufacturing uncertainty.”¹² Big tobacco is the most prominent,¹³ but the examples

9. FDA, What We Do, <http://www.fda.gov/AboutFDA/WhatWeDo/default.htm> (last visited Apr. 12, 2010).

10. Union of Concerned Scientists, *supra* note 5.

11. FDA, The FDA’s Drug Review Process: Ensuring Drugs Are Safe and Effective, <http://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucml43534.htm> (last visited Apr. 12, 2010).

12. See DAVID MICHAELS, DOUBT IS THEIR PRODUCT: HOW INDUSTRY’S ASSAULT ON SCIENCE THREATENS YOUR HEALTH x (2008) (defining the strategy of “manufacturing uncertainty” as “preventing or postponing the regulation of hazardous products by questioning the science that reveals the hazards in the first place”).

13. See *id.* at 9 (The tobacco industry “worked tirelessly for decades to support their preordained conclusions and suppress any findings that suggested otherwise The industry understood that the public is in no position to distinguish good science from bad. Create doubt, uncertainty, and confusion. Throw mud at the ‘antismoking’ research under the assumption that some of it is bound to stick. And buy time”); see Deborah E. Barnes & Lisa A. Bero, *Why Review Articles on the Health Effects of Passive Smoking Reach Different Conclusions*, 279 J. AM. MED. ASS’N. 1566, 1566–69 (1998). The authors determined that “the only factor associated with concluding that passive smoking is not harmful was whether an author was affiliated with the tobacco industry.” *Id.* at 1566. They went on to note that the study’s “findings suggest that the tobacco industry may be attempting to influence scientific opinion by flooding the scientific literature with large numbers of review articles supporting its position that passive smoking is not harmful to health.” *Id.* at 1569.

where corporations have funded scientific studies to manufacture doubt are legion. Some other notable offenders include asbestos,¹⁴ vinyl chloride,¹⁵ and lead.¹⁶ This Article will make the case that the artificial sweetener industry deserves a spot among this illustrious group.

Part I briefly sets the background for artificial sweeteners by describing America's obesity epidemic and sugar addiction. Together, these factors explain why artificial sweeteners have developed into such a profitable industry. Next, Part II explores the controversies surrounding the three most popular artificial sweeteners: saccharin, aspartame, and sucralose. By using artificial sweeteners as a case study, the article shows why the FDA must be reformed.¹⁷ This section will make it clear that the FDA's close ties to pharmaceutical companies and the agency's blind reliance on industry-funded science are threatening consumer safety. Afterwards, Part II further stresses the ill effects of agency capture by describing how industry groups pressured the FDA to ban stevia, a safe, natural sweetener.

After ominously noting that "[t]he Congress and federal agencies are already being dealt with ... by the Tobacco Institute," one tobacco executive suggested that the American people must be made to doubt the scientific evidence regarding the harms of smoking. See *Smoking and Health Proposal*, Brown & Williamson document no. 680561778-1786, 4, available at <http://legacy.library.ucsf.edu/tid/nvs40f00>. The tobacco executive wrote, "Doubt is our product since it is the best means of competing with the 'body of fact' that exists in the minds of the general public. It is also the means of establishing a controversy." *Id.*

14. See MICHAELS, *supra* note 12, at 12–18.

15. See GERALD MARKOWITZ & DAVID ROSNER, *DECEIT AND DENIAL: THE DEADLY POLITICS OF INDUSTRIAL POLLUTION* 173–78 (2003). Although the industry knew of vinyl chloride's dangers, it "released only the information that would reassure people as to the essentially benign nature of the finished products." *Id.* at 173. This practice continued for years. "Motivated by money and power rather than health, the industry was largely successful in hiding its information about cancer from the government and in deflecting national attention away from the potential hazards . . ." *Id.* at 178.

16. See *id.* at 60–64. (After independent studies determined that lead is poisonous, the Lead Industry Association "portray[ed] this growing body of scientific literature as 'prejudice against lead' rather than the documentation of a serious public health concern. The [Lead Industry Association] still sought to cast doubt on virtually every report of lead poisoning, focusing on the reports' methodological problems rather than the underlying reality." To manufacture uncertainty, the lead industry mounted a "thirty-five year advertising campaign to convince people that lead was safe.").

17. Change is unlikely to be initiated by the legislative or executive branch. Even President Clinton instructed the FDA to treat the pharmaceutical companies as "partners, not adversaries." David Willman, *How a New Policy Led to Seven Deadly Drugs*, L.A. TIMES, Dec. 20, 2000, available at <http://www.latimes.com/news/nationworld/nation/la-122001fda,1,539362.story>.

Finally, Part III proposes two potential reforms. Americans must lock the revolving door and take industry out of the approval process. Only then should we trust the FDA with our health.

I. THE OBESITY EPIDEMIC

A. *Economic Effects*

$\text{Calories in} - \text{Calories out} = \text{Change in bodyweight.}$

This equation is the key to combating obesity.¹⁸ Start with the number of calories eaten in a day, and subtract the number of calories burned. If the result is positive, you gain weight. If it is negative, you lose weight.

Every 3500 calories adds up to an extra pound.¹⁹ Whether the caloric excess come from apples or chocolate cake, the same amount of weight is gained. This means someone can get fat from eating health foods such as fruits, vegetables, whole grains, and lean meats. Likewise, one could eat nothing but McDonald's Big Macs and manage to lose weight.²⁰ It all comes down to calories in versus calories out. The key to weight control really is that simple.

Despite this clear formulation, obesity is a growing problem. In 2006, the Centers for Disease Control and Prevention (CDC) conducted a study to determine what proportion of Americans have a weight problem.²¹ The CDC derived its data by calculating people's Body Mass Index (BMI).²² The following table illustrates how BMI relates to the various weight categories.²³

18. See Frank M. Sacks et al., *Comparison of Weight-Loss Diets with Different Compositions of Fat, Protein, and Carbohydrates* 360 NEW ENG. J. MED. 859, 859 (2009) (concluding that "[r]educed-calorie diets result in clinically meaningful weight loss regardless of which macronutrients they emphasize").

19. ROBERTA LARSON DUYFF, AMERICAN DIETETIC ASSOCIATION COMPLETE FOOD AND NUTRITION GUIDE 29 (2002).

20. Obviously, for nutritional reasons, such a diet would be a poor choice.

21. Centers for Disease Control and Prevention, Obesity and Overweight, <http://www.cdc.gov/nchs/fastats/overwt.htm> (last visited Apr. 12, 2010).

22. Because BMI is derived solely from height and weight, some athletes or bodybuilders may be misclassified as overweight even though they have low body fat percentages. However, because only a small percentage of people fall within these exceptions, the CDC's findings are still useful. For the general population, there is a strong correlation between body fat and BMI. See Magnus Dencker et al., *BMI and Objectively Measured Body Fat and Body Fat Distribution in Prepubertal Children*, 27 CLINICAL PHYSIOLOGY AND FUNCTIONAL IMAGING 12, 12-16 (2006) (concluding that "[p]ercentage body fat [was] closely associated with BMI, suggesting that

Height	Weight	BMI	Considered
5'9"	124 lbs or less	Below 18.5	Underweight
5'9"	125 lbs to 168 lbs	18.5 to 24.9	Healthy weight
5'9"	169 lbs to 202 lbs	25.0 to 29.9	Overweight
5'9"	203 lbs or more	30 or higher	Obese

The data show that thirty-four percent of Americans over age twenty are obese and another thirty-three percent are overweight.²⁴ Eighteen percent of adolescents and more than ten percent of children are overweight.²⁵ Another eight to nine percent of Americans are underweight,²⁶ and, incredibly, only one-quarter of Americans are a healthy weight. More adults fall into the obese category than any other classification. Today, obese people outnumber healthy and underweight individuals combined, and the problem is only getting worse. Thomas Frieden, the head of the CDC noted that "[t]he average American is now 23 pounds overweight and collectively we are 4.6 billion pounds overweight."²⁷ In other words, Americans have eaten sixteen trillion calories too many.²⁸

The National Center for Health Statistics found that between 1960 and 2006, the percentage of obese adults has nearly tripled.²⁹

BMI serves as a good surrogate marker for obesity in population studies"); See Centers for Disease Control and Prevention, About BMI for Adults, http://www.cdc.gov/healthyweight/assessing/bmi/adult_bmi/index.html ("BMI does not measure body fat directly, but research has shown that BMI correlates to direct measures of body fat . . .").

23. Centers for Disease Control and Prevention, Overweight and Obesity: Defining Overweight and Obesity, <http://www.cdc.gov/obesity/defining.html> (last visited Apr. 12, 2010).

24. Centers for Disease Control and Prevention, *supra* note 21.

25. *Id.*

26. Meghan A.T.B. Reese, *Underweight: A Heavy Concern* TODAY'S DIETITIAN Jan. 2006, at 56, available at <http://www.todaysdietitian.com/newarchives/tdjan2008pg56.shtml>.

27. Thomas Frieden, Director, Centers for Disease Control and Prevention, CDC Weight of the Nation Press Briefing (July 27, 2009), available at <http://www.cdc.gov/media/transcripts/2009/t090727.htm>.

28. Sixteen trillion calories is equivalent to nine billion Burger King Whopper meals with large fries and a large soda. See Shereen Jegtvig, *Burger King® Whopper® With Cheese, Large Fries and a Large Soda*, <http://nutrition.about.com/od/rateameal/a/whoppermeal.htm> (last visited Apr. 12, 2010).

29. National Center for Health Statistics, Prevalence of Overweight, Obesity, and Extreme Obesity among Adults: United States, Trends 1960-62 through 2005-

During this same period, the proportion of Americans who are “extremely obese” increased more than 600%.³⁰

This shift seems to indicate a fundamental change in caloric intake and expenditure.³¹ Indeed, over that time, the “calories in” and “calories out” variables in the equation have shifted drastically.³² Americans now eat more³³ and exercise less.³⁴ In 1958, the average American consumed less than 1900 calories per day.³⁵ By 2007, that number had grown to 2,775,³⁶ more than 500 calories above the USDA’s Recommended Energy Allowance of 2,247.³⁷

If people needed these extra calories to supply energy for increased physical activity, this trend would not be troubling. We can return to the formula to see why. If the number of calories burned

2006, http://www.cdc.gov/nchs/data/hestat/overweight/overweight_adult.htm (noting an increase from 13.4% to 35.1%).

30. *Id.* (noting an increase from 0.9% to 6.2%).

31. See World Health Organization, Obesity and Overweight, <http://www.who.int/dietphysicalactivity/publications/facts/obesity/en> (last visited Apr. 12, 2010) (“The key causes [of obesity] are increased consumption of energy-dense foods high in saturated fats and sugars, and reduced physical activity.”).

32. For a graph charting the increase in caloric intake from 1970–2000, see Judy Putnam, Jane Allshouse, & Linda Scott Kantor, *U.S. Per Capita Food Supply Trends: More Calories, Refined Carbohydrates, and Fats*, 25 FOOD REV. 2, 3, Winter 2002, available at <http://www.ers.usda.gov/publications/FoodReview/DEC2002/frvol25i3.pdf>.

33. Judy Putnam, *U.S. Food Supply Providing More Food and Calories*, 22 FOOD REV. 2, 2, Sep.–Dec. 1999, available at <http://www.ers.usda.gov/publications/foodreview/sep1999/frsept99.pdf> (noting that “[a]ll three major per capita food supply measurements—food available for consumption, nutrients available for consumption, and the food supply adjusted for spoilage and other losses in the home and marketing system—suggest that Americans in the 1990’s are consuming more food and several hundred more calories per person per day than did their counterparts in the late 1950’s.”).

34. See Dana E. King et al., *Adherence to Healthy Lifestyle Habits in US Adults, 1988–2006*, 122 AM. J. MED. 528, 530 (2009) (“The percent of adults aged 40–74 [engaged in] physical activity 12 times a month or more has decreased from 53% to 43%”). Incredibly, in gym class, children are active an average of 3.5 minutes. KELLY D. BROWNELL & KATHERINE BATTLE HORGAN, *FOOD FIGHT* 78 (2004).

35. Putnam, *supra* note 33, at 2.

36. UNITED STATES DEPARTMENT OF AGRICULTURE, ECONOMIC RESEARCH SERVICE, LOSS-ADJUSTED FOOD AVAILABILITY DATA, available at <http://www.ers.usda.gov/data/foodconsumption/FoodGuideSpreadsheet.htm#calories>.

37. Linda Scott Kantor, Food and Rural Economics Division, Economic Research Service, U.S. Dept. of Ag., Agricultural Economic Report No. 772, A DIETARY ASSESSMENT OF THE U.S. FOOD SUPPLY: COMPARING PER CAPITA FOOD CONSUMPTION WITH FOOD GUIDE PYRAMID SERVING RECOMMENDATIONS (1998), available at <http://www.ers.usda.gov/publications/aer772/aer772.pdf>; see also MARION NESTLE, *FOOD POLITICS* 8 (2002) (noting that “overeating [is] the most probable cause of excessive weight gain”).

had increased alongside the number of calories consumed, the equation would have remained in stasis, and obesity would not be a problem. Unfortunately, the exact opposite has occurred. People are now burning fewer calories and are less active than at any other time in our history.³⁸

The U.S. Bureau of Labor Statistics found that, on an average day, only sixteen percent of Americans participate in sports or exercise activities.³⁹ In another study, the CDC determined that fifty-five percent of adults do not meet the minimum level of recommended exercise (thirty minutes of moderate activity five times per week).⁴⁰ Although this sounds like a lot of exercise, activities such as vacuuming and gardening meet the CDC's requirements for "moderate activity." Surprisingly, even under this lenient definition, twenty-six percent of Americans fail to get any physical activity.⁴¹

These statistics should trouble us because poor diet and physical inactivity cause 16.6% of all deaths in America.⁴² More specifically, twenty-three percent of the deaths from major chronic diseases—such as stroke, heart disease, and diabetes—are caused by Americans' sedentary lifestyle.⁴³ Proper nutrition and exercise could save 400,000 American lives every year.⁴⁴

The problems of obesity, however, are not confined to the overweight individuals themselves. Losing excess weight is not just about looking and feeling better; there are also powerful economic reasons to trim the fat. With obesity-related diseases costing the medical system an additional \$147 billion annually, obesity is now a greater burden on the health care system than cigarettes or alco-

38. See World Health Organization, *supra* note 31 ("[L]arge shifts towards less physically demanding work have been observed worldwide. Moves towards less physical activity are also found in the increasing use of automated transport, technology in the home, and more passive leisure pursuits.").

39. U.S. Bureau of Labor Statistics, *BLS Spotlight on Statistics: Sports and Exercise*, May 2008, available at http://www.bls.gov/spotlight/2008/sports/pdf/sports_bls_spotlight.pdf (last visited Apr. 9, 2010).

40. Centers for Disease Control and Prevention, *Prevalence of Physical Activity, Including Lifestyle Activities Among Adults—United States, 2000–2001*, 52 MORBIDITY & MORTALITY WKLY. REP. 764, 764–79, available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5232a2.htm> (last visited Apr. 9, 2010).

41. *Id.*

42. Ali H. Mokdad et al., *Actual Causes of Death in the United States, 2000*, 291 J. AM. MED. ASS'N. 1238, 1238 (2004).

43. Robert A. Hahn et al., *Excess Deaths from Nine Chronic Diseases in the United States, 1986*, 264 J. AM. MED. ASS'N. 2654, 2656 (1990).

44. See Mokdad, *supra* note 42, at 1240.

hol.⁴⁵ On average, an obese individual spends forty percent more on health care than a normal-weight person.⁴⁶ That amounts to an extra \$1500 per year for every overweight person. Approximately half of that cost is born by Medicare and Medicaid.⁴⁷ That means you, the taxpayer, are subsidizing other people's bad decisions.

Although the most direct effects of obesity are felt by the health care system, its problems are not limited to that sector. The entire U.S. economy suffers due to decreased productivity. Annually, obesity causes the loss of 39.3 million workdays. It is also responsible for 239 million restricted-activity days, 89.5 million bed days, and 62.7 million physician visits.⁴⁸ These direct economic effects check in at \$254 billion, nearly twice as high as the medical costs.⁴⁹ In comparison, smoking only reduces productivity by seventy-nine billion dollars.⁵⁰

Curing the obesity problem would not only increase economic output, it would also redirect current spending. Overweight drivers burn an additional one billion gallons of gas each year.⁵¹ Airlines would save another billion gallons of gas, and the industry would actually become profitable once again. Clothing costs would be reduced by ten billion dollars, and food expenditures would decline by the billions.⁵² Between the direct effects on the economy and health care, obesity costs the nation \$487 billion per year.⁵³ Eliminate all these expenses and each U.S. household would end the year with an extra \$4,270 in its checking account.⁵⁴

45. Roland Sturm, *The Effects of Obesity, Smoking, and Drinking on Medical Problems and Costs* 21 HEALTH AFF. 245, 245 (2002).

46. Frieden, *supra* note 27.

47. Centers for Disease Control and Prevention, Obesity and Overweight: Economic Consequences, <http://www.cdc.gov/obesity/causes/economics.html> (last visited Apr. 9, 2010).

48. Anne M. Wolf & Graham A. Colditz, *Current Estimates of the Economic Cost of Obesity in the United States*, 6 OBESITY RES. 97 (1998).

49. Ross DeVol & Armen Bedroussian, *An Unhealthy America: The Economic Burden of Chronic Disease—Charting a New Course to Save Lives and Increase Productivity and Economic Growth* ii-iii (2007), available at http://www.milkeninstitute.org/pdf/chronic_disease_report.pdf.

50. *Id.* at iii.

51. Shirley Skeel, *What if no One were Fat?*, <http://articles.moneycentral.msn.com/Insurance/Advice/WhatIfNoOneWereFat.aspx> (last visited Apr. 9, 2010).

52. *Id.*

53. *Id.*

54. *Id.*

Unfortunately, this is just the tip of the iceberg. Once reduced longevity and quality of life are taken into consideration, the true cost is incalculable.⁵⁵ Being overweight reduces one's life-expectancy by three years, and being obese reduces one's life-expectancy by 6.5 years.⁵⁶ For comparison, smoking has a similar effect on longevity.⁵⁷ Not only do overweight people die sooner, but also their quality of life is lower.⁵⁸

If the problems from obesity are so serious and the formula to shed those excess pounds is so simple, why are two-thirds of Americans overweight? An insatiable sweet tooth is a major cause.

B. The Sugar Addiction

On the one hand, sugar⁵⁹ is delicious. On the other hand, sugar causes premature aging,⁶⁰ diabetes, and heart disease, raises cholesterol and blood pressure,⁶¹ suppresses the immune system,⁶² and

55. See David S. Ludwig & Harold A. Pollack, *Obesity and the Economy: From Crisis to Opportunity*, 301 J. AM. MED. ASS'N. 533, 534 (noting that the economic and health costs are "likely to be dwarfed by reasonable economic valuation of reduced longevity and quality of life").

56. Anna Peeters et al., *Obesity in Adulthood and its Consequences for Life Expectancy: A Life-Table Analysis*, 138 ANNALS INTERNAL MED. 24, 28 (2003) (see table 3).

57. *Id.* at 24.

58. See Jennifer Klingemann et al., *Relationship between Quality of Life and Weight Loss 1 Year after Gastric Bypass*, 26 DIGESTIVE SURGERY 430, 430 (concluding that a reduction in BMI "dramatically" improves health-related quality of life); See Rebecca M. Puhl, *Perceptions of Weight Discrimination: Prevalence and Comparison to Race and Gender Discrimination in America*, 32 INT'L J. OBESITY 992, 998 (finding that "weight/height discrimination occurs in employment settings and daily interpersonal relationships virtually as often as race discrimination, and in some cases even more frequently than age or gender discrimination").

59. Throughout the paper, sugar is used to denote the sugar that has been added to foods, not the sugar that occurs naturally in fruits. This added sugar generally takes the form of sucrose (refined table sugar) and high-fructose corn syrup (a mixture of fructose and glucose).

60. See Antoine E. Roux et al., *Pro-Aging Effects of Glucose Signaling through a G Protein-Coupled Glucose Receptor in Fission Yeast*, PLOS GENETICS Mar. 2009 at 1 (noting that "substantial evidence supports the idea that excess glucose acts as a pro-aging and pathogenic factor").

61. Harry G. Preuss et al., *Sugar-Induced Blood Pressure Elevations Over the Lifespan of Three Substrains of Wistar Rats*, 17 J. AM. C. NUTRITION 36, 38 (1998) (finding that "rats ingesting diets high in sucrose . . . eventually showed statistically higher [systolic blood pressure] over their lifespan compared to those consuming the baseline").

62. W. M. Ringsdorf et al., *Neutrophilic Phagocytosis and Resistance to Disease*, 52 DENTAL SURVEY 46, 46-48 (finding that drinking twenty-four ounces of cola depresses the activity of neutrophils, white blood cells that kill bacteria).

contributes to obesity. The choice seems obvious, but for most Americans, the short-term benefit of taste outweighs all of these long-term negative effects.

It is quite obvious that Americans have a sweet tooth. The USDA sets the maximum daily allowance of sugar at ten teaspoons, less than the amount of sugar in a twelve-ounce can of Pepsi.⁶³ The American Heart Association recommends even less: six teaspoons for women and nine teaspoons for men. The average American far exceeds both upper limits, consuming 22.2 teaspoons each day. In 2008, the USDA determined that, after adjusting for loss during transport, processing, and uneaten food, per capita sugar consumption was more than 85 pounds.⁶⁴ Each year, every person is eating 154,221 empty calories from sugar.⁶⁵ That's more calories than the average person eats in the first two months of the year.

Where is all this added sugar coming from? Soft drinks are by far the biggest contributor, accounting for nearly thirty-three percent of our sugar intake.⁶⁶ The sheer amount of soda that we consume is staggering. On average, Americans drink fifty-two gallons of soft drinks a year, and teenage girls get ten to fifteen percent of their total caloric intake from these sugary beverages.⁶⁷

A large part of the remaining two-thirds of our sugar intake is, of course, derived from the usual suspects: sweetened fruit drinks (ten percent), candy (five percent), cake (five percent), cookies (four percent), and cereal (four percent).⁶⁸

63. Center for Science in the Public Interest, *America: Drowning in Sugar*, <http://www.cspinet.org/new/sugar.html> (last visited April 11, 2010).

64. See USDA, Sugar and Sweeteners Yearbook: Table 51—Refined cane and beet sugar: estimated number of per capita calories consumed daily, by calendar year, <http://www.ers.usda.gov/Briefing/Sugar/data.htm> (Per capita consumption is 46.8 pounds); see USDA, Sugar and Sweeteners Yearbook: Table 52—High fructose corn syrup: estimated number of per capita calories consumed daily, by calendar year, <http://www.ers.usda.gov/Briefing/Sugar/data.htm> (Per capita consumption is 37.9 pounds).

65. There are four calories in every gram of sugar.

66. John Casey, The Hidden Ingredient that can Sabotage Your Diet, <http://www.medicinenet.com/script/main/art.asp?articlekey=56589> (last visited April 11, 2010); Rachel K. Johnson et al., *Dietary Sugars Intake and Cardiovascular Health: A Scientific Statement from the American Heart Association* 120 CIRCULATION: J. AM. HEART ASS'N. 1011, 1011 (2009) (noting that "[s]oft drinks and other sugar-sweetened beverages are the primary source of added sugars in Americans' diets").

67. James E. Tillotson, *Food Brands: Friend or Foe?* NUTRITION TODAY, Mar.-Apr. 2002, at 78-79.

68. Casey, *supra* note 66.

The rest tends to come from “hidden” sugar. Over the years, manufacturers have become ever more creative, managing to hide sugar in even seemingly healthy foods. Ketchup appears innocuous enough, right?⁶⁹ After all, it’s made from tomatoes, one of the best antioxidants.⁶⁹ Well, ketchup producers have managed to squeeze a full teaspoon of sugar into every tablespoon of ketchup.⁷⁰ Think about that. One-third of the ketchup bottle is sugar.

Peanut butter is another food that seems healthy. After all, it is filled with “good” mono- and polyunsaturated fats.⁷¹ Unfortunately, many brands have also been loaded with sugar.⁷²

Ironically, low-fat foods that are marketed to health conscious consumers are another favorite hiding place for sugar. When manufacturers take out the fat, the product loses its great taste. To compensate, producers add additional sugar. Although low-fat snack foods tend to have fifty-nine percent less fat per serving than their regular counterparts, the low-fat foods contain only fifteen percent fewer calories.⁷³

At first glance, a fifteen percent reduction may still seem like a positive step. However, people tend to eat larger quantities of low-fat foods, more than offsetting any potential caloric savings.

In one study, researchers gave half the subjects a bowl of “low-fat” granola. The remaining subjects were given a bowl of regular granola. Although the granola in both bowls were identical, the subjects who believed the granola were low-fat ate forty-eight percent more.⁷⁴ The researchers concluded as follows:

If participants in [the study] had eaten real low fat granola, and if the low fat granola had the average level of fat and calories for the category, participants would have consumed 35% less fat from the low fat granola

69. See Jeanie Lerche Davis, *The Tasty Tomato: An Antioxidant Power Blast*, <http://www.webmd.com/food-recipes/features/tasty-tomato-antioxidant-power-blast> (last visited April 11, 2010) (“Tomatoes are loaded with health-protective antioxidants such as lycopene, vitamin C, and vitamin A.”).

70. See, Gayle A. Alleman, *USDA Nutrition Guidelines*, <http://recipes.howstuffworks.com/usda-nutrition-guidelines-ga9.htm> (last visited April 11, 2010).

71. See Walter C. Willett, *Ask the Doctor: Why is Peanut Butter “Healthy” if it has Saturated Fat?*, HARV. HEART LETTER July 2009, available at http://www.health.harvard.edu/newsletters/Harvard_Heart_Letter/2009/July/Ask-the-doctor-Why-is-peanut-butter-healthy-if-it-has-saturated-fat.

72. See The Daily Plate, *Peanut Butter*, <http://www.thedailyplate.com/nutrition-calories/food/jif/peanut-butter> (last visited April 11, 2010) (noting that there are three grams of sugar in every serving of Jif Peanut Butter).

73. Brian Wansink & Pierre Chandon, *Can Low Fat Nutrition Labels Lead to Obesity*, 43 J. MARKETING RES. 605, 609 (2006).

74. *Id.* at 611.

but would have consumed 33% more total calories. This is a conservative estimate . . . [T]he calorie increase would have probably been even higher because the ingredients used to replace fat tend to make people hungrier.⁷⁵

So, we have a situation where people think they are eating fewer calories but are actually consuming thirty-three percent more. If nothing else, one has to marvel at the brilliant marketing. The food industry has managed to increase revenue by producing “health” foods that are more unhealthy than their normal counterparts.

Although not surprising, it is disconcerting that corporations choose to exploit consumer misbeliefs instead of working to correct them. This action does raise an important question. If companies are willing to take advantage of existing consumer ignorance, are they also willing to actively create misperceptions in order to boost profits? As the rest of this article will show, the answer is a resounding yes. From tobacco to trans-fat to artificial sweeteners, the food industry has been waging a war against science. Through backroom political bargains, corporate America and the U.S. government are trading your long-term health for short-term profits.

Returning to our earlier equation,⁷⁶ we find that the average American could lose nearly ten pounds a year just by cutting his sugar consumption by a modest twenty-five percent. Keep in mind that, even with this reduction, Americans would still far exceed the USDA maximum daily allowance.

Such a weight loss would go far in alleviating many of the problems discussed in the previous section. Even if Americans compensate by eating additional calories from other foods, it would still be a beneficial dietary change.

This is true because sugar is full of “empty” calories,⁷⁷ meaning that it lacks vitamins, minerals, and fiber. These are the nutrients that our bodies need to function properly. Due, in large part, to excessive sugar consumption, most Americans are not getting sufficient quantities of many essential nutrients.⁷⁸ Sugar has the effect of

75. *Id.* at 614.

76. Calories divided by 3,500 equals change in weight. See Part I.A for a detailed explanation.

77. Roger W. Miller, *Empty Calories; Putting on Pounds with Poor Nutrition*, FDA CONSUMER, Nov. 1986, available at http://findarticles.com/p/articles/mi_m1370/is_v20/ai_4531709.

78. See e.g., Adit A. Ginde et al., *Demographic Differences and Trends of Vitamin D Insufficiency in the US Population, 1988-2004*, 169 ARCHIVES INTERNAL MED. 626, 631-

crowding out more nutritious foods. As an example, consider the following: "Over the last 16 years, the percent of adults aged 40–74 ... [who eat] 5 or more fruits and vegetables a day has decreased from 42% to 26%."⁷⁹ During the same time, sugar consumption has increased significantly.

Given all the harmful effects of sugar and its close association with obesity, it is not surprising that health-conscious Americans are looking elsewhere to satisfy their sweet cravings.

II. ARTIFICIAL SWEETENERS AND STEVIA

Non-caloric and hundreds of times sweeter than sugar, artificial sweeteners seemed like a godsend, both for America's sweet tooth and its waistline. Unfortunately, these products did not live up to their promises.

First, artificial sweeteners lack the magical weight loss properties many people associate with them. In fact, they may actually cause weight gain.⁸⁰ It turns out our bodies have a natural ability to count calories based on the sweetness of foods. Artificial sweeteners disrupt that mechanism by tricking our brains into thinking sweet foods have fewer calories. In turn, people overindulge when they eat sweet products, further aggravating the obesity epidemic discussed in the prior sections.

Setting this indirect problem aside, artificial sweeteners are harmful in their own right. Ironically, in a quest to eat healthier foods, the public has embraced even less healthy alternatives. There are currently five FDA-approved artificial sweeteners: saccharin, aspartame, acesulfame potassium, sucralose, and neotame. This paper will focus on the most popular ones: saccharin, aspartame, and sucralose. The first three sections will document the suspicious circumstances surrounding each additive's approval and examine what independent studies actually concluded about these sweeteners. The fourth section will contrast these products with stevia, a safe, natural, non-caloric sweetener. Stevia's lengthy approval history will show that corporations manipulate the FDA to increase their own profits. In the end, regardless of one's thoughts on the merits of

32 (finding that only one in four Americans gets an adequate amount of Vitamin D).

79. King, *supra* note 34, at 530.

80. See T.L. Davidson & S.E. Swithers, *A Pavlovian Approach to the Problem of Obesity*, 28 INT'L J. OBESITY & RELATED METABOLIC DISORDERS 933, 934–35 (2004).

these sweeteners, the FDA approval process will be cause for concern.

A. *Saccharin*

In 1879, two researchers at Johns Hopkins University discovered saccharin, the world's first artificial sweetener.⁸¹ Although the scientists realized saccharin's commercial potential early on, the product was not marketed in the United States until 1901. Due to the chemical's intense sweetness,⁸² it soon became popular. The sweetener also stirred up controversy.

In 1907, the USDA launched an investigation to determine whether saccharin was safe. Fearing that the USDA would ban the sweetener, future vice president James Sherman met with President Theodore Roosevelt on behalf of a New York food manufacturing firm. Sherman told the President how the sweetener had saved his company thousands of dollars in production costs. Harvey Wiley, the first commissioner of the FDA,⁸³ also happened to be at this meeting. He was extremely concerned about the dangers of saccharin consumption and warned President Roosevelt that "[e]veryone who ate that sweet corn was deceived. He thought he was eating sugar, when in point of fact he was eating a coal tar product totally devoid of food value and extremely injurious to health."⁸⁴ Roosevelt angrily responded, "Anybody who says saccharin is injurious to health is an idiot."⁸⁵

Nevertheless, to placate Wiley, the President appointed a Referee Board of Consulting Scientific Experts to reexamine saccharin's safety. Since the head of the Board was Ira Remsen, one of the Johns Hopkins researchers who discovered the sweetener, the outcome was predetermined.⁸⁶ From the beginning, big business had managed to intervene and prevent the government from seriously reviewing saccharin's health risks.

81. Victoria Gilman, *Artificial Sweeteners*, 82 SCI. & TECH. 43, 43. (2004).

82. Depending on how saccharin is used, it is between 200 and 700 times sweeter than sugar. See SUGAR ASS'N, ARTIFICIAL SWEETENERS, http://www.sugar.org/consumers/sweet_by_nature.asp?id=283 (last visited April 2, 2010).

83. At the time, the agency was known as the Bureau of Chemistry.

84. Suzanne White Junod, *Sugar: A Cautionary Tale*, available at <http://www.fda.gov/AboutFDA/WhatWeDo/History/ProductRegulation/SelectionsFromFDLIUpdateSeriesonFDAHistory/ucm091680.htm>.

85. *Id.*

86. *Id.*

A few years later, World War I sugar shortages created additional demand for saccharin, and with the health concerns forgotten, the artificial sweetener market expanded for half a century. Then, in 1972, the safety controversy was reignited.

That year, saccharin came directly under attack when two studies linked consumption of the sweetener with cancer in lab animals.⁸⁷ Although the Delaney Clause now required the FDA to ban saccharin, commissioner Charles Edwards refused to act. In 1977, yet another study linked saccharin to bladder tumors in rats,⁸⁸ and within a few years, the carcinogenicity of saccharin was reaffirmed by additional trials.⁸⁹

Within months, Canada instituted a ban on saccharin that is still in effect today.⁹⁰ The FDA, now under the leadership of a new commissioner, also proposed a ban. However, fearing large financial losses,⁹¹ the U.S. sweetener industry immediately mounted a campaign to save saccharin.⁹² Industry pressure prevailed, and Congress passed the Saccharin Study and Labeling Act which forbade the FDA from banning the sweetener for 18 months.⁹³ This short-term prohibition has since been extended numerous times,⁹⁴ preventing the FDA from regulating saccharin up until the present day.

Although Congress ultimately preempted any saccharin ban, one must wonder why the FDA failed to act sooner. It was not until

87. PETER BARTON HUTT & RICHARD A. MERRILL, *FOOD & DRUG LAW: CASES AND MATERIALS*, 923 (2d ed. 1991).

88. 42 FED. REG. 19996, 19999 (proposed April 15, 1977)

89. See R.A. Squire, *Histopathological Evaluation of Rat Urinary Bladders from the IRDC Two-Generation Bioassay of Sodium Saccharin*, 23 *FOOD & CHEM. TOXIC.* 491, 493-496 (1985); J.M. Taylor et al, *Chronic Toxicity and Carcinogenicity to the Urinary Bladder of Sodium Saccharin in the In Utero-Exposed Rat*, 54 *TOXIC. & APPLIED PHARMA.* 57, 74 (1980) (reaffirming that saccharin causes an increase in bladder neoplasia and hyperplasia in rats).

90. See Robert Trumbull, *Canada's Saccharin Ban Leaves a Bitter Taste*, *N.Y. TIMES*, May 14, 1978, at F3.

91. See *id.* (In Canada, "[f]inancial losses to food and beverage concerns have been heavy. The head of one major Canadian concern involved in the saccharin trade said his company had lost two-thirds of its sales. The production chief of another hard-hit company called the costs converting to different food lines crippling.").

92. See *The Great Saccharin Snafu*, *CONSUMER REPORTS*, July 1977, at 410, 410-14.

93. Pub. L. No. 95-203, § 1, 3; 91 Stat. 1451, 1452 (1977).

94. See Pub. L. No. 96-88, § 509(b), 93 Stat. 695 (1979); Pub. L. No. 96-273, 94 Stat. 536 (1980); Pub. L. No. 97-42, § 2, 95 Stat. 946 (1981); Pub. L. No. 98-22, § 2, 97 Stat. 173 (1983); Pub. L. No. 99-46, 99 Stat. 81 (1985); Pub. L. No. 100-71, § 101, 101 Stat. 431 (1987); Pub. L. No. 102-142, 105 Stat. 910 (1991); Pub. L. No. 104-180, § 602, 110 Stat. 1594 (1996).

five years after studies began showing saccharin's carcinogenic properties that the FDA seriously contemplated doing something. When discussing his failure to regulate the sweetener, Commissioner Charles Edwards explained, "American consumers demand the availability of diet food products. It is irrelevant whether these diet products produce quantifiable health benefits or whether consumers simply like them . . . [Saccharin] has come to be accepted and expected by the American public, and any law which does not recognize this simply will not work."⁹⁵

At its most basic level, this is appealing. Let the American people determine what additives they want to consume. However, Edwards's position breaks down for several reasons. First, by claiming that he deferred to majority rule, Edwards actually undermined majority rule. Because it is impossible for Americans to evaluate the safety of every potential product, they have assigned this task to the FDA. The public essentially views the FDA as "the mechanism through which the government attempts to compel corporations to act responsibly, and to not damage our health"⁹⁶ By allowing saccharin to remain on the market, the FDA is implicitly stating that the sweetener is not a health risk. This seal of approval allows consumers to discount research that provides evidence of saccharin's dangers. Regardless of the FDA's true motives for not banning the sweetener, the fact that it is on the market is a powerful signal of safety.

Second, and more importantly, if the FDA actually wants to respect consumer preferences, it is doing a terrible job. The agency consistently bans safe, natural substances only to turn around and legalize prescription drugs that are nothing more than patented knock-offs.

One of the most egregious examples involves lovastatin and red yeast rice. When the pharmaceutical industry isolated lovastatin, a cholesterol lowering drug, the market potential seemed enormous. There was just one problem. Red yeast rice, a product that had been in the food supply for more than two thousand years,⁹⁷ contained monacolin K, a naturally occurring compound identical to

95. Oversight of Food Safety, 1983: Hearings Before the Senate *Comm. on Labor and Human Resources*, 98th Cong., 1st Sess. 21 (1983) (statement of Charles Edwards).

96. See MICHAELS, *supra* note 12, at 232.

97. Özlem Erdoğrul & Sebile Azirak, *Review of the Studies on the Red Yeast Rice*, 2 TURKISH ELECTRONIC J. BIOTECH. 37, 38 (2004).

lovastatin.⁹⁸ Because red yeast rice could not be patented, supplements derived from it would severely hamper sales of lovastatin.

Big Pharma brought this problem to the FDA, and the agency set about finding a solution. The FDA ultimately determined that because red yeast rice contains a substance identical to a drug, it can be regulated as a drug. Essentially, the FDA allowed pharmaceutical companies to patent a substance in red yeast rice. The agency then turned around and banned red yeast rice for containing that patented compound. It is simply incredible that the FDA can redefine a natural substance as a drug and then subsequently ban any natural products that contain the "drug." This would be no different if a pharmaceutical company had patented vitamin C, and the FDA had then banned oranges because they naturally contain vitamin C.

The FDA has proven time and again that it is willing to ban safe products if it will increase the profits of pharmaceutical companies. Some additional examples include L-tryptophan,⁹⁹ pyridoxamine (vitamin B6),¹⁰⁰ ephedra,¹⁰¹ estriol,¹⁰² and even information regarding the health benefits of cherries.¹⁰³ One second the FDA proclaims

98. Mayo Clinic, Red Yeast Rice (*Monascus Purpureus*), http://www.mayoclinic.com/health/red-yeast-rice/NS_patient-redyeast (last visited Apr. 9, 2010).

99. The FDA banned L-tryptophan but allowed the substance to be used in prescription drugs. This caused the effective price of tryptophan to increase by 500%. The ban was eventually lifted after more than a decade of vocal opposition from consumers and organizations such as the Mayo Clinic. See Dean Wolfe Manders, *The FDA Ban of L-Tryptophan: Politics, Profits and Prozac*, 26 SOC. POL'Y. 55, 55-58 (1995).

100. See American Association for Health Freedom, When is a Vitamin Not a Vitamin? When the FDA Says So!, http://aahf.nonprofitsoapbox.com/index.php?option=com_content&task=view&id=677&Itemid (last visited Feb. 26, 2010).

101. See Mike Adams, *FDA Declares Form of Vitamin B6 a Drug, Effectively Banning Pyridoxamine from Dietary Supplements*, <http://www.naturalnews.com/025606.html> (last visited Feb. 26, 2010) ("The same thing happened with ephedra, a Traditional Chinese Medicine herb known as *ma huang*. The FDA banned the herb, saying it was 'dangerous at any dose,' but pharmaceuticals containing the very same molecules (ephedrine) are still being sold over-the-counter as cold medicines, meaning they're available to any child without a prescription.").

102. See American Association for Health Freedom, *Natural Substance Knock Offs in the FDA Pipeline Could be Dangerous*, Sep. 6, 2008, http://foodconsumer.org/7777/8888/C_onsumer_A_ffair_26/090606512008_Natural_Substance_Knock_Offs_in_the_FDA_Pipeline_Could_be_Dangerous.shtml.

103. See American Association for Health Freedom, *Big Pharma and the FDA: Suppress the Science, Ban the Natural Substances, Sell the Drugs*, http://www.organicconsumers.org/articles/article_18219.cfm (last visited Feb. 26, 2010) ("When the 2005 ban was instituted, the FDA sent warning letters to twenty-nine companies that

that a natural substance is dangerous, despite independent scientific consensus to the contrary. The very next moment, it determines that a prescription drug derived from that same substance is perfectly safe.¹⁰⁴ The Article will further explore the FDA's double standard with respect to the natural sweetener stevia in Part II.D.

The agency's past actions have led to a worrisome process: base approval decisions on consumer preferences when doing so enriches big business, and base approval decisions on food safety when doing so enriches big business. This shadowy practice does make one thing very clear. The FDA is broken.¹⁰⁵ The following sections will make it even more apparent that the agency must be reformed.

B. Aspartame

Consumed by over two hundred million people and used in more than six thousand products, aspartame is the king of artificial sweeteners.¹⁰⁶ In the U.S., it is marketed under the brand names NutraSweet and Equal. Aspartame is found in everything from diet sodas and sugar-free desserts to children's vitamins¹⁰⁷ and vegetable juice.¹⁰⁸ At one point, it accounted for sixty-two percent of the world artificial sweetener market.¹⁰⁹ Americans alone ingest more than 8,000 tons of aspartame each year.¹¹⁰ That statistic is even more in-

market cherry products. In these letters, they ordered the companies to stop publicizing scientific data about cherries. According to the FDA, when cherry companies disseminate this peer-reviewed scientific information, the cherries become 'unapproved new drugs' and are subject to seizure. The FDA warned that if those involved in 'cherry trafficking' continue to inform consumers about these scientific studies, criminal prosecutions would ensue.”).

104. See Adams, *supra* note 101 (noting that “another classic oppression tactic of the FDA [is to] [b]an the herb, but promote the drug using the same chemicals”).

105. See, e.g., American Association for Health Freedom, *supra* note 102 (arguing that, if you pay off the FDA, “the Agency will try to reward you with monopoly control of the market”).

106. Aspartame Information Center, Products, http://www.aspartame.org/aspartame_products.html (last visited Apr. 9, 2010).

107. See, e.g., Bayer, Flintstones FAQs, <http://flintstonesvitamins.com/faqs> (last visited Apr. 9, 2010) (stating that “the Flintstones Complete formula and Plus Calcium formula contain aspartame”).

108. For a partial list of products containing aspartame, see Aspartame Information Center, *supra* note 106.

109. James Fry, *The World Market for Intense Sweeteners*, 85 WORLD REV. NUTRITION & DIETETICS 201, 204 (1999).

110. United States National Library of Medicine, Hazardous Substances Data Bank: Aspartame, <http://toxnet.nlm.nih.gov/cgi-bin/sis/htmlgen?HSDB> (search for “aspartame”) (last visited Apr. 9, 2010).

credible when one considers that aspartame is 200 times sweeter than table sugar.¹¹¹ This sweetener has become so pervasive that it is almost impossible to find certain consumer products without it.¹¹²

In addition to being the most prominent artificial sweetener in the world, aspartame also has the distinction of receiving more complaints than any other substance in FDA history.¹¹³ By 1992, Americans had filed more than ten thousand aspartame-related complaints, and approximately eighty percent of all non-drug complaints to the FDA involved the sweetener.¹¹⁴ People complained that aspartame caused, among other side effects, headaches, rashes, dizziness, menstrual problems, and seizures.¹¹⁵ Unfortunately, because the FDA stopped tracking aspartame complaints in 1992, the current number of aspartame-related problems is unavailable.¹¹⁶ Nevertheless, the danger is still present. The following sections will examine the evidence regarding aspartame's safety and the unsettling circumstances surrounding its approval.

1. The Evidence

In the course of writing *Aspartame Disease: An Ignored Epidemic*, the author clinically observed 1200 patients who had suffered aspartame reactions. He found that common side effects include vision problems, tinnitus, headaches, memory loss, depression, heart palpitations, diarrhea, itching, and severe joint pain.¹¹⁷ Additional studies have reinforced these observations, strengthening the link between aspartame and depression,¹¹⁸ headaches,¹¹⁹ and seizures.¹²⁰ Other case

111. Sugar Association, *supra* note 82.

112. Nearly every brand of chewing gum has aspartame. Even gum that contains sugar is now supplemented with the artificial sweetener. See e.g., Wrigley, Doublemint, <http://www.wrigley.com/global/brands/doublemint.aspx> (last visited Apr. 9, 2010) (indicating that regular Doublemint gum now includes sugar, aspartame, and acesulfame K).

113. Aspartame earned this honor in just three short years. See Janet Starr Hull, *How Many Aspartame Complaints are Registered with the FDA?*, Oct. 7, 2005, <http://www.janethull.com/askdrhull/article.php?id=044>.

114. *Id.*

115. 131 CONG. REC. 9981, 10807 (1985).

116. See Janet Starr Hull, *Is it True that the Majority of FDA Complaints are for Aspartame?*, Oct. 7, 2005, <http://www.janethull.com/askdrhull/article.php?id=043> (The FDA "began putting the complaints into generic categories not related to aspartame, such as death. If death by seizure was reported as a reaction to aspartame, the death was recorded as seizure only and not as an 'aspartame' seizure.").

117. See ROBERTS, *supra* note 1, at 68–71.

118. See Ralph G. Walton et al., *Adverse Reactions to Aspartame: Double-blind Challenge in Patients from a Vulnerable Population*, 34 BIOLOGICAL PSYCHIATRY 13, 13

studies have also connected aspartame to “angry outbursts”,¹²¹ skin lesions,¹²² and panic attacks.¹²³ Aspartame has even been linked to cancer.¹²⁴ The FDA complaints present a similarly stark picture.¹²⁵

Given all of these dangerous side effects, how could the FDA have ever approved this artificial sweetener? Well, it turns out that there is also evidence supporting aspartame’s safety. Funding for the trials providing this “evidence,” however, came from the NutraSweet industry. A survey of aspartame research found that “[o]f the 166 studies felt to have relevance for questions of human safety, 74 had NutraSweet industry related funding and 92 were independently funded. One hundred percent of the industry funded research attested to aspartame’s safety, whereas 92 percent of the independently funded research identified a problem.”¹²⁶

These numbers actually understate the unanimity of independent scientific opinion. Of the seven non-industry funded studies that were favorable to aspartame, one was a literature review that focused on industry research, and six were conducted by the FDA.¹²⁷ Due to the FDA’s pro-business bias and controversial ties to G.D.

(1993) (concluding “that individuals with mood disorders are particularly sensitive to this artificial sweetener and its use in this population should be discouraged”).

119. See e.g., Stephen K. Van Den Eeden et al., *Aspartame Ingestion and Headaches: A Randomized Crossover Trial*, 44 NEUROLOGY 1787, 1787 (1994) (“Subjects reported headaches on 33% of the days during aspartame treatment . . .” The paper concluded “that some people are particularly susceptible to headaches caused by aspartame and may want to limit their consumption.”); see e.g., Rebecca B. Lipton et al., *Aspartame as a Dietary Trigger of Headache*, 29 HEADACHE 90, 90 (“[A]spartame may be an important dietary trigger of headache in some people.”).

120. See T.J. Maher & R.J. Wurtman, *Possible Neurologic Effects of Aspartame, a Widely Used Food Additive*, 75 ENVTL. HEALTH PERSP. 53, 56 (1987).

121. See 131 CONG. REC. 10,805–6 (1985).

122. See Nelson Lee Novick, *Aspartame-Induced Granulomatous Panniculitis*, 102 ANNALS INTERNAL MED. 206, 206–7 (1985).

123. See J.M. Ferguson, *Panic Attacks and Excessive Aspartame Ingestion*, 328 LANCET 631, 631 (1986).

124. See John Olney et al., *Increasing Brain Tumor Rates: Is There a Link to Aspartame?*, 55 J. NEUROPATHOLOGY & EXPERIMENTAL NEUROLOGY 1115, 1115–23 (1996) (concluding that “there is need for reassessing the carcinogenic potential of aspartame”); see generally Morando Soffritti et al., *First Experimental Demonstration of the Multipotential Carcinogenic Effects of Aspartame Administered in the Feed to Sprague-Dawley Rats*, 114 ENVTL. HEALTH PERSP. 379, 379–85 (2006).

125. See ROBERTS, *supra* note 1, at 72.

126. Ralph G. Walton, *Survey of Aspartame Studies: Correlation of Outcome and Funding Sources* (1998) (unpublished manuscript, available at <http://www.dorway.com/peerrev.html>).

127. *Id.*

Searle, the maker of aspartame, the independence of these six studies is questionable.¹²⁸

Moreover, thirty-three of the industry funded studies were, with minor changes, published in different journals from two to six times each.¹²⁹ Repeatedly publishing the same study in multiple journals is a deceptive and unethical practice commonly employed by pharmaceutical companies.¹³⁰ It seems that Searle was more interested in swamping the media with pro-aspartame studies than in actually ascertaining the safety of a product that could harm millions of people.¹³¹

Aspartame producers routinely state that the sweetener is the most tested food additive ever approved by the FDA. However, this wonderful marketing line hides the fact that a single valid study is more useful than any number of flawed studies. Because Searle could not boast of the quality of its studies, the company relied on sheer quantity. The experiments were so poorly run that Alexander Schmidt, the FDA commissioner at the time Searle submitted its research, called the studies “incredibly sloppy science,” adding that “[w]hat was discovered was reprehensible.”¹³²

Two of the most extensive trials on aspartame were run by a group of Italian researchers.¹³³ Unlike the Searle safety tests, their studies were both independently funded and published in peer-reviewed journals, the gold standard in science. The scientists were motivated to perform their first “mega-experiment” because Searle’s studies “did not comply with today’s basic requirements for testing the carcinogenic potential of a physical or chemical agent.”¹³⁴ In particular, the scientists noted that Searle’s experiments were termi-

128. See *infra* Part II.B.2.

129. Walton, *supra* note 126 (indicating that “[v]irtually all journals require that an affidavit be signed by all authors to the effect that neither the manuscript nor the data it contains have been previously published or concurrently submitted elsewhere for publication. Violation of this policy may have a detrimental impact on scientific progress and ethics.”).

130. See MICHAELS, *supra* note 12, at 149.

131. Many industries have employed a similar strategy. See *supra* notes 13–16 and accompanying text.

132. 131 CONG. REC. 10,808 (1985).

133. See Soffritti *supra* note 124; Morando Soffritti et al., *Life-Span Exposure to Low Doses of Aspartame Beginning during Prenatal Life Increases Cancer Effects in Rats*, 115 ENVTL. HEALTH PERSP. 1293, 1293 (2007).

134. Soffritti, *supra* note 124 at 380.

nated prematurely and failed to include a large enough population sample.¹³⁵

A major purpose of this study was to determine a safe acceptable daily intake (ADI) for aspartame. On the basis of Searle's trials, the FDA set the ADI at 50 mg/kg of bodyweight.¹³⁶ In more concrete terms, a 150-pound adult would need to drink twenty cans of diet soda to reach this limit.¹³⁷ The makers of aspartame went even further, claiming that not even this high amount would be dangerous because the ADI has a "built-in safety factor."¹³⁸

Since most people do not consume that much aspartame, Soffritti and his group of researchers sought to determine if aspartame is a carcinogen when ingested in smaller quantities. Their study showed that aspartame's "carcinogenic effects are evident even at a daily dose of 20 mg/kg of bodyweight."¹³⁹

This is the equivalent of eight cans of diet soda, a limit many Americans exceed.¹⁴⁰ Because aspartame is found in over 6,000 products, it is easy to see how a person can quickly surpass this level. Nonetheless, aspartame proponents are likely to claim that this is a relatively high limit, so it is still safe to ingest a lesser amount of aspartame on a daily basis.

However, just because most people drink less does not mean they are safe from the harmful effects. Recall that the FDA set the ADI at fifty mg/kg of bodyweight. Soffritti's team of researchers showed that aspartame is carcinogenic at a mere forty percent of the FDA's supposedly safe level. Future research at lower quantities is necessary, but the outcome for aspartame looks bleak.

To see why, it is perhaps easiest to draw an analogue to smoking. Adhering to the previous ratios, the FDA has, in effect, claimed that smoking five packs of cigarettes a day is safe. Soffritti's study showed that not even two packs a day would be safe. Although we

135. *Id.* FDA statistician Robert J. Condon expressed similar concerns, finding problems in the conduct and power of the studies. 131 CONG. REC. 10,807 (1985). Satya D. Dubey, a statistician at the FDA's Center for Drugs and Biologics also noted "certain statistical difficulties" with Searle's studies. *Id.*

136. The NutraSweet Company, How much aspartame do people actually consume?, <http://www.nutrasweet.com/articles/article.asp?Id=46> (last visited Apr. 2, 2010).

137. *Id.*

138. *Id.*

139. Soffritti *supra* note 124, at 384.

140. *Good Morning America* (ABC television broadcast May 19, 2007), available at <http://abcnews.go.com/GMA/weekend/story?Id=3191903&page=1>.

would certainly want to explore whether smoking fewer cigarettes would cause cancer, even pack-a-day smokers should be worried.

The equivalent holds true for aspartame. The FDA has set a high ADI of twenty cans of diet soda for the average adult. Scientists undercut this number by showing that consuming a more plausible eight cans of diet soda increases the likelihood of cancer. At this point, even people who only drink a few cans of diet soda a week may want to consider whether it is worth the health risk.

The same group of researchers conducted an additional experiment that confirmed the first study and further determined that, when pregnant rats eat aspartame, there is an increased incidence of cancer among their offspring.¹⁴¹

Unhappy with these results, the aspartame industry went on the offensive by funding a literature review that attacked the Soffritti studies.¹⁴² This particular piece was sponsored by Ajinomoto, a Japanese supplier of aspartame. Therefore, it is not surprising that the authors of the review accepted industry-research as gospel and discounted any independently-funded research that showed evidence of aspartame's dangers. Interestingly, after this review concluded that the sweetener's "safety is clearly documented," Ajinomoto rebranded aspartame as AminoSweet. The company did this to hide aspartame's history of causing health problems and to trick the public into thinking it is a natural product.¹⁴³

Given all of this evidence, one cannot help but wonder how aspartame has remained on the market for nearly thirty years. The FDA's close relationship with G.D. Searle will resolve this mystery. Unfortunately, the FDA—the very agency established to protect Americans from unsafe food and drugs—placed corporate earnings above our health.

2. FDA Approval

G.D. Searle, the creator of aspartame, has an extensive history of manipulating reports to hide the dangers of its drugs. Between

141. See Life-Span Exposure, *supra* note 133, at 1297 (demonstrating that "when life-span exposure to APM [aspartame] begins during fetal life, its carcinogenic effects are increased").

142. B.A. Magnuson et al., *Aspartame: A Safety Evaluation Based on Current Use Levels, Regulations, and Toxicological and Epidemiological Studies*, 37 CRITICAL REV. TOXICOLOGY 629, 669 (2007).

143. See Ethan Huff, *Aspartame Has Been Renamed and is Now Being Marketed as a Natural Sweetener*, http://www.naturalnews.com/028151_aspartame_sweeteners.html (last visited Apr. 2, 2010).

1975 and 1977 alone, the FDA investigated Searle for fraud involving the safety testing of Aldactone, Flagyl, Norpace, and aspartame.¹⁴⁴ The FDA reported its findings to the Subcommittee on Health of the Senate Judiciary Committee, and what they found was startling. In some of the Aldactone studies, gross lesions requiring histopathological examinations were never examined, malignant tumors were removed and never reported, and a full thirty percent of the animal tissues earmarked for examination were never examined.¹⁴⁵ FDA commissioner Alexander Schmidt noted one study was so bad that even “after three separate reviews by Searle personnel of the same data . . . we are continuing to discover errors that complicate review of this study.”¹⁴⁶

Searle used even more dubious practices while preparing reports for its other drugs. In the clinical trials for Flagyl, Searle often had two pathologists examine the animals. When the pathologists’ opinions differed, Searle used the reports that cast Flagyl in the more favorable light,¹⁴⁷ and any data that questioned Flagyl’s safety was conveniently withheld from the FDA. Searle went even further in its quest to approve aspartame. When pathologists submitted unfavorable reports, Searle simply changed the findings.¹⁴⁸

In a study of the drug Norpace, the FDA found “inadequate ante-mortem observations: e.g. animals reported in good condition were actually dead”¹⁴⁹ Searle’s data are so contradictory that individual rats die and come back to life as many as four times. When manipulating data wasn’t enough, Searle forced its scientists to lie. Despite voicing his objections, John W. Sargatz, Searle’s principal pathologist, was ordered to write “reassuring comments on post-mortems of rats”

This pattern of serious errors led the FDA to question the validity of all of Searle’s studies. The agency noted that “the *cumulative* findings of problems within and across the studies we investigated

144. JOHN BRAITHWAITE, *CORPORATE CRIME IN THE PHARMACEUTICAL INDUSTRY* 75–78 (1984).

145. *Id.* at 76.

146. *Id.*

147. *Id.* In a 1976 report to the Subcommittee on Health of the Senate Judiciary Committee, FDA Commissioner Alexander Schmidt criticized Searle for this practice.

148. *Id.* at 77 (Commissioner Schmidt noted that FDA “investigators found that a pathologist’s summary was edited in such a manner as to alter, generally in a favorable direction, some of the pathologist’s findings.”).

149. *Id.* (internal quotations omitted).

reveal a pattern of conduct which compromises the scientific integrity of the studies.”¹⁵⁰

Due to Searle’s actions regarding Aldactone, Flagyl and Norpace, the FDA General-Counsel’s office wanted the government to launch a criminal investigation. However, the Justice Department decided that a criminal prosecution would be useless because senior executives would pass the blame to a handful of junior managers.

Searle handled the aspartame approval process in a similarly deceptive manner. In 1980, the FDA had two separate panels evaluate aspartame. Both panels recommended not approving the sweetener due to concerns about brain tumors.¹⁵¹ The FDA task forces determined that the Searle experiments were seriously flawed.¹⁵² Raw data were missing, and the information that was available contained numerous errors and discrepancies. The Searle’s researchers had disposed of dead rats without checking to see if aspartame killed them and had operated on others to remove evidence of tumors.¹⁵³ The scientists even secretly administered antibiotics.¹⁵⁴ Searle’s scientists also failed to properly mix aspartame with the lab animals’ food. This allowed the rats to eat around the chemical. It’s pretty hard to find aspartame-related side effects when the rats aren’t even ingesting the aspartame.

The tactics uncovered in the FDA reports show that Searle misrepresented the carcinogenic effects of aspartame and hid incriminating data from the agency.¹⁵⁵ Adrian Gross, a lead researcher on the FDA task force, noted the following: “At the heart of FDA’s regulatory process is its ability to rely upon the basic safety data submitted by sponsors of regulated products. Our investigation clearly demonstrates that, in the G. D. Searle Co., we have no basis for such reliance now.”¹⁵⁶ Gross went on to state that, ironically,

150. *Id.* (internal quotations omitted).

151. *See 60 Minutes* (CBS television broadcast Dec. 29, 1996), available at <http://video.google.com/videoplay?docid=5805190307148690830#>.

152. *See* FDA, The “Bressler Report”, available at <http://www.dorway.com/bressler.txt>.

153. *See 60 Minutes*, *supra* note 151.

154. *Id.*

155. *Id.* (The FDA investigation revealed “a pattern of conduct which compromises the scientific integrity of the studies.” Former Senator Howard Metzenbaum, an active opponent of aspartame, said that “according to the FDA themselves, Searle, in making their presentation to the FDA, had willfully misrepresented the facts and had withheld some of the facts that they knew would possibly jeopardize the approval of the product.”).

156. Morton Mintz, *Metzenbaum: NutraSweet Inquiry Needed*, WASH. POST, Feb. 7, 1986, at B9.

Searle's own studies "established beyond a reasonable doubt that aspartame is capable of inducing brain tumors in experimental animals."¹⁵⁷

FDA officials were so upset by Searle's deception that they sent the file to the U.S. Attorney's office and urged them to present the information to a grand jury. Unfortunately, it was never presented. Samuel Skinner, the head of the grand jury probe, withdrew from the case to accept a position at Searle's Chicago law firm Sidley & Austin. During this delay, the statute of limitations ran out.¹⁵⁸

Skinner was not the only government official tainted by Searle. After leaving the FDA, former Acting Commissioner Michael Friedman was hired as vice president of G.D. Searle. Unsurprisingly, Friedman defended aspartame by arguing that despite the numerous problems, "the scientists looking at that information decided that the basic strength of the conclusions remains intact."¹⁵⁹ Apparently, Friedman failed to read any of the FDA task force's reports that directly contradict this statement.

The most striking corruption, however, involves FDA Commissioner Arthur Hayes, Jr. and Donald Rumsfeld. Between 1977 and 1985, Donald Rumsfeld served as CEO, President, and eventually Chairman of Searle. On January 21, 1981, a mere day after President Reagan's inauguration, Searle resubmitted its aspartame application to the FDA. Hayes quickly appointed a five-member committee to determine whether aspartame should be approved. When it became apparent that the committee would reject the application by a vote of three to two, Hayes installed a sixth member. This tied the vote and allowed Hayes, as FDA Commissioner, to break the deadlock and approve aspartame. Shortly after this incident, Hayes left the FDA to take a job at Bursen-Marsteller, Searle's public relations firm.¹⁶⁰ Even if one fervently believes that aspartame is safe, this underhanded process by which it was approved should be unsettling.

C. Sucralose

If aspartame is the king of artificial sweeteners, sucralose is the upstart prince making a grab for the crown. Since receiving FDA approval in 1999, sucralose has become the most popular artificial sweetener in the United States and aspartame's main rival in the

157. *Id.*

158. *60 Minutes*, *supra* note 151.

159. *Id.*

160. *Id.*

global market. Sucralose is marketed by McNeil Nutritionals¹⁶¹ under the brand name Splenda. It is currently used in more than 4,000 products and is 600 times sweeter than sugar.¹⁶² Sucralose's main advantage over aspartame is that it remains stable at high temperatures.¹⁶³ This property allows the sweetener to be used in baked goods. Because sucralose can be added to a much wider variety of products, people will have more opportunities to consume it. Therefore, it is even more important to ensure that the sweetener is safe.

Sucralose's problems start with its name. The similarity to sucrose is not a coincidence. McNeil wants the public to think that sucralose is a natural product.¹⁶⁴ Even before approval, consumer advocacy groups alerted the FDA that the name sucralose would create confusion. They suggested that the product be labeled in a manner that would accurately describe its chemical structure.¹⁶⁵ The FDA rejected this idea because other artificial sweeteners had not been named according to this convention.¹⁶⁶ The FDA made the absurd argument that because people had not confused aspartame with sucrose, they would not confuse sucralose with sucrose.

McNeil won this round, but in its quest to fool the public, the company thought that similar names would not be enough. It also developed slogans that would force consumers to mentally align sugar with sucralose. One example is "Think sugar, say Splenda."¹⁶⁷ Another successful approach was to substitute "Splenda" for "sugar" in childhood fairy tales. This led to such memorable advertisements

161. McNeil Nutritionals is a subsidiary of Johnson & Johnson. LinkedIn, McNeil Nutritionals, <http://www.linkedin.com/companies/mcneil-nutritionels> (last visited Apr. 6, 2010).

162. Tate & Lyle, About SLENDA® Sucralose, http://www.tateandlyle.com/TateAndLyle/products_applications/_products/sucralose/default.htm (last visited Apr. 6, 2010).

163. *Id.* ("SLENDA® Sucralose retains its sweetness through all commonly used food and beverage manufacturing processes and also throughout the shelf life of finished products.").

164. McNeil Nutritionals' deceptive marketing has tricked forty-seven percent of Splenda users into thinking that it is a natural product. Center for Science in the Public Interest, "Splenda Should Stop Confusing Consumers, Says CSPI: Statement of CSPI Executive Director Michael F. Jacobson," Feb. 14, 2005 <http://www.cspinet.org/new/200502141.html> (last visited Apr. 6, 2010).

165. Sucralose's chemical name is trichlorogalactose.

166. FDA Final Rule on Sucralose, §102.5(a), <http://vm.cfsan.fda.gov/~lrd/fr980403.html>.

167. Pallavi Gogoi, *How Far from Sugar Is Splenda?*, Feb. 2, 2005, available at http://www.businessweek.com/technology/content/feb2005/tc2005022_7832_tc024.htm.

as “The Dance of the Splenda Plum Fairy,” “Splenda and Spice and Everything Nice,” and “Roses are Red, Violets are Blue, Splenda is Sweet and So Are You.”¹⁶⁸

Rival Merisant, the maker of aspartame-based Equal, felt that these marketing techniques had gone too far. In 2006, the company sued McNeil Nutritional for unfair profits and lost sales due to these misleading advertisements.¹⁶⁹ After it became clear that the jury would find against McNeil, the two companies settled.

A major focus of the trial was the main promotional slogan for Splenda: “Made from sugar, so it tastes like sugar.”¹⁷⁰ Apparently, the marketing team that thought up this line was unfamiliar with even the most basic principles of chemistry. Two products with similar constituent elements are often vastly different, both in terms of safety and function.¹⁷¹

By McNeil Nutritionals’ standard, we could create a similar slogan for table salt: “Made from chlorine, so it tastes like chlorine.” No doubt this seems laughable. As anyone who has swallowed pool water can confirm, fast food chains are unlikely to start putting chlorine packets next to the salt shaker. Nevertheless, McNeil Nutritionals has successfully promoted sucralose with a slogan that uses identical reasoning.

In its elemental form (Cl_2), chlorine is a powerful disinfectant and bleaching agent. However, when the chlorine atom combines with sodium (Na), we get common table salt (NaCl). One was used

168. For a discussion of McNeil Nutritionals’ distinct marketing campaign, see Elizabeth Esfahani, Finding the Sweet Spot, Nov. 1, 2005, http://money.cnn.com/magazines/business2/business2_archive/2005/11/01/8362835/index.htm (“[T]he bottom line is, Splenda is not sugar. It is a completely artificial chemical compound.”).

169. See Amy S. Clark, Equal and Splenda Settle Lawsuit, May 11, 2007 <http://www.cbsnews.com/stories/2007/05/11/business/main2793207.shtml> (last visited Apr. 6, 2010) (“Merisant was seeking more than \$200 million from McNeil — at least \$183 million for unfair profits since 2003 and compensation for at least \$25 million in lost sales.”); For additional details of the lawsuit, see Associated Press, Splenda Settles Lawsuit Over ‘Sugar’ Claim, May 11, 2007, <http://www.msnbc.msn.com/id/18618557> (last visited Apr. 6, 2010).

170. Clark, *supra* note 169.

171. As early as the 1820s, scientists had discovered this property of chemical compounds. See JOHN THEODORE MERZ, A HISTORY OF EUROPEAN THOUGHT IN THE NINETEENTH CENTURY 406 (1904) (“Wöhler in 1823, Liebig in 1824, and Faraday in 1825 found that entirely different qualities indicating a different constitution, could belong to bodies that have the same elements in the same numerical proportions.”).

as a weapon during World War I,¹⁷² and the other is a common food ingredient.

Another familiar example is carbon monoxide (CO) and carbon dioxide (CO₂). If McNeil Nutritionals were charged with making up a slogan for this gas, it might go something like the following: "Carbon Monoxide! Made with the same elements as carbon dioxide, so it's just as safe as carbon dioxide." Again, this is obviously false, but it operates under the same mistaken assumption as the sucralose slogan, namely that chemicals with similar constituent elements have similar qualities.

Sucrose (C₆H₁₂O₆) and sucralose (C₁₂H₁₉Cl₃O₈) are even less alike than the preceding examples. McNeil Nutritionals makes sucralose by chlorinating sugar. This process involves replacing three of the hydroxyl groups (OH) with chlorine atoms and results in a major change to the molecular structure. Ethanol provides a clear example of how replacing a hydroxyl group creates an entirely unrelated chemical. When ethanol (C₂H₆O) is chlorinated, it becomes chloroethane (C₂H₅Cl). The substance starts as the alcohol found in drinks and ends up as an effective refrigerant and aerosol spray propellant.

When sugar undergoes this chlorination process to become sucralose, it is converted into a chlorocarbon. McNeil Nutritionals tries to brush this matter aside by pointing out that we eat chlorine every day in the form of table salt. By making this argument, McNeil conveniently ignores a fundamental difference in the chemical bonds. The defining feature of chlorocarbons such as sucralose is a covalently bonded chlorine atom. In table salt, however, sodium and chlorine form an ionic bond to become sodium chloride.¹⁷³ The difference between a covalent and ionic bond is night and day.¹⁷⁴

As a class, chlorocarbons consist of insecticides, pesticides, bleaches, chemical weapons, and sucralose.¹⁷⁵ Because McNeil did

172. See New York State Department of Health, The Facts about Chlorine, Aug. 5, 2004, http://www.health.state.ny.us/environmental/emergency/chemical_terrorism/chlorine_tech.htm (last visited Apr. 6, 2010).

173. For further discussion of the difference between chlorine and chloride, see Roald Hoffman, *Legally Sweet*, Vol. 95, 310 (2007), available at <http://www.americanscientist.org/issues/id.3749,y.0,no.,content.true,page.1,css.print/issue.aspx> (last visited Feb. 26, 2010).

174. "If the logic of [McNeil's] argument were correct, we could all be guzzling drain cleaner without consequence because, after all, lye, also known as sodium hydroxide, is merely sodium, hydrogen, and oxygen—all very common components of food." *Sucralose Q&A Setting the Record Straight Part 2*, 1 INTEGRATED SUPPLEMENTS NEWSLETTER, July 2007, at 2, available at <http://www.integratedsupplements.com/articles/Newsletter200704.pdf>.

175. For a table of chlorocarbons, see MERCOLA, *supra* note 1, at 81–83.

not want its artificial sweetener to be associated with these toxic substances, it created a completely new chemical category: chloro-carbohydrates. Conveniently for McNeil, sucralose is the only chloro-carbohydrate in the world.

Since McNeil Nutritionals can magically create a new chemical category, perhaps it has also miraculously developed a safe chloro-carbon. Let's see what science has to say. McNeil boasts that "[s]ucralose has been extensively tested in more than 100 studies during a 20-year period and found to be a safe and remarkably inert ingredient."¹⁷⁶ This is an incredibly crafty sentence. Anyone who reads it would reasonably assume that those studies were long-term and focused on human safety. Both of these assumptions, however, would be wrong. Only three studies lasted a year or more, and none of those involved humans. On top of this, the vast majority of trials went unpublished. If these unpublished studies had safe results, why would McNeil withhold them from the public? Equally disturbing, more of the published studies examined whether sucralose causes tooth decay rather than if the product is safe to consume.¹⁷⁷ You can sleep soundly at night knowing that McNeil thoroughly investigated any potential dental problems. Unfortunately, whether sucralose has a toxic effect on the rest of your body was not a concern.

The current state of safety literature is reminiscent of aspartame twenty years ago. No long-term studies have been done on humans,¹⁷⁸ the manufacturer's own tests found evidence of toxicity in rats,¹⁷⁹ and consumers have reported many adverse reactions.¹⁸⁰ The Sucralose Toxicity Information Center has received complaints linking the following ailments to sucralose: "skin rashes/flushing, panic-like agitation, dizziness and numbness, diarrhea, swelling,

176. All About Sucralose, Sucralose Facts, <http://www.sucralose.org/facts/brochure.asp> (last visited Apr. 10, 2010).

177. Oddly, all of the safety studies involving animals were published in a single issue of one journal.

178. See MERCOLA, *supra* note 1, at 89 (noting that the longest safety study involving humans was just thirteen weeks).

179. Marcelle Pick, Sugar substitutes and the potential danger of Splenda, Nov. 14, 2005, <http://www.womentowomen.com/healthyweight/splenda.aspx> (last visited Apr. 10, 2010) (noting that pre-approval studies showed that sucralose "caused shrunken thymus glands, enlarged livers, and kidney disorders in rodents").

180. See Food and Diet, Splenda, <http://www.foodanddiet.com/NewFiles/splenda-story-list.html> (last visited Apr. 8, 2010) (listing consumer complaints that include headaches, depression, anxiety, diarrhea, vomiting, extreme fatigue, drug-like feelings of disorientation and confusion, and more).

muscle aches, headaches, intestinal cramping, bladder issues, and stomach pain.”¹⁸¹

McNeil Nutritionals states that sucralose “passes rapidly through the body virtually unchanged.”¹⁸² Note the qualification. By its own estimates, McNeil believes that fifteen percent of the sucralose humans ingest is absorbed into the body.¹⁸³ Apparently to McNeil, “virtually unchanged” is equivalent to a significant rate of absorption. Let’s give McNeil the benefit of the doubt. Perhaps it meant that fifteen percent of a single dose of sucralose is “virtually” negligible. Unfortunately, this fails to account for the fact that people will be consuming multiple servings of sucralose every day for years. Is fifteen percent over a lifetime really insignificant? Until long-term human studies have been conducted, we won’t know the answer for certain.¹⁸⁴ Until then, I ask you to consider whether a corporation that has repeatedly deceived consumers really views public health as a top priority.

D. Stevia

In the previous sections, we examined how pharmaceutical companies can push their unsafe products through the FDA approval process. This section is even more alarming. It demonstrates how powerful corporations can prevent safe, natural products from obtaining FDA approval. The FDA’s treatment of stevia provides the clearest example of how the agency’s decisions are made to maximize corporate profits and have nothing to do with science or consumer health. However, before we explore the extent of this corruption, let’s briefly look at why this herb is a threat to the artificial sweetener industry.

Stevia is a natural, non-caloric sweetener derived from the South American plant *Stevia rebaudiana* Bertoni. When refined

181. *Id.*

182. All About Sucralose, <http://www.sucralose.org/facts/brochure.asp> (last visited Apr. 8, 2010).

183. See B.A. John et al., *The Pharmacokinetics and Metabolism of Sucralose in the Mouse*, 38 FOOD & CHEM. TOXIC. S107 (2000). The FDA estimates that between eleven and twenty-seven percent is absorbed. Food Additives Permitted For Direct Addition to Food for Human Consumption; Sucralose, 63 FED. REG. 16, 417, 16419 (Apr. 3, 1998).

184. See Betty Kovacs, Artificial Sweeteners, http://www.medicinenet.com/artificial_sweeteners/page9.htm (last visited Apr. 8, 2010) (stating that “the only way to be sure of the safety of sucralose is to have long-term studies on humans done”).

into a white powder extract, stevia is approximately 300 times sweeter than sugar.¹⁸⁵

Unlike artificial sweeteners, independent clinical studies have confirmed that stevia is not toxic.¹⁸⁶ The earliest safety study was conducted in 1931, and since then, the findings have been reaffirmed by multiple experiments. In that first study, the researchers determined that humans cannot digest stevia. Unlike McNeil's sucralose trials, this study did not need to qualify its findings with words like "virtually" or "almost." Stevia passes through our bodies completely unchanged.

During the 1970s, while stevia was going through the approval process in Japan, many Japanese scientists conducted additional tests. These trials uniformly indicated that the sweetener is safe for human consumption.¹⁸⁷ Since that time, stevia has been widely used in Japan, Australia, New Zealand, and Switzerland with no ill effects. In Japan, stevia became so popular that, at one point, 1700 tons were consumed annually,¹⁸⁸ accounting for forty percent of the sweetener market.¹⁸⁹ More recent studies have once again confirmed stevia's safety.¹⁹⁰ It bears emphasizing that, unlike the artificial sweetener safety tests, these trials were independently funded.

185. See David Richard, Questions & Answers about Stevia, http://www.stevia.com/Stevia_Article.aspx?Id=2269 (last visited Apr. 8, 2010).

186. See e.g., H. Fujita & T. Edahiro, *Safety and utilization of stevia sweetener*, 22 THE FOOD INDUSTRY 1, 1-8 (1979); IKHLAS A. KHAN & EHAB A. ABOURASHED, LEUNGS ENCYCLOPEDIA OF COMMON NATURAL INGREDIENTS: USED IN FOOD, DRUGS AND COSMETICS 577 (2009) ("Subacute toxicity studies on rats over a 50-day period up to 7.0% concentration of stevioside in feed produced no remarkable toxic effects.").

187. See e.g., H. Akashi & Y. Yokoyama, *Dried Leaf Extracts of Stevia: Toxicological Test*, 18 J. JAPANESE SOC. FOOD SCI. & TECH. 34, 34-43 (1975); H. Fujita & T. Edahiro, 22 J. JAPANESE SOC. FOOD SCI. & TECH. 66 (1979).

188. See IKHLAS A. KHAN & EHAB A. ABOURASHED, LEUNGS ENCYCLOPEDIA OF COMMON NATURAL INGREDIENTS: USED IN FOOD, DRUGS AND COSMETICS 577 (2009) (citing M. BLUMENTHAL, WHOLE FOODS 29 (1992)).

189. "[F]ood manufacturers there began using Stevia extracts to sweeten everything from sweet soy sauce and pickles to Diet Coke. Stevia and its extracts have since captured more than 40 percent of the Japanese sweetener market." Herbal Advantage, Stevia - the 'Herbal Advantage' Over Sugar (and its Substitutes), <http://www.stevia-products.com> (last visited Apr. 8, 2010).

190. See K. Toyoda et al., *Assessment of the Carcinogenicity of Stevioside in F344 Rats*, 35 FOOD & CHEM. TOXIC. 597, 597-603 (1997) (concluding "that stevioside is not carcinogenic in rats under the experimental conditions described"); for a review of additional studies, see RAY SAHELIAN & DONNA GATES, THE STEVIA COOKBOOK 28-31 ("[R]esearchers determined that giving laboratory rats 550 mg/kg of stevioside every day for two years did not cause any abnormalities.").

At one point, upon reviewing the literature on stevia, one researcher noted the following:

Few substances have ever yielded such consistently negative results in toxicity trials as have stevia. Almost every toxicity test imaginable has been performed on stevia extract [concentrate] or stevioside at one time or another. The results are always negative. No abnormalities in weight change, food intake, cell or membrane characteristics, enzyme and substrate utilization, or chromosome characteristics. No cancer, no birth defects, no acute and no chronic untoward effects. Nothing.¹⁹¹

Perhaps the best proof of stevia's safety, however, is that it has been consumed, with no adverse effects, for more than fifteen hundred years by the indigenous people of South America.¹⁹² In fact, the Guaraní tribes of Paraguay, Brazil, and Bolivia have long used stevia to lower blood sugar¹⁹³ and treat heartburn and hypertension.¹⁹⁴ Recent research has corroborated stevia's medicinal properties.¹⁹⁵ Additionally, since stevia is an excellent source of the antioxidant superoxide dismutase, the herb may also reduce the risk of cancer.¹⁹⁶ Not only is stevia safe, it actually has health benefits, something no artificial sweetener can claim.

The interesting part is that the FDA should have approved stevia even without this safety evidence. The Federal Food, Drug, and

191. James May, *Stevia - Sweetener of Choice for Future Generations*, http://www.stevia.com/Stevia_Article.aspx?Id=2413 (last visited Apr. 8, 2010) (quoting Daniel Mowrey).

192. See MERCOLA, *supra* note 1, at 205.

193. *Id.*

194. See Ashraf Tanvir, *Sugar Leaf - A New Breed of 'Sweetener'*, http://www.parc.gov.pk/articles/sugar_leaf.htm (last visited Apr. 8, 2010).

195. See M.H. Hsieh et al., *Efficacy and Tolerability of Oral Stevioside in Patients with Mild Essential Hypertension: A Two-Year, Randomized, Placebo-Controlled Study* 25 CLINICAL THERAPY 2797, 2798 (2003) ("In this 2-year study in Chinese patients with mild hypertension, oral stevioside significantly decreased SBP and DBP compared with placebo. QOL was improved, and no significant adverse effects were noted."); see R. Curi et al., *Effect of Stevia Rebaudiana on Glucose Tolerance in Normal Adult Humans*, 19 BRAZ. J. MED. BIO. RES. 771, 771 (1986) (finding that "[t]he extract of Stevia rebaudiana increased glucose tolerance [and] significantly decreased plasma glucose levels during the test and after overnight fasting in all volunteers"); see J.O. Atteh et al., *Evaluation of Supplementary Stevia (Stevia Rebaudiana, Bertoni) Leaves and Stevioside in Broiler Diets: Effects on Feed Intake, Nutrient Metabolism, Blood Parameters and Growth Performance*, 92 J. ANIMAL PHYSIOLOGY & ANIMAL NUTRITION 640, 646-47 (2008) (finding that stevia leaves reduced blood levels of glucose, triglycerides and triiodothyronine).

196. See S. Ghanta et al., *Oxidative DNA Damage Preventive Activity and Antioxidant Potential of Stevia Rebaudiana (Bertoni) Bertoni, a Natural Sweetener*, 65 J. AGRICULTURAL & FOOD CHEM. 10962, 10962 (2007) (concluding "that Stevia rebaudiana may be useful as a potential source of natural antioxidants").

Cosmetic Act has a carve-out for food additives Generally Recognized as Safe (GRAS). The statute provides that the FDA has no regulatory power over any “substance used in food prior to January 1, 1958, [that is determined] through either scientific procedures or *experience based on common use in food* to be safe under the conditions of its intended use.”¹⁹⁷ As already noted, stevia had been used for more than a millennium in South America. In addition, prior to 1958, the sweetener had been commonly used in the United States.

Nevertheless, this did not stop the FDA from banning stevia in 1991 to satisfy an anonymous trade complaint.¹⁹⁸ After nearly twenty years and numerous Freedom of Information Act requests, the FDA has steadfastly refused to release the name of the company that requested the ban. These suspicious circumstances led Arizona congressman Jon Kyl to conclude that the FDA’s stevia ban is “a restraint of trade to benefit the artificial sweetener industry.”¹⁹⁹ Evidence for this claim has mounted in recent years.

In 1992, the American Herbal Products Association submitted a petition to the FDA requesting that stevia be granted GRAS status. The introduction to the petition states that “various extract forms of stevia have been extensively studied and tested. These tests include acute, sub-acute, carcinogenic evaluation and mutagenicity studies. These scientific data . . . demonstrate cumulatively that there is no safety problem associated with the use of an extract of stevia. It appears to be extraordinarily safe.”²⁰⁰ The GRAS affirmation petition went on to cite over 900 articles dealing with stevia, and not a single one reported any adverse health effects.²⁰¹

197. 21 U.S.C. 321, §201(s).

198. See FDA, Import Alert No. 45-06 (May 17, 1991).

199. Healthy News Service, *FDA Continues Pushing Natural Herb Sweetener Stevia Out of U.S.*, http://stevia.com/Stevia_article/FDA_Continues_Pushing_Natural_Herb_Sweetener_Stevia_Out_of_US/8134 (last visited Feb. 26, 2010) (quoting a 1993 letter from John Kyl to former FDA Commissioner David Kessler).

200. *Id.*

201. *Id.* (A 1995 supplement to the petition indicates that “[t]he petition cites over 120 articles about stevia written before 1958, and over 900 articles published to date. In this well-chronicled history of stevia, no author has ever reported any adverse human health consequences associated with consumption of stevia leaf.” The petition itself states “Stevia leaf is a natural product that has been used for at least 400 years as a food product, principally as a sweetener or other flavoring agent. None of this common usage in foods has indicated any evidence of a safety problem. There are no reports of any government agency in any of the above countries indicating any public health concern whatsoever in connection with the use of stevia in foods.”).

Despite this overwhelming evidence, the FDA refused to act until Congress forced its hand in 1994. That year, Congress passed the Dietary Supplement and Health Education Act.²⁰² This law prevented the FDA from regulating any dietary supplement unless it was proven unsafe. Because studies did not attribute any health risks to stevia, the FDA was forced to allow manufacturers to market the herb as a dietary supplement. The agency, however, still refused to approve stevia for use as a sweetener.

Due to the strict regulations regarding the labeling, marketing, and sales of dietary supplements,²⁰³ many consumers still wanted the partial ban lifted. In spite of public support for stevia,²⁰⁴ the FDA refused to grant approval. At one point, the FDA claimed its concerns were largely based on the work of Mauro Alvarez.²⁰⁵ Upon learning of this, Alvarez wrote that the FDA had clearly misinterpreted his research:

[T]he only possible way to report that the results showed detrimental effects is by taking information out of context. If this is the case, one concludes that these FDA scientists are incompetent and irresponsible, or if not, they must belong to some sort of conspiracy group to carry on a sinister agenda against this plant with the objective to keep it away from American consumers by attributing to it safety issues that do not exist.²⁰⁶

Nevertheless, for more than a decade, the FDA stuck to the bizarre position that stevia was a safe “dietary supplement” but a toxic “food additive.”²⁰⁷ Never mind the fact that stevia could legally be added to foods in the exact same manner as a food additive so long

202. Dietary Supplement and Health Education Act of 1994, Pub. L. No. 103-417, 108 Stat. 4325 (1994).

203. See *Cooking with Stevia, The FDA and the 1st Amendment or Why The Book Cooking With Stevia Was Banned!*, <http://www.cookingwithstevia.com> (last visited Apr. 7, 2010) (“Simply suggesting that the stevia be mixed with water could be construed as mislabeling and force a recall of the products.”).

204. Recall that the FDA refused to ban saccharin because it would upset some consumers. Apparently, consumer support only matters when it aligns with corporate profits. See note 95 and accompanying text.

205. Stevia.net, *The 19 Studies*, <http://www.stevia.net/19studies.htm> (last visited Apr. 7, 2010).

206. Letter from Mauro Alvarez, Professor, Parque Tecnológico Agro-Industrial do Oeste (Jan. 19, 1998) *available at* <http://www.stevia.net/19studies.htm>.

207. Many have attributed stevia’s paradoxical state to the power of big business. See e.g., Alexandra Marks, *Bitter Dispute Over All-Natural Sweetener*, CHRISTIAN SCI. MONITOR, Sept. 1, 1999, at 2, *available at* <http://www.csmonitor.com/1999/0901/p2s1.html> (“They say it’s safe as long as you use it as a dietary supplement, but if you try to use it as a food it’s unsafe? The battle goes back to influence on the FDA from the artificial sweetener industry.” (quoting James Kirkland, author of *The Stevia Cookbook*)).

as the product was labeled a “dietary supplement.”²⁰⁸ These strict supplement regulations, however, did have several important effects. They made major grocery chains reluctant to carry the herb, relegating the sale of stevia to health food stores. This ensured that the vast majority of consumers were unaware of stevia and, in doing so, preserved the market share of artificial sweeteners. For these reasons, the FDA’s partial ban could not have been due to safety concerns. It was done purely for economic profit. Remember, in the FDA’s view, corporate health comes before consumer health.

Then suddenly, in 2008, the FDA had a change of heart and began allowing stevia to be marketed as a sweetener. What could engender this reversal? Had a new conclusive scientific study been published? Nope, merely the players supporting stevia had changed. In May 2008, Cargill, Merisant, Coca-Cola, and Pepsi submitted petitions to the FDA asking that stevia be granted GRAS approval. For the past two decades, the FDA had denied the exact same requests from consumer groups. However, now that major corporations were behind stevia, the FDA decided it must be safe for consumption. It seems like corporate backing and not science dictates safety. Maybe if corporations wished hard enough, cigarettes would magically become safe, too?²⁰⁹

At any rate, in order to fully appreciate the FDA’s reversal, one must understand the companies behind the petitions. Merisant is the maker of aspartame-based Equal. Due to the rising popularity of sucralose, Merisant’s share of the artificial sweetener market had declined substantially. In fact, sales had fallen so much that the company was pushed into bankruptcy.²¹⁰

Since sucralose had become the dream artificial sweetener in terms of taste and usability, Merisant needed a completely new approach if it hoped to return to profitability. The company ultimately decided to capitalize on the natural and organic trends that are spreading across America. This meant finding a natural product

208. See e.g., Erica Orden, *Calorie-Free, Stevia’s 11-Year War with FDA*, *Newsday*, May 2, 2006, available at http://www.steaz.com/pdf/news_2006/Newsday0506.pdf. “In January 2004, Steaz, a Pennsylvania-based natural soda manufacturer, introduced a diet line made with stevia rather than aspartame or Nutrasweet. To comply with the legal guidelines, the company can’t market it as a soda or even as a beverage (it calls the product a dietary supplement) and must list ‘supplement facts’ rather than ‘nutrition facts’ on its back label.

209. See generally MICHAELS, *supra* note 12, at 3–11.

210. See Chelsea Emery et. al., *Merisant, Maker of Equal, Gets \$20 mln DIP Financing*, *REUTERS*, <http://in.reuters.com/article/privateEquity/idINN1232403220090112> (last visited Apr. 12, 2010).

that could compete with sucralose. Lo and behold, stevia was the perfect candidate. Merisant developed a stevia-based sweetener called PureVia²¹¹ and teamed up with Pepsi to market a line of diet soft drinks.²¹²

Cargill followed a somewhat similar path. Although it is America's largest agricultural corporation,²¹³ it had never entered the artificial sweetener market. Like Merisant, Cargill saw that the trend was moving towards natural products. Therefore, it developed Truvia,²¹⁴ another stevia-based sweetener, and teamed up with Coca-Cola to produce diet soft drinks.²¹⁵

At this point, there was still one minor problem. The FDA had consistently claimed that stevia was not safe for humans. But with four major corporations now backing stevia (Coca-Cola, Pepsi, Cargill, and Merisant), the agency's stance quickly changed.

As previously noted, these corporations asked that stevia be given GRAS approval in May of 2008. The FDA handled this request in an extremely clever way. Instead of granting GRAS approval which would have allowed every company to use the sweetener, the FDA issued a letter of "no objection."²¹⁶ This means that the FDA does not object now, but it may object later. Essentially, the FDA has reserved the right to selectively target companies. Although it has not yet done so, the FDA can allow Coca-Cola and Pepsi to market stevia while preventing smaller companies from producing the sweetener.²¹⁷

211. PureVia contains the following ingredients: erythritol, isomaltulose, stevia extract, cellulose powder, and natural flavors. Lynn Smythe, Zero Calorie Stevia Sweeteners, http://spices.suite101.com/article.cfm/zero_calorie_stevia_sweeteners (last visited Apr. 12, 2010).

212. Betsy McKay, *FDA Clears Use of Herb As Sweetener*, WALL ST. J., Dec. 18, 2008, at B3.

213. Andrea D. Murphy & John J. Ray, America's Largest Private Companies, http://www.forbes.com/2009/10/28/largest-private-companies-business-private-companies-09_land.html (last visited Apr. 12, 2010) (listing Cargill as #1 with revenue of \$106.3 billion);

214. Truvia contains the following ingredients: stevia extract, erythritol, and natural flavors. Smythe, *supra* note 211.

215. Cargill, *Honestly Sweet*, <http://www.cargill.com/connections/more-stories/truvia-natural-sweetener/index.jsp> (last visited Aug. 6, 2010).

216. McKay, *supra* note 212; see Mike Adams, FDA Approves Stevia, Ends the Era of Oppression of this Herbal Sweetener - Update 1, http://www.naturalnews.com/News_000626_stevia_Truvia_FDA.html (last visited Apr. 12, 2010) (stating that the FDA's issuance of "no objection" letters really means "the FDA hasn't technically granted approval to stevia but has affirmed it will not object to companies using it in foods and beverages.").

217. See Adams, *supra* note 216.

Over the past twenty years, stevia has had quite the adventure. One commentator sums up the sweetener's history quite nicely:

When stevia threatened the profits of aspartame, it was routinely suppressed by the agency. FDA thugs seized imports of stevia at the border, destroyed millions of dollars in stevia products, threatened companies with fines for daring to sell stevia, and even ordered one company to destroy its recipe books that mentioned stevia in dessert recipes. But now, when Coca-Cola and Pepsi want stevia approved, the FDA suddenly reverses its oppression and decides to legalize the herb.²¹⁸

Although stevia's use as a food additive benefits Americans, the process by which it was approved presents a disturbing picture. Corporations routinely manipulate the FDA to maximize profits. If a product hurts the bottom line, the FDA bans it. If it helps the bottom line, the FDA approves it. Science and safety are irrelevant. Obviously, fundamental change is needed.²¹⁹ Minor tweaks will only whitewash the problem. Industry must no longer be permitted to corrupt the FDA. The final part of this Article presents two major reforms that can provide the change we need.

III. TAKING INDUSTRY OUT OF THE FDA

Senator Charles Grassley plainly identified the problem when he said that the FDA "needs to reestablish its relationship with its own scientists and distance itself from the drug industry. The FDA needs to get rid of its mind-set that it's a facilitator for the drug industry and become regulator once again. The FDA's focus should be only on science and the public good."²²⁰

The first section describes the current FDA approval process. The final two sections present reforms that will take industry out of the FDA and ensure that the agency adheres to its mission of "protecting the public health," not filling the corporate coffers.²²¹

218. *Id.*

219. See H.R. REP. NO. 104-436, at 12-13 (1995) ("Manipulation of the food additive review process for anti-competitive purposes is inconsistent with the purposes of premarket review.")

220. Jonathan D. Rockoff, *FDA Scientists Report Their Safety Concerns in Poll*, L.A. TIMES, July 21, 2006, available at <http://articles.latimes.com/2006/jul/21/nation/na-fda21>.

221. FDA, *supra* note 9.

A. *FDA Approval Process*

After a pharmaceutical company develops a drug,²²² it conducts preclinical testing in laboratory animals. Next, the company submits its results to the FDA in the form of an Investigational New Drug Application (IND). By examining the IND, the FDA determines whether it is safe for the drug company to begin testing on humans.

If the FDA approves the IND, the pharmaceutical company can begin the first of three clinical stages. Phase one studies generally use small sample sizes and are conducted on healthy volunteers. The main objective is to identify common side effects and determine how humans absorb and excrete the drug.

The FDA reviews these results and allows the corporation to move onto phase two if the product does not appear unacceptably dangerous. The corporation's goal in phase two is to prove effectiveness. These studies use a moderate sample size (up to 300 participants). To determine if the drug works, subjects in the test group are given the new drug and subjects in the control group are given a placebo or a different FDA-approved drug.

If the corporation can provide evidence of the drug's efficacy, the FDA allows phase three to begin. In this final phase, the pharmaceutical company conducts large-scale tests with up to 3,000 subjects. The purpose of this phase is to check the drug's safety and effectiveness in different populations and at different dosages.

After phase three, the drug company submits a New Drug Application to the FDA. This report should contain all of the data and results gathered during the previous tests. However, as evidenced most prominently by G.D. Searle's aspartame reports, damning data is often withheld.

The FDA forms a review team consisting of medical doctors, chemists, statisticians, microbiologists, pharmacologists, and other experts to evaluate whether the drug company's trials show conclusive evidence of safety and effectiveness. At times, the FDA calls on advisory committees for help. Finally, higher level directors determine whether the drug should be approved.²²³

At first glance, this appears to be a relatively sound approval process. However, there are two major flaws that should make Americans question the reliability of the FDA's conclusions. First, due to their close financial ties to the businesses they are regulat-

222. Food additives undergo a similar but less rigorous process.

223. For a more detailed explanation of the process, *see* FDA, *supra* note 11.

ing,²²⁴ the people making the final decisions are often guided more by politics than scientific analysis.²²⁵ This is particularly true of top directors and commissioners who often leave the FDA and join pharmaceutical companies or lobbying firms for especially lucrative salaries.²²⁶ As a remedy to this problem, the next section will propose life tenure and strengthened conflict-of-interest regulations.

The second major flaw in the current approval process is that pharmaceutical companies conduct the studies to determine their own products' safety and effectiveness. Since drug companies only care about profit maximization, they are not concerned with accurately assessing a product's health risks. This has caused the industry to employ countless deceptive strategies to trick the FDA and the general public into believing that toxic chemicals are actually safe. To guarantee that the FDA's decisions are based on valid data, the final section advocates adopting a system that takes industry out of science.

B. Locking the Revolving Door

Currently, thirty-six percent of FDA scientists feel they cannot express "concerns about public health without fear of retaliation."²²⁷ Since more than one-third of researchers are afraid to do their jobs, the FDA obviously needs to reform its entire culture.

224. See Andrew Bridges, Ex-FDA Chief Pleads Guilty in Stock Case, THE WASH. POST, Oct. 17, 2006, available at <http://www.washingtonpost.com/wp-dyn/content/article/2006/10/17/AR2006101700573.html> ("Former FDA Commissioner Lester Crawford pleaded guilty Tuesday to conflict of interest and false reporting of information about stocks he owned in food, beverage and medical device companies he was in charge of regulating.").

225. Union of Concerned Scientists, *supra* note 5, at 3 (quoting a scientist from the Center of Devices and Radiological Health as saying "In my experience, it is never the 'low level' reviewers in the FDA who breach the integrity of our work. It is usually at much higher levels, such as center directors and above. Those higher levels are so far removed from the scientific work we do that politics has even more sway over their decisions.").

226. The FDA's revolving door is well documented. See e.g., Mike Palmedo, Revolving Door Between the U.S. Government and Industry, <http://www.cptech.org/ip/health/politics/revolvingdoor.html> (last visited Apr. 12, 2010); Jennifer Ferrara, *Revolving Doors: Monsanto and the Regulators*, 28 THE ECOLOGIST 280, 280-87 (1998); Policy Directions Inc., Professionals: Lester M. Crawford, DVM, PhD, Senior Science Advisor, <http://www.policydirections.com/professionals.php?queue=crawford> (last visited Apr. 12, 2010) (Former FDA Commissioner Lester Crawford is now working for a Washington lobbying firm, Policy Directions Inc.).

227. Union of Concerned Scientists, *supra* note 5, at 3.

Agency scientists have made it clear that any solution should start with high level directors.²²⁸ Therefore, the new system must focus on developing a culture of independence at the top. For our purposes, the top means the FDA Commissioner and the forty-eight advisory committees.

In order to create an independent agency, all conflicts of interest must first be eliminated. "A conflict of interest is a set of conditions in which professional judgment concerning a primary interest (such as a patient's welfare or the validity of research) tends to be unduly influenced by a secondary interest (such as financial gain)."²²⁹ Because even the smallest secondary ties can create undue influence,²³⁰ committee members must be completely removed from the industries they will be regulating.

In theory, each committee should consist of independent experts who advise the agency on product safety and effectiveness.²³¹ Recognizing that an extremely important requirement is independence, federal law already forbids anyone with a conflict of interest from serving on an advisory committee.²³² However, given the ease with which waivers are granted, this prohibition has become meaningless.²³³

The FDA published a whopping twenty-two page document for determining a conflict of interest.²³⁴ Despite these lengthy rules,

228. *Id.* at 2, ("Less than half (44 percent) say they 'respect the integrity and professionalism of FDA leadership.'").

229. Dennis F. Thompson, *Understanding Financial Conflicts of Interest*, 329 NEW ENG. J. MED. 573, 573 (1993).

230. *See generally*, JEROME P. KASSIRER, ON THE TAKE: HOW MEDICINE'S COMPLICITY WITH BIG BUSINESS CAN ENDANGER YOUR HEALTH 1-24 (2005) (describing how even insignificant gifts like pens and coffee mugs can create a conflict of interest that influences doctors).

231. *See* Food and Drug Administration, Advisory Committees, <http://www.fda.gov/AdvisoryCommittees/default.htm> (last visited Feb. 26, 2010) (The FDA "uses 48 committees and panels to obtain *independent* expert advice on scientific, technical, and policy matters." (emphasis added)).

232. *See* Food and Drug Administration, *Guidance for the Public, FDA Advisory Committee Members, and FDA Staff on Procedures for Determining Conflict of Interest and Eligibility for Participation in FDA Advisory Committees* (2008), available at <http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM125646.pdf>.

233. *See* MERCOLA, *supra* note 1, at 163 ("[B]etween 1998 and 2000, the FDA waived [the conflict of interest] restriction more than 800 times.").

234. *See* Food and Drug Administration, *Draft Guidance for the Public, FDA Advisory Committee Members, and FDA Staff on Procedures for Determining Conflict of Interest and Eligibility for Participation in FDA Advisory Committees* (2007), available at <http://www.fda.gov/OHRMS/DOCKETS/98fr/07d-0101-gdl0001.pdf>.

“doctors who earn hundreds of thousands of dollars each year in ‘consulting fees’ from drug companies are not only allowed to vote on the recommendations for FDA approval of their drugs, there is not even any FDA requirement to disclose such conflicts of interest.”²³⁵ Instead of complex guidelines, the agency could use a straightforward one-sentence test: Within the past five years, have you or your immediate family had financial ties to the industry you will be regulating? If the answer is yes, the person is disqualified, regardless of expertise. Financial ties would include more than monetary compensation. Any sort of remuneration would preclude someone from serving in a top level position. This is a necessary measure so that corporations do not influence experts with vacations, televisions, cars, meals, or other incentives.

So where do we get enough pure souls to staff the FDA committees? After all, more than half of the current advisory committees have financial ties to the companies they are regulating.²³⁶ This is a troubling statistic, but there is a bit of hope contained within it. Nearly half of the advisory committees did not have financial conflicts of interest. Since the FDA can currently staff almost half of its panels with independent experts, there is no reason it cannot fill all of its panels with such people. Although this Article has painted a stark picture, the vast majority of scientists at the FDA are committed to protecting the public health. Therefore, promoting from within is one viable option.

Because only the FDA commissioner and the committee members will be subject to the five year regulation, people with recent ties to industry will still be able to work at the FDA. However, by barring them from immediately taking high-level positions, the culture of the agency will change. This top-down approach will foster a sense of independence within the FDA. It will also allow low level scientists to do their job without fear of retribution from their superiors. No longer will the FDA and corporations be partners in a quest for greater profits.

Another option is to recruit scientists from universities. Admittedly, industry has tainted medical schools, but in recent years, many have committed to regaining independence. This past year, Harvard Medical School strengthened its conflict of interest regulations,

235. Mike Adams, *Americans Fed up with Drug Industry Influence, FDA Corruption, Reveals Remarkable Consumer Reports Survey*, <http://www.naturalnews.com/021795.html> (last visited Apr. 12, 2010).

236. See MERCOLA, *supra* note 1, at 163.

and other schools have followed suit.²³⁷ Trade organizations have pressured other schools to make similar policy changes. The Association of American Medical Colleges views connections between researchers and industry as a “peril to academic medicine and public health.”²³⁸ The American Medical Student Association now rates schools based on their conflict of interest policies. In 2008, just eight schools obtained an “A” ranking.²³⁹ In 2009, that number increased to twelve, with forty-seven other schools earning a “B” ranking.²⁴⁰ As universities continue their reforms, they will become an even better resource for the FDA.

Now that we have identified our candidate pool, how does the FDA make its selection? Because the judiciary is the most trusted branch,²⁴¹ it serves as a good model for FDA committees. To begin, an oversight committee should be created. The members of this panel should be granted life tenure. They shall be appointed by the President and confirmed by the Senate.

When vacancies need to be filled on any of the forty-eight subcommittees, the FDA commissioner will nominate a candidate and the oversight committee will approve or reject the nomination. When a new drug or food additive application is submitted, the appropriate subcommittee will review the available studies and make a recommendation. The oversight committee will have the final say

237. See Liz Kowalczyk, Harvard Will Stiffen Rules for Staff at Med School, BOSTON GLOBE, Feb. 3, 2009, available at http://www.boston.com/news/local/massachusetts/articles/2009/02/03/harvard_will_stiffen_rules_for_staff_at_med_school (last visited Feb. 26, 2010) (“Many top medical schools, including Stanford University, the University of Pennsylvania, the University of California at Los Angeles and at San Francisco, and the University of Massachusetts have adopted stricter policies in the past two years.”).

238. Susan Ehringhaus & David Korn, *Conflicts of Interest in Human Subjects Research*, ISSUES IN SCIENCE AND TECHNOLOGIES (Winter 2002), available at <http://www.issues.org/19.2/ehringhaus.htm> (last visited Apr. 7, 2010).

239. Dane Secor, *AAMC Joins Movement to Restrict Pharmaceutical Company-Physician Relationships*, 3 ACAD. INTERNAL MED. INSIGHT 6 (2008) (“Only eight out of the approximately 150 medical schools surveyed received an ‘A,’ which indicates the institution has strong policies that address conflicts of interest caused by pharmaceutical industry marketing.”).

240. See AMERICAN MEDICAL STUDENT ASSOCIATION, CONFLICT OF INTEREST POLICIES AT ACADEMIC MEDICAL CENTERS, <http://www.amsascorecard.org> (last visited Apr. 7, 2010).

241. See generally Frank Newport, Americans’ Trust in Legislative Branch at Record Low, GALLUP, Sept. 10, 2009, <http://www.gallup.com/poll/122897/americans-trust-legislative-branch-record-low.aspx> (Since 1974, Americans have trusted the judiciary more than the executive or legislative branches.).

on all applications, but great deference should be given to the decision of the subcommittees.

For five years after stepping down, the FDA commissioner and committee members will be unable to accept any compensation from a regulated industry. This is a necessary measure to prevent corporations from making promises of future gain to entice regulators to approve a drug or food additive. This is not an unfamiliar proposal, but its enforcement would be novel. In the past, Presidents have placed similar restrictions on some of their appointees. Unfortunately, they have merely served as talking points rather than stringent policies.²⁴²

The proposal does not provide for a perfect selection mechanism, but any effective system will inevitably produce false positives. If the policy is overly restrictive, we can rest assured that it is much better to exclude too many people than to permit those with bad intentions to control the FDA.

The most common argument in favor of the revolving door is that industry consultants are the only people with sufficient expertise to evaluate the latest drugs. Jerome P. Kassirer, the former Editor-in-Chief of the *New England Journal of Medicine*, calls this claim the “fallacy of unique expertise.”²⁴³ He argues that we should not need to rely on conflicted experts because independent scientists quickly develop the necessary skills.²⁴⁴ In fact, relying on industry experts may be detrimental for reasons beyond the obvious conflict of interest. When people with similar views come together, they are subject to group polarization.²⁴⁵ Because the industry experts are already sympathetic to pharmaceutical companies, this bias will be amplified when they try to reach a group consensus.²⁴⁶

242. President Clinton enacted a measure that prevented certain appointees from working in regulated industry. In the last days of his presidency, he repealed the measure. Likewise, President Obama’s restrictions are set to expire at the end of his presidency.

243. KASSIRER, *supra* note 230, at 204.

244. *See id.* at 204–05 (“[N]obody has provided any evidence that people with financial ties to industry are better in assessing evidence on any a particular subject than those without such ties There is no fundamental reason to think that such panels of intelligent clinicians who have no industry connections would be unable to assess a body of clinical data and arrive at useful recommendations.”).

245. *See generally*, Cass Sunstein, *The Law of Group Polarization* 1–15 (John M. Olin Law & Econ., Working Paper No. 91, 1999), available at www.law.vchicago.edu/Files/Files/91.CRS_Polarization.pdf.

246. *See* KASSIRER, *supra* note 230, at 205 (“[T]here is real risk that like-minded people with ‘unique’ knowledge may have similarities of thought and come up with a uniform conclusion that is biased (or even completely wrong).”).

Even if one concedes that industry scientists are the most qualified experts, this argument ignores a more fundamental issue. The FDA will make better decisions if it is run by good, independent scientists than if it is run by excellent, corrupt scientists. Nonetheless, as discussed above, there is no reason to believe that the FDA will be unable to staff its committees with excellent, independent scientists.

Now that we have setup independent committees, the next step is to determine what standard they should apply when approving new substances. It is clear that the FDA must presume a product is unsafe until studies show otherwise,²⁴⁷ so three possibilities jump to mind: preponderance of the evidence,²⁴⁸ clear and convincing evidence,²⁴⁹ and beyond a reasonable doubt.²⁵⁰ In choosing a standard, our goal should be to build in a margin of safety without unduly restricting food and drugs from reaching the market.

For this reason, I think it is fair to rule out preponderance of the evidence. If the committee determines it is only slightly more probable than fifty percent that the food or drug is safe, it should deny the application. On balance, it is better to reject a product that is harmless than approve a product that is dangerous. After all, the rejected substance can undergo additional tests to better ascertain

247. The law already provides for this presumption, even though recent history seems to indicate that the FDA presumes a substance is safe until proven otherwise. See 21 U.S.C. § 348(c)(3)(A) ("No such regulation shall issue if a fair evaluation of the data before the Secretary—fails to establish that the proposed use of the food additive, under the conditions of use to be specified in the regulation, will be safe . . .").

248. See Neil Orloff & Jerry Stedinger, *A Framework for Evaluating the Preponderance-of-the-Evidence Standard*, 131 U. PA. L. REV. 1159, 1159 (1983) (noting that the traditional preponderance of the evidence standard "requires demonstrating that the existence of the contested fact is more probable than its nonexistence").

249. BLACK'S LAW DICTIONARY 596 (8th ed. 2004) (defining clear and convincing evidence as "evidence indicating that the thing to be proved is highly probable or reasonably certain. This is a greater burden than preponderance of the evidence, the standard applied in most civil trials, but less than evidence beyond a reasonable doubt, the norm for criminal trials.").

250. BLACK'S LAW DICTIONARY 1293 (8th ed. 2004) (quoting *Commonwealth v. Webster*, 59 Mass. (5 Cush.) 295, 320 (1850)) (defining reasonable doubt as "a term often used, probably pretty well understood, but not easily defined. It is not a mere possible doubt; because every thing relating to human affairs, and depending on moral evidence, is open to some possible or imaginary doubt. It is that state of the case, which, after the entire comparison and consideration of all the evidence, leaves the minds of jurors in that condition that they cannot say they feel an abiding conviction, to a moral certainty, of the truth of the charge.").

its safety, but once the toxic food or drug enters the market, the damage is done.

The more difficult decision involves choosing between clear and convincing evidence and beyond a reasonable doubt. They both prove useful in their own way.

At present, food additives require less rigorous testing than drugs. This is backwards. Although it may seem counterintuitive at first, the standard required to approve food additives should be higher than drugs. Accordingly, I recommend using the beyond a reasonable doubt standard for food additives and the clear and convincing evidence standard for drugs.

Food additives are generally marketed on a national scale and included in many products. Due to the sheer number of options, most people do not know which products contain which additives. Therefore, when someone consumes an additive, it is, with few exceptions, the result of an indirect choice.

For example, no one buys Swedish Fish gummy candies because they want to eat the food dye Red No. 40. People buy the candy because they like the taste. In fact, I would wager that most people who have eaten Swedish Fish never even thought about what food additive is used to make the red coloring. To go one step further, despite the fact that Red No. 40 is the most widely used food coloring,²⁵¹ the vast majority of Americans have likely never even considered its safety. FDA approval is such a powerful signal that millions of people are willing to eat food additives everyday just because the FDA says it is okay. The faith is so strong that the average American consumes 150 pounds of food additives each year,²⁵² ten pounds of which are chemical in nature.²⁵³

Another argument for a beyond a reasonable doubt standard is that the costs of a false negative are much lower. Rejecting a safe food additive will not lead to deaths or prevent the cure of diseases. On the other hand, denying the application for a safe drug can

251. The History of Food Dyes, <http://www.red40.com/pages/history.html> (last visited Apr. 9, 2010). Manufacturers use this orange-red color in all sorts of gelatins, beverages, dairy products and condiments. FDA certified more than 3 million pounds of the dye in fiscal year 1992—almost a million pounds more than the runner-up, FD&C Yellow No. 5. *Id.*

252. DEANNA MINICH, AN A-Z GUIDE TO FOOD ADDITIVES: NEVER EAT WHAT YOU CAN'T PRONOUNCE 10 (2009).

253. *The Myth of Convenience- Which Nutritional Supplement Ingredients May Be Silently Undermining Your Health?*, 1 INTEGRATED SUPPLEMENTS NEWSLETTER 4 (Integrated Supplements), April 2007, at 1, available at <http://www.integratedsupplements.com/articles/Newsletter200704.pdf>.

cause people to die or otherwise reduce their quality of life. Furthermore, although Americans consume more drugs than people in any other nation,²⁵⁴ the total still pales in comparison to the amount of food additives we consume.

But the principal reason that the FDA should use a clear and convincing evidence standard for drugs is that taking medicine is a concerted choice. Although chemical additives are crammed into nearly every food imaginable, drugs are not. No one buys a different brand of cereal one day only to find out that it is loaded with drugs.

There is also a line of defense between the FDA and the consumer. As experts on medication, doctors are supposed to inform the patient of the side effects and benefits of prescriptions. This process adds a layer of reflection to taking drugs, something that is absent from food additives. For these reasons, the FDA should reverse its policy, and food additives should be held to a higher standard than drugs.

Now that we have laid out an approval process, one key feature is still missing: data. Even if the committee members are independent experts, their decisions can only be as good as the studies they review. Therefore, it is imperative that industry no longer be permitted to participate in the testing process. The following section explores an alternative system that can ensure these new independent FDA committees are only reviewing high quality studies.

C. Taking Industry out of Safety Trials

Pharmaceutical companies are skilled at manipulating data in ways that cast their products in a favorable light. One common tactic is to fund dozens of clinical trials with the expectation that only a few studies will be published.²⁵⁵ Random chance explains why this is a useful but deceptive strategy. To be accepted by the scientific community, the results of an experiment must be statistically significant at the five percent level. In statistical terms, the p-value must be $\leq .05$. This means that if a drug is no different than a placebo,²⁵⁶ only five percent of the experiments will have data at least this extreme.

254. Associated Press, *Americans Remain World's Most Medicated People*, ST. PETERSBURG TIMES, April 17, 2005, http://www.sptimes.com/2005/04/17/Worldandnation/Americans_remain_worl.shtml (last visited Feb. 26, 2010).

255. See MICHAELS, *supra* note 12, at 150.

256. This is the null hypothesis.

From the pharmaceutical industry's perspective, if a drug is ineffective, ninety five percent of its clinical trials will yield data supporting this conclusion. However, due to random chance, five percent of its trials will still provide evidence that the drug is beneficial. By funding dozens of experiments, corporations are exploiting the test for statistical significance. The drug manufacturer holds back the ninety five percent of trials that show the product's inefficacy.²⁵⁷ At the same time, it publishes the five percent of trials that attest to the drug's usefulness.²⁵⁸

Another common ploy is to truncate data. If a clinical trial lasts for two years and the results show that a given drug is ineffective, industry scientists simply look at smaller chunks of the data. Maybe the trial passes the test for statistical significance during a one year period. Maybe six months is the magic number.²⁵⁹ If cutting out time doesn't work, the beneficiaries can also be reframed. Instead of using data for the entire population, industry scientists often look at smaller demographics. If the drug doesn't have an effect on Asians, don't worry. Simply drop them from the study. Do Hispanics meet the test for significance? If so, leave them in. When that doesn't work, get more creative. Maybe the magic group is women aged twenty-seven to thirty-two with blue eyes.²⁶⁰ Never mind that only a couple trial participants may have fallen into this category.

Even more deceptive tactics include fabricating data, discontinuing studies that yield unfavorable results, and excluding individual subjects that develop adverse reactions, such as malignant tumors. When these strategies are insufficient, corporations have

257. Although data for all of the trials is required to be submitted to the FDA, many corporations withhold adverse studies.

258. See, Erik H. Turner et al., *Selective Publication of Antidepressant Trials and its Influence on Apparent Efficacy*, 358 NEW ENG. J. MED. 252, 255 (2008) (Ninety-four percent of the published studies reported positive results, whereas only 51% of the FDA-registered studies had positive results. "Overall, the studies that the FDA judged as positive were approximately 12 times as likely to be published" as neutral or negative studies.); see also David S. Liebeskind et al., *Evidence of Publication Bias in Reporting Acute Stroke Clinical Trials*, 67 NEUROLOGY 973, 973 (2006) (concluding that "publication bias is evident in the acute stroke research literature").

259. The drug manufacturer Pharmacia used this strategy to provide evidence that Celebrex reduces the incidence of ulcers. The highly respected *Journal of the American Medical Association* was fooled into publishing this "science." See MICHAELS, *supra* note 12, at 150.

260. VaxGen manipulated the data for AidsVax, an AIDS vaccine, in a similarly absurd manner. See MICHAELS, *supra* note 12, at 151.

simply ordered their scientists to write favorable reports regardless of the evidence.²⁶¹

The extent of these manipulative practices is easily observed when independent scientists conduct meta-analyses. Although this article has focused on how pharmaceutical companies employed these misleading tactics to gain FDA approval for artificial sweeteners, the problem is much more pervasive. Richard Smith, the Editor-in-Chief of the *British Medical Journal*, has pointed out several other notable examples of industry bias:

"The major determinant of whether reviews of passive smoking concluded it was harmful was whether the authors had financial ties with tobacco manufacturers. In the disputed topic of whether third-generation contraceptive pills cause an increase in thromboembolic disease, studies funded by the pharmaceutical industry find that they don't, and studies funded by public money find that they do."²⁶²

This abuse of the scientific process undermines both industry and independent research. It essentially creates a presumption that corporate science is false, going so far as to taint companies that do not engage in deceptive practices. As the junk science piles up, the public is pushed towards a tipping point.²⁶³ When distrust of science reaches this critical mass, it will be extremely hard to convince Americans that scientific results cannot be bought by the highest bidder. The inevitable result is that the public will lose confidence in science as a whole. The first effects of this phenomenon are already being felt.

For example, many parents refuse to vaccinate their children because they do not believe the science that shows vaccines are safe.²⁶⁴ Fear of industry deception has led to actual problems, such

261. See Keith J. Winstein & David Armstrong, *Top Pain Scientist Fabricated Data in Studies, Hospital Says*, WALL ST. J., Mar. 11, 2009, at A12. (Scott S. Reuben, former chief of acute pain at Baystate Medical Center fabricated data for twenty-one studies involving Vioxx, Celebrex, and Lyrica. Pfizer (maker of Celebrex and Lyrica) funded part of Reuben's research and paid him generous speaking fees.) For additional examples of these tactics, see footnotes 144–149 and accompanying text.

262. Richard Smith, *Making Progress with Competing Interests*, 325 BRIT. MED. J. 1375, 1375–76 (2002).

263. Malcolm Gladwell describes the tipping point as "the moment of critical mass, the threshold, the boiling point." See MALCOLM GLADWELL, *THE TIPPING POINT: HOW LITTLE THINGS CAN MAKE A BIG DIFFERENCE* 12 (2002).

264. See Nadja Popovich, *Vaccine Scare Shows How Emotions Can Trump Facts*, NPR http://www.npr.org/blogs/health/2010/02/risky_business_reactions_to_th.html (last visited May 23, 2010).

as an increased incidence of measles.²⁶⁵ A more salient example involves the H1N1 vaccine.²⁶⁶ Many people declined to get vaccinations because they believed the pharmaceutical companies were promoting unsafe vaccines.²⁶⁷ Although the H1N1 virus did not become a major threat, it is easy to envision a scenario in which an actual epidemic breaks out and people refuse to get vaccinated.

The loss of faith in science is not limited to health issues. The polarizing debate over global warming has accentuated the problem.²⁶⁸ Ralph Cicerone, president of the National Academy of Sciences noted that “[t]here is evidence that the corrosion in the public attitude to climate science has spread over to other areas of science.”²⁶⁹

The lesson to be learned is that industry-funded science undermines legitimate science. Government agencies must stop using it as a basis for decisions. Given the importance of public health, the FDA, in particular, should only rely on independently funded trials.

With this in mind, an entirely new pre-market approval system must be implemented. There are two options for such a system. First, the FDA could take on the responsibility of conducting the clinical trials. This presents some tangible benefits. For instance, because studies would be done in-house, an intermediate layer of FDA scientists would not need to review the trials. Additionally, as

265. Rong-Gong Lin II, *Rise in Measles Prompts Concern*, L.A. TIMES, May 2, 2008, available at <http://articles.latimes.com/2008/may/02/local/me-vaccine2> (last visited May 23, 2010); see also BBC News, *Rise in Measles ‘Very Worrying’*, <http://news.bbc.co.uk/2/hi/health/7872541.stm> (last visited May 23, 2010).

266. See Paul A. Offit, *Nothing to Fear but the Flu Itself*, N.Y. TIMES, Oct. 12, 2009, at A23, http://www.nytimes.com/2009/10/12/opinion/12offit.html?_r=2&em (last visited May 23, 2010).

267. *Id.*

268. See Rasmussen Reports, *Americans Skeptical of Science Behind Global Warming*, http://www.rasmussenreports.com/public_content/politics/current_events/environment_energy/americans_skeptical_of_science_behind_global_warming (last visited May 23, 2010). A recent poll noted the following:

Fifty-nine percent (59%) of Americans say it’s at least somewhat likely that some scientists have falsified research data to support their own theories and beliefs about global warming. Thirty-five percent (35%) say it’s Very Likely. Just 26% say it’s not very or not at all likely that some scientists falsified data. This skepticism does not appear to be the result of the recent disclosure of e-mails confirming such data falsification as part of the so-called “Climategate” scandal. *Id.*

269. Clive Cookson, *Public Losing Faith in Science*, FINANCIAL TIMES <http://www.ft.com/cms/s/2/1700ab46-1dbc-11df-9e98-00144feab49a.html> (last visited May 23, 2010).

the people running the studies and the people making approval decisions would be working within the same agency, communication should be more open. This may lead to better information when questions arise at the top.

On the downside, the federal government is not known for its efficiency.²⁷⁰ Even if one does not subscribe to this view, a majority of the American people do, and that provides a compelling reason to prevent an FDA expansion. First, the public no longer trusts the federal government.²⁷¹ They think it is corrupt and inefficient.²⁷² The average American believes the federal government wastes half of all its revenues.²⁷³ In addition, a majority of Americans want smaller government.²⁷⁴ These views have become even more dominant during the current recession.

As another matter, corporate America constitutes a powerful interest group that will oppose any reform of the FDA's regulatory system. An expansion of government would provide powerful am-

270. Friedrich Hayek nicely sums up a major tenet of classical liberalism, calling the free market a "more efficient allocation of resources than any design could achieve." CHRISTINA PETSOULAS, *HAYEK'S LIBERALISM AND ITS ORIGINS: HIS IDEA OF SPONTANEOUS ORDER AND THE SCOTTISH ENLIGHTENMENT* 2 (2001).

271. See Jason Iuliano, *Eliminating Earmarks: Why the Congressional Line Item Veto can Succeed Where the Presidential Line Item Veto Failed*, 112 W. VA. L. REV. 947, 957-58 (2010); Andy Barr, *Poll Finds Low Trust in Feds*, <http://www.politico.com/news/stories/0109/17424.html> (last visited May 23, 2010) (For example, a recent poll of registered voters found that "[o]nly 5 percent said they have a 'great deal' of trust that the federal government will manage its finances responsibly, while 23 percent expressed 'some' trust that the government will be financially responsible. Meanwhile, an overwhelming 63 percent of respondents described their amount of trust as 'not very much' or 'none at all.'").

272. See CNN, *Half of Americans Think Congress is Corrupt*, <http://www.cnn.com/2006/POLITICS/10/19/congress.poll/index.html> (last visited May 23, 2010).

273. See Lydia Saad, *Americans: Uncle Sam Wastes 50 Cents on the Dollar*, <http://www.gallup.com/poll/122951/americans-uncle-sam-wastes-50-cents-dollar.aspx> (last visited May 23, 2010) (finding that "Americans believe 50 cents of every tax dollar that goes to the government in Washington, D.C., today are wasted").

274. See e.g., David Boaz, *Americans Want Smaller Government*, <http://www.cato-at-liberty.org/2009/06/23/americans-want-smaller-government> (last visited May 23, 2010) (citing a Washington Post-ABC News poll that found Americans prefer smaller government to larger government by a margin of 54 to 41); Rasmussen Reports, *National Survey of 1,000 Likely Voters Conducted March 18-19, 2009*, http://www.rasmussenreports.com/public_content/politics/toplines/pt_survey_toplines/march_2009/toplines_benchmarks_march_18_19_2009 (last visited May 23, 2010) (finding that 66% of Americans prefer a smaller government with lower taxes and only 25% prefer a larger government with higher taxes).

munity, allowing corporations to mobilize public opposition. Hence, keeping the research process privatized is preferable.

This leads to the second option. The FDA could hire independent universities and clinical research centers²⁷⁵ (CRCs) to perform the safety trials. This would maximize efficiency, alleviate public concern over government expansion, and still remove conflicts of interest. Since pharmaceutical companies already use CRCs to conduct their safety tests, this may seem like a misguided recommendation. However, the problem with the current system is that it lacks independence. Because CRCs contract directly with corporations, they are unwilling to bite the hand that feeds them. This causes CRCs to rig the data and draw faulty conclusions. If we can insert an intermediary into this process, the CRCs incentives will change. Their goal will no longer be to please the pharmaceutical industry, but rather, to please the intermediary. The FDA can fill this role well.

When a corporation submits a new food or drug to the FDA for approval, the agency will construct the specifications for clinical trials and hold an auction to select the CRC or university lab that will test the new product. The sponsoring corporation will pay the FDA the low bid amount, and the FDA will pass this money along to the winner. The government routinely uses sealed first-price auctions to grant procurement contracts and to lease the mining rights to land,²⁷⁶ so there is no reason such a system cannot work in this context.

Naturally, not all CRCs and universities will be permitted to bid at the auction. If this were not the case, corporations could simply fund their own CRCs and underbid all the competitors. Instead, only labs with strict conflict of interest policies will be permitted to participate. At present, there are nearly a thousand CRCs, so finding a sufficient number of bidders should be easy. Even if few labs currently meet the FDA's strict standards, a market for independent CRCs will quickly develop. Also, as noted in the preceding section, many universities are tightening their rules regarding conflicts of interest.

275. The FDA defines a clinical research center as "a person [i.e., a legal person, which may be a corporation] that assumes, as an independent contractor with the sponsor, one or more of the obligations of a sponsor, e.g., design of a protocol, selection or monitoring of investigations, evaluation of reports, and preparation of materials to be submitted to the Food and Drug Administration." 21 CFR 312.3(b).

276. See R. Preston McAfee & John McMillan, *Auctions and Bidding*, 25 J. ECON. LIT. 699, 702 (1987).

To promote independence, a blind review process should be setup. The corporation should not know which CRC is evaluating its product. Likewise, the CRC should not know which corporation developed the test substance. Due to the number of companies that are researching similar drugs, this should not pose a problem, but even if determined CRCs figure out which corporation's drug they are testing, they have no incentive to act on that information. Because of the conflict of interest rules, their loyalties will lie with the FDA, not the pharmaceutical industry.

When the tests are completed, all data should be made available for public examination.²⁷⁷ Then the appropriate FDA advisory committee should review the studies and vote to approve or reject the product. Because the advisory committees will be composed of experts in specific fields and will have more time to evaluate individual substances, the oversight committee should grant strong deference to the lower committees' decisions. In judicial terms, the standard of review should be akin to abuse of discretion.

Taken together, these two changes can reform the entire culture of the FDA. No longer will industry be able to control the food and drug approval process.

CONCLUSION

In the last half century, an obesity epidemic has swept across America, leading to a surge in health problems. Excessive sugar consumption has further aggravated this situation. The problem persists because the public wants to both trim its waistline and satisfy its sweet tooth. To fill this market, corporations developed a series of non-caloric artificial sweeteners. It was truly a miracle: hundreds of times sweeter than sugar and none of the calories. Unfortunately, like most things that are too good to be true, artificial sweeteners came with a heavy price. They may not add extra calories to your diet, but they will cause a litany of health issues.

Corporations, which stood to make billions if their products succeeded, hid the dangers of artificial sweeteners from the Ameri-

277. The public overwhelmingly supports this reform. See Consumer Reports, *Consumer Reports Survey Finds Strong Backing for Drug Reforms*, <http://www.consumerreports.org/health/prescription-drugs/consumer-reports-survey-finds-strong-backing-for-drug-reforms-4-07/overview/consumer-reports-survey-finds-strong-backing-for-drug-reforms.htm> (last visited May 23, 2010) ("Ninety-two percent of Americans agree that pharmaceutical companies should make public the results of all of their clinical trial studies, which reveal a drug's effectiveness as well as possible hazardous side effects.").

can people. Some FDA scientists caught on to this deception and alerted their superiors. Sadly, the decision makers at the FDA had serious conflicts of interest. Like the corporations they were supposed to be regulating, these people would profit greatly if the artificial sweeteners were approved. Quite simply, FDA leaders put their personal welfare above everyone's safety.

If the FDA is to break free of industry control, reform is necessary.²⁷⁸ First, conflict of interest regulations must be strengthened. The public can only be confident in the FDA's decisions if its leadership does not have ties to corporations. The second proposed change requires hiring independent organizations to conduct the clinical trials. Corporations have repeatedly shown that they will employ deceptive tactics to get their drugs and food additives approved. Because the profit motive has corrupted their ability to perform legitimate studies, corporations should no longer be permitted to participate in the safety and efficacy tests. America's health is too important to trust with conflicted actors. To restore the agency's integrity, industry must be taken out of the FDA.

278. Although this Article focused on the FDA, the recommendations are equally applicable to other government agencies. Even those that have resisted industry capture can benefit by adopting more stringent conflict of interest regulations. The public's perception of the entire government is so poor that every agency has room to improve its image.

