One hundred years ago, in the wake of Upton Sinclair’s *The Jungle*, the ancestor of the FDA was created. The main sparkplug behind the agency was Harvey Wiley, a USDA chemist who became the agency’s first director. Wiley was a real champion of safer food and honest labeling, and the Bureau of Chemistry as it was then called, was a real tiger, making life hard for marketers of quack medicines, among other products. But as is customary for regulatory agencies, the agency created powerful enemies and eventually lost its original public health fervor.

That isn’t to say that the FDA is always wrong and never does anything useful. Its career employees are dedicated and would like nothing more than to vigorously enforce the law and protect consumers. And faced with threats like food-poisoning outbreaks from contaminated imported foods, the FDA swings into action, albeit after the fact. But several major factors have left the agency a shadow of its former self.

- This administration denigrates the value of the FDA. Nothing demonstrates that more clearly than the absence of a confirmed commissioner for just over one-fourth of this presidency—16½ out of 65 months. This administration simply puts deregulation above consumer protection.

- Annual budgets demonstrate concretely how Congress values the FDA. Since 1978, the headquarters staff of the FDA’s Center for Food Safety and Applied Nutrition (CFSAN) shrank by 11 percent, from 995 to 881 employees—despite there being more people to protect, more companies to regulate, and more laws to enforce (such as the Infant Formula Act, Nutrition Labeling and Education Act, and Dietary Supplement Health and Education Act).

- Congress has not served the FDA well in another important way. Congressional oversight hearings, which were once held frequently, serve to ferret out problems, look for solutions, and simply let the agency know that Congress cares how it’s doing. However, with the notable exception of Senator Chuck Grassley’s investigations of FDA’s handling of drug safety, the Republican-controlled Congress rarely holds oversight hearings, particularly on matters related to food safety and nutrition.
Salt: The Forgotten Killer

The issue:
Perhaps the single most harmful substance in the American food supply receives the least attention from the FDA: salt (sodium chloride). Because high dietary sodium levels increase blood pressure and the risk of hypertension, strokes, and heart attacks, the National Heart, Lung and Blood Institute (NHLBI)—a sister agency within the Department of Health and Human Services—has called for a 50 percent reduction in the sodium content of packaged and restaurant foods. In 2004, the NHLBI director estimated that cutting sodium levels in half could prevent about 150,000 deaths annually. Over the years, though, the FDA has been indifferent to that health crisis.

History:
In 1978, CSPI petitioned the FDA to revoke salt’s status as an unregulated “generally recognized as safe” (GRAS) ingredient, as well as to label sodium on all food packages and to limit sodium levels. The following year, an official FDA advisory committee concluded that salt should not be considered GRAS. The FDA, thanks to Commissioner Arthur Hull Hayes, a hypertension expert, publicized the link between salt and hypertension and added sodium to the voluntary nutrition labeling regimen then used, but never changed salt’s regulatory status. Hence, in 1982, CSPI sued the agency. The FDA mollified the court by saying that it would first try educational approaches to reducing sodium levels before regulating salt. In fact, though, the FDA did almost nothing. Over the next quarter-century, and despite nutrition labeling of almost all packaged foods, sodium consumption has increased, not decreased.

In late 2005, following countless government reports calling for reductions in sodium consumption, CSPI once again petitioned the FDA to revoke salt’s GRAS status and set limits on its use. The FDA has not responded. Indeed, salt reduction has never been included in the CFSAN’s annual list of priorities, and the FDA does not have a single staff member focused on devising regulatory or other approaches to lowering sodium levels in the food supply.

Trans Fat: The Deadliest Fat of All

The issue:
Once thought to be harmless, trans fat is now considered the most dangerous type of fat in the food supply. Trans fat, an odd sort of monounsaturated fat, causes heart disease by raising LDL cholesterol, lowering HDL cholesterol, and directly affecting arterial function. The great majority of trans fat comes from partially hydrogenated oil, which is used in countless products and restaurant fryers. Margarines, microwave popcorn, cookies, crackers, and French fries have been major sources of trans fat. (A modest amount of trans fat is naturally present in beef, lamb, and dairy products, though there’s no evidence that natural trans fats pose a problem.) A recent report from the Harvard School of Public Health estimates that trans fat has been causing between 72,000 and 228,000 fatal and non-fatal heart attacks every year. The FDA’s response to that major health problem has been minimal.
History:

In the 1970s and 1980s, two FDA advisory committees concluded that partially hydrogenated oil and trans fat were “generally recognized as safe” substances. That all changed in 1990, when a clinical study showed that trans fat changed cholesterol levels in ways that increased the risk of heart disease. Because of that and other preliminary research, the FDA did not allow trans fat to be included with monounsaturated fats on food labels, but did not require trans-fat labeling.

In 1993, CSPI first urged the FDA to require trans fat to be included in the new Nutrition Facts labels and in 1994 filed a formal petition asking for that. It wasn’t until 1999 that the FDA proposed labeling. In its proposal, the FDA stated that labeling alone would spur enough changes in product composition and consumer behavior that would save several thousand lives a year. That indicated that replacing all partially hydrogenated oil in all foods would save about 30,000 lives a year. It took another three years before the FDA finalized the regulation and almost three more before it went into effect. Each year of delay meant thousands of unnecessary premature deaths. The labeling requirement has impelled numerous food processors, including Kraft, PepsiCo (Frito-Lay, Quaker), and ConAgra, to largely switch to healthier oils. However, because restaurants are not required to disclose ingredients, few restaurants have changed oils.

During the lengthy regulatory proceeding, new research accumulated that demonstrated conclusively just how harmful partially hydrogenated oil is. In response, the Danish government effectively banned that oil, and companies, including McDonald’s and Burger King, switched to healthier oils in Denmark. In 2004, CSPI petitioned the FDA to require restaurants to disclose the presence of trans fat by means of signs or notices on menus. CSPI also petitioned the FDA to revoke the GRAS status of partially hydrogenated oil. The FDA has not acted on either petition, even though its inaction is resulting in possibly tens of thousands of deaths annually. Fortunately, additional companies are switching to healthier oils, with Wendy’s recently becoming the biggest restaurant chain to do so.

Safe Food: Buyers Still Need to be Aware

The issue:

Consumers expect the government to ensure that food is safe. FDA regulates about 80 percent of the food we consume—almost everything except meat and poultry, which are regulated by the U.S. Department of Agriculture (USDA). But the large number of illnesses linked to FDA-regulated foods each year shows that many foods are hazardous and some are deadly. The Centers for Disease Control and Prevention (CDC) estimates that food sickens 76 million people a year and causes about 300,000 hospitalizations and 5,000 deaths. Foods regulated by FDA, such as fresh fruits and vegetables, seafood, milk, and eggs, cause the vast majority of food-poisoning outbreaks. Even though many people think that meat and poultry cause most foodborne illnesses, in fact over two-thirds of all documented outbreaks are linked to foods regulated by FDA.
The history:

FDA has failed to control several well-known hazards in food. Egg-related outbreaks of *Salmonella* went on for over a decade while FDA and USDA squabbled over who should regulate egg producers. In the late 1990s the Clinton administration finally declared that FDA was in charge of shell eggs, but the agency has yet to mandate on-farm controls to control and eliminate *Salmonella* in egg-laying chickens and eggs.

Shellfish from the Gulf of Mexico contaminated with *Vibrio* bacteria kill about 20 people every year. Instead of simply requiring pasteurization of potentially tainted shellfish, FDA has relied on an industry-dominated state organization. Gulf Coast shellfish remain on the market today in every state except California—and there the FDA tried to stop the state from implementing its ban.

For mercury-contaminated seafood, it took over a decade of activism and several reports by the National Academy of Sciences to spur the FDA to warn certain consumers to avoid fish prone to high mercury levels. Such warnings—including advice on a government web site—help protect fetuses and young children from mercury’s harmful effects on the nervous system, but more action is needed. Information at fish counters is essential to warn consumers of the fish they should avoid.

While food imports are soaring, FDA lacks the authority to review the inspection programs in countries that want to ship food to the United States (a tool that USDA employs for meat and poultry products). Thus, audits of foreign food-safety programs are conducted only occasionally, at the invitation of the country involved. That is true even when FDA is investigating a foodborne-illness outbreak linked to food from another country. Instead, FDA relies on border inspections to find contaminated foods. Unfortunately, while FDA’s budget for inspections has increased significantly, the number of border inspectors has always been small and the percentage of imports that are inspected has dropped in half over the past decade.

With so little action by FDA, California (and several grocery chains) have taken matters into their own hands, by banning unsafe products or providing more effective warning labels. However, the FDA, despite the Republican party’s historic defense of states rights, has pressured California to stop trying to warn people about acrylamide (a cancer-contaminant in numerous processed foods), to warn people about mercury in seafood, and to ban the sale of Gulf Coast shellfish during the risky summer months. Fortunately, California has repeatedly rejected the FDA’s pressure (though a court overruled California’s mercury-labeling requirement for canned tuna).

Food Labels: Cheating Consumers (and Honest Companies)

The issue:

Consumers depend on honest, reliable information on food labels to protect their health and get the most for their food dollar. The FDA, since 1938, has had an express mandate to prevent false and misleading food labeling and, since 1990, to ensure that health and nutrition information on labels is accurate and not misleading. Despite that responsibility, food labels continue to be virtual minefields of misinformation. The FDA claims it must give priority to other matters because of shrinking resources. However,
enforcement of laws prohibiting misleading labeling has suffered not just because of budget cuts, but also because of a lack of will, institutional neglect, and political interference.

History:

In light of the FDA’s abdication of its traditional role, CSPI has sued, or threatened to sue, leading companies engaged in misleading labeling. In the last year, we obtained settlements, with or without actual litigation, from such companies as Tropicana, Quaker Oats, Frito-Lay, and Pinnacle Foods. If a small non-profit group can force quick settlements with major companies, then surely the FDA could find a couple of motivated lawyers among its 11,000-person staff to stop illegal labeling practices. If the Agency had the will to act, it could find the necessary resources.

FDA needs to take enforcement action against a wide range of misleading claims, such as the following:

- “Made with Whole Wheat” when the product also contains ordinary white flour;
- “Trans fat free” when the product contains significant levels of saturated fat;
- “Natural” claims on products that contain decidedly unnatural ingredients, like high-fructose corn syrup;
- “Contains fruit or vegetable” when the food contains little or none of the fruit or vegetable;
- “Burns fat” claims on yogurt and weight-loss claims for other dairy products.

Presently, only four people at FDA’s headquarters are assigned to stopping deceptive labeling, and they say they only have time to respond to questions, not to be proactive. Even when FDA field inspectors scrutinize a manufacturing plant for food-safety violations, they superficially examine only a few labels. The most efficient way to inspect labels would be to comb grocery store shelves, but the FDA has not done that for several decades. The FDA’s failure to stop deceptive labels has drawn the ire not just of consumer groups, but also of some companies that have publicly (in the case of the Sugar Association) or privately tried to get the FDA failure to stop competitors’ deceptive claims.

According to a new report to Congress, the FDA reports that in a recent 15-month period it issued only 10 warning letters for deceptive food label claims related to nutritional health issues (another 46 letters focused on allergenic ingredients, dietary supplements, and other topics). CSPI, which has filed complaints with the FDA concerning claims on more than 100 products over the past 10 years, suspects that at any one time hundreds of labels bear deceptive nutrition-related claims.

Rather than stopping labeling violations, the FDA has squandered significant resources on a program favored by industry—allowing disease-prevention label claims based on incomplete scientific data—but not authorized by its statute. Since 2003, under the guise of respecting the First Amendment free-speech rights of manufacturers, the FDA has approved “qualified” health claims for foods even though they are not supported by “significant scientific agreement” (the standard in the law). In an attempt to protect consumers, companies are required to qualify the claim by a disclosure indicating
the uncertainty of the evidence. Even though the FDA’s own research indicates that consumers are misled by such claims, the Agency continues to authorize them.

Obesity Epidemic: the FDA’s Effort Fizzles

The issue:

Obesity is one of the most serious health problems in the United States. Over the past three decades, rates of obesity have doubled in young children and adults, and tripled in teenagers. One of the major contributors to obesity appears to be soft drinks, both because they contain large amounts of sugar (10 teaspoons per 12-ounce container) and because beverages appear to be more conducive to obesity than solid foods. Soft drink consumption has soared in the last several decades.

The history:

In August, 2003, with much attendant publicity, FDA Commissioner Mark B. McClellan declared FDA’s intention “to confront the current obesity epidemic … and to develop new and innovative ways to help consumers lead healthier lives through better nutrition.” A year later, the FDA issued an “action plan” consisting of weak measures. Today, almost three years later, the FDA has accomplished essentially nothing.

Meanwhile, CSPI has urged the FDA to take several specific actions that would help prevent obesity:

- In 1999, to set a Daily Value (DV) for added sugars and then list added sugars and the percentage of the DV on nutrition labels.
- In 2004, to require large containers of foods (such as 20-ounce soft drinks and 4-ounce pastries) that are likely to be consumed at a single sitting to list the calories and other nutrients in the entire package.
- In 2005, to require health messages on soft drinks, because of the growing evidence that soft drinks are particularly conducive to obesity.

The only regulatory measure the FDA has moved forward with was in April 2005 when it issued an advance notice of proposed rulemaking on the labeling of single-serving containers and increasing the prominence of the calories statement on food labels. It will take years to finalize any regulation that the agency might propose. Also, the FDA sponsored a conference on restaurants and obesity, but the FDA doesn’t have much authority or plans to follow up with regulations. Overall, the FDA is fighting obesity not with a cannon, but a peashooter. The FDA’s battle has fizzled.