



Voluntary or Regulated? The Trans Fat Campaign in New York City

Artificially produced trans fatty acids—or partially hydrogenated oils—had been part of the American diet since the early 20th century. They gave foodstuffs a long shelf life, provided stability during deep-frying, and enhanced the taste of baked goods and sweets. For decades, they were the food industry's darling: in the 1970s, margarine was vigorously promoted as a healthier alternative to butter.

But in the 1990s, new studies showed that trans fats, as they were commonly known, might be dangerous. Further research confirmed that trans fats caused an increase in “bad” cholesterol and decreased “good” cholesterol, creating an increased risk of heart disease. By the early 2000s, the verdict was in—trans fats were a public health risk that contributed to heart disease. They were, unfortunately, everywhere—in the grocery store, at the school cafeteria, at high-end restaurants.

In 2004, Dr. Lynn Silver was named Assistant Commissioner, heading the Bureau of Chronic Disease Prevention and Control at the New York City Department of Health and Mental Hygiene. Combatting heart disease was high on her agenda because, in New York City, it was the leading cause of death—with even higher rates in the boroughs of Brooklyn, the Bronx, Staten Island and Queens than in Manhattan. One of the first issues Silver looked at was trans fat, a subject her predecessor had identified as a possible target for a public health policy change.

As much as a third of trans fat consumed in New York came from restaurant food. In spring 2005, Silver and her team decided to ask restaurants—as a public good—to change the way they prepared food. The department launched a highly visible public education campaign with the hope that pressure from customers, along with the desire to do the right thing, would persuade restaurants to stop using trans fat. But a year later, a survey revealed no change—its presence in restaurant food remained stubbornly high.

Silver concluded that it was time to take the next step: make the restriction mandatory, and restrict trans fat. The team began work on a regulation that would be both enforceable and fair.

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They had to decide: should the policy be informational or restrictive? Whom would it cover, and would it apply to all kinds of trans fat? What would be the maximum allowed trans fat in any product? How long would they give eating establishments to comply? What would be the sanctions for violations?

The team anticipated strong opposition from restaurant owners. They knew there would also be charges of a “nanny state”—government intrusion into the private decisions of citizens. But their first hurdle was closer to home. Both New York City Health Commissioner Thomas R. Frieden and Mayor Michael Bloomberg would have to sign off on the proposed regulation before it could go to the Board of Health for final authorization. They would want ironclad assurances that the science supported what would likely be a difficult sell politically.

Trans Fat

Trans fat occurs naturally in some meat and dairy products. But artificial trans fat forms when liquid vegetable oils are converted into partially hydrogenated semi-solid fats, such as margarine and shortening, by adding hydrogen to the oils through a process called hydrogenation.¹ The hydrogenation process was patented in 1903 and, in 1911, Crisco became the first partially hydrogenated oil widely marketed in the United States. Prior to that time all foods were made without artificial trans fat. Because partially hydrogenated oils allowed for extended product shelf life and greater fry oil stability, they became increasingly popular in the 1950s.²

As of 2005, naturally occurring trans fat accounted for only 21 percent of total US trans fat intake. The remainder was artificial—found mostly in processed foods, especially baked and fried goods and spreads. For decades, these chemically modified oils entered the food supply without a full evaluation of their effect on people’s health. But in the 1990s, studies began to identify trans fat as a health hazard.

In 2003, the federal Food and Drug Administration (FDA) required that all packaged goods display information on trans fat content by 2006. At the time, the median American intake of trans fat was 2 percent of daily calories.³ The American Heart Association recommended a daily trans fat intake of no more than 1 percent of daily calories—roughly 2 to 2.5 grams of trans fat per day.⁴ But trans fats were found in a range of popular foods—French fries, bread, donuts, cookies,

¹ For a fuller description of trans fatty acids, see Appendix 1.

² Angell, S., L. Silver, G. Goldstein, C. Johnson, D. Deitcher, T. Frieden, and M. Bassett, “Cholesterol Control Beyond the Clinic: New York City’s Trans Fat Restriction,” *Annals of Internal Medicine*, July 21, 2009. Much of the information in the following paragraph also comes from this article.

³ “Fat in Margarine is Tied to Heart Problems,” *New York Times*, May 16, 1994. See: <http://www.nytimes.com/1994/05/16/us/fat-in-margarine-is-tied-to-heart-problems.html>

⁴ Alice H. Lichtenstein et al, “Diet and Lifestyle Recommendations Revision 2006,” American Heart Association, <http://circ.ahajournals.org/content/114/1/82.long>

crackers—which made it difficult to avoid, and meant people were consuming far more than the recommended daily allowance. One McDonald’s order of large fries, for example, then contained 8 grams of trans fat; a typical Danish breakfast pastry had more than 3 grams; even microwave popcorn had 1.1 grams.⁵

The new science and the FDA regulation prompted many food manufacturers to reformulate their products to reduce the amount of trans fat. But the federal regulation did not apply to restaurants, which accounted for one third of daily caloric intake. If the US government would not address the problem, perhaps states would have to take it on. Or, in the case of New York City, the city health department.

New York City Department of Health

The New York City Department of Health was created in 1866, in part in response to a cholera outbreak in the city. From its beginning, the department focused especially on the health problems of children and the poor. In November 1866, Dr. Elisha Harris, of what was then the Metropolitan Board of Health, wrote:

We cannot fail to note the marked increase in the death rate, year by year, for nearly 20 years past... There is reason to believe that all this increase of the death rate is caused in particular classes of inhabitants. It is found to be mainly in those classes from which the paupers are derived, viz the ignorant and poor classes... Already we know that, as regards periods of life, the excess of mortality is in children under five years of age.⁶

To stop the spread of cholera, the new department stepped up efforts to improve sanitation, even going so far as to send workers to clean floors, fumigate rooms and burn the clothes of suspected cholera victims. Partly due to these efforts, New York in 1866 suffered one-tenth the number of cholera deaths that it had in an 1849 outbreak.

The department stayed consistently ahead of the public health curve. In the early 1900s, it opened the first public health laboratory using new discoveries about bacteria to prevent and control disease. By the 1950s, it had adopted strategies to control the spread of most infectious diseases. Antibiotics were used to treat and stop the spread of tuberculosis and sexually transmitted diseases and, by 1955, polio vaccination was a regular part of the New York City schools’ health program; by 1960, the city was virtually polio free. The department then turned its

⁵ Charlene Laino, “Trans Fats up Heart Disease Risk,” *Web MD*, November 15, 2006. See: <http://www.webmd.com/heart/news/20061115/heart-disease-risk-upped-by-trans-fats>

⁶ *Protecting Public Health in New York City: 200 Years of Leadership; 1805-2005*, The New York City Department of Health and Mental Hygiene, April 2005.

attention to diabetes, cancer and other chronic diseases, establishing in 1958 the Health Research Council with a \$7 million budget to study chronic and infectious diseases. Chronic diseases, including heart disease, cancer, chronic lower respiratory diseases and diabetes are the top causes of death in New York City.

In 2002, the Department of Health merged with the Department of Mental Health, Mental Retardation and Alcoholism Services to form the Department of Health and Mental Hygiene. The new department continued to focus on preventative health measures as well as policy changes to create healthy environments. With an annual budget of \$1.5 billion, the department's 6,000 employees dealt with issues as varied as monitoring the temperature of water in hot dog vendors' carts to battling avian flu. In 2003, Health Commissioner Frieden (who was a medical doctor) convinced Mayor Bloomberg to take the politically risky move of passing the Smoke Free Air Act, which banned smoking in most indoor places, including bars and restaurants.

"The mayor says he was warned that tourists from Ireland and Italy would never come to New York if we did it," Commissioner Frieden later said.⁷ "Now those countries have banned smoking too. It doesn't happen until it's happened in New York." Frieden took some innovative approaches to combating infectious and chronic diseases in the city because he believed that public health was essentially about social justice. "When anyone dies at an early age from a preventable cause in New York City, it's my fault," he noted.

The department was unusual among city health authorities. Thanks to New York City's sizeable population of 8.4 million, it could combine the resources and regulatory power of a state-level public health agency with direct implementation capacity and access to a large population.⁸ It also had a well-developed infrastructure, expertise in communications using modern media, the critical regulatory authority of a technical and independent Board of Health, and, most importantly, political support.⁹ "In New York City, we tend to be on the cutting edge—taking more aggressive actions than other cities," says Gail Goldstein, then-deputy director of the Cardiovascular Disease Prevention and Control Program.¹⁰ She adds:

I think certainly the reason we were able to implement all the cutting edge initiatives of the past 10 years was because we have a public health mayor [Bloomberg]. He has a very strong commitment to public health and was willing to fight those fights, from tobacco to ... calorie labeling to salt. And

⁷ Christopher Grimes, "How New York City Took the Lead in World Action on Health," *Financial Times*, June 27, 2006.

⁸ Duffy J., *A History of Public Health in New York City, 1866-1966*, New York: Russell Sage Foundation; 1974.

⁹ Frieden, Bassett, Thorpe & Farley, "Public Health in New York City, 2002-2007: Confronting Epidemics of the Modern Era," *International Journal of Epidemiology*, 37(5), 966-77. October 2008, <http://ije.oxfordjournals.org/content/37/5/966.full>

¹⁰ Author's interview with Gail Goldstein in New York City, on November 2, 2011. All further quotations from Goldstein, unless otherwise attributed, are from this interview.

when you have that kind of political will, you can do more aggressive things than you can elsewhere.

Trans fat/heart disease. As of the 21st century, heart disease had emerged as the leading cause of death in New York City, regardless of race, ethnicity or gender. The Centers for Disease Control (CDC) reported that for 2005, heart-related death rates in the boroughs of Brooklyn, the Bronx, Staten Island and Queens exceeded 300 per 100,000, compared with a national average of 253 (Manhattan rates were about average).¹¹ Dr. Lorna Thorpe, then-New York City deputy commissioner of health, said heart-related death rates were high due in part to high levels of poverty. “The national poverty level is 12 percent, and citywide we’re a lot higher than that,” she said in August 2005.¹²

Heart disease was caused by a range of factors, including genetics, obesity, tobacco use, diet and high blood cholesterol levels. While heart disease affected all New Yorkers, those in low-income areas were at special risk when it came to diet and cholesterol levels. Studies showed that with more fast food restaurants in lower-income and minority neighborhoods, as well as fewer supermarkets selling healthy foods, residents of low-income neighborhoods were more likely to consume high levels of trans fat, putting them at greater risk of developing heart disease.¹³

Choosing a campaign

When Assistant Commissioner Silver joined the Bureau of Chronic Disease Prevention and Control in February 2004, she set herself a goal to aggressively promote prevention efforts. One approach was to change diet and the physical environment. The question was how. And which disease? What would have the widest impact? What would be sustainable? In general, the Health Department decided which health problems to tackle based on data from school health surveys, phone surveys and hospital statistics, as well as the epidemiology of the city, in order to focus on issues affecting the greatest number of people. “We were creating a bureau of chronic disease here, and trying to figure out what our strategic approach would be to reducing the burden of chronic disease in the city,” says Silver.¹⁴

We’ve got 8 million people, we’ve got millions with chronic diseases, so it’s not something you do one by one, outside of the healthcare system. We had to figure out approaches that could have significant impact, reach

¹¹ Ford Fessenden, “Health Mystery in New York: Heart Disease,” *New York Times*, August 18, 2005. See: <http://www.nytimes.com/2005/08/18/nyregion/18heart.html?pagewanted=all>

¹² Fessenden, “Health Mystery in New York: Heart Disease,” *New York Times*.

¹³ Nicole I. Larson, Mary T. Story, Melissa C. Nelson, “Neighborhood Environments: Disparities in Access to Healthy Foods,” *U.S. American Journal of Preventive Medicine*; Volume 36, Issue 1, January 2009, Pages 74-81.e10

¹⁴ Author’s interview with Dr. Lynn Silver in New York City, on November 4, 2011. All further quotations from Dr. Silver, unless otherwise attributed, are from this interview.

most of the population, and be sustainable to reduce the burden of chronic disease. That was the challenge, because in the past most chronic disease public health interventions had focused on individual behavioral change, or healthcare system interventions, with limited success, rather than addressing the underlying environmental causes.

Silver's predecessor, Dr. Colin McCord, had taken an interest in trans fat. "I got a message from Dr. McCord and from Dr. Mary Bassett, the deputy commissioner for health promotion and disease prevention, who hired me: 'You should look at trans fat and figure out whether there's any danger,'" Silver recalls. "[But] we first had to figure out if the magnitude of the influence on cardiovascular disease was sufficient to merit public action. I started reading about it and essentially realized that this was a substance that was in the food supply that was clearly associated with harm, based on the epidemiologic literature."

McCord had talked to Dr. Walter Willett, professor of epidemiology and nutrition at Harvard, about the dangers of trans fat. Willett was one of the country's most active campaigners against trans fat. His 1997 study estimated that use of partially hydrogenated oils resulted in 30,000 heart disease deaths per year, representing "the biggest food processing disaster in US history." He subsequently helped persuade the FDA to require trans fat labeling on food products.¹⁵

But Silver had other priorities in her early months on the job.¹⁶ In fall 2004, six months after joining the department, Silver created the Cardiovascular Disease Prevention and Control Program and hired Gail Goldstein as deputy director. Dr. Sonia Angell, an internist trained in clinical epidemiology, started as director a month later. The bureau was charged with developing city-wide, community-level initiatives designed to prevent cardiovascular morbidity and mortality, and primarily addressed two modifiable risk factors for cardiovascular disease: high blood pressure and high cholesterol. "This concentrated effort to collectively address chronic disease had never existed before," says Goldstein.

There were two of us with a very small budget and we thought, 'What can we do to make an impact on a population of 8 million, where heart disease is the number one cause of death?' We did an assessment of the entire spectrum of interventions in cardiovascular disease, looking at what people were doing in terms of prevention and control, and we concluded that city-wide policies were activities where we could get the biggest bang for our buck. Policy would affect a lot of people, more than community-based programs which tend to require more staff for implementation and reach a smaller number of people.

¹⁵ Amanda Spake, "The Truth on Foods and Fats," *U.S. News and World Report*, July 4, 2004. See: http://health.usnews.com/usnews/health/articles/040712/12willett_2.htm

¹⁶ Sarah Perl, a policy advisor to Bassett, conducted initial research into the trans fat issue for the department.

In their early discussions, Silver, Angell and Goldstein considered a wide spectrum of initiatives to address the major risk factors for cardiovascular disease, such as high blood pressure and cholesterol.¹⁷ The program did launch a public health campaign on hypertension that sent health educators into doctors' offices to share new guidelines and best practices for treating high blood pressure. This focus on clinical treatment began to address the goal of controlling cardiovascular risk factors. But the team started to think about how people could avoid heart disease all together. The hypertension campaign had included educational materials on a heart-healthy diet (for example, low sodium). This focus on diet led the team to think about cholesterol. "High cholesterol is often controlled by medications, but diet and exercise are important factors as well," says Goldstein.

We really started looking at dietary factors that contribute to heart disease. And I think that's how [trans fat] came up. We felt like the harmful effects of [trans fat] were really clear in the scientific literature, that there was a real body of literature that said this stuff is not good for us and will have a significant effect on our health.

As Silver recalls it, they considered tackling saturated fats, which raise cholesterol and can increase the risk of heart attacks and strokes. But trans fat made more sense because, unlike saturated fats, which occur naturally in foods, most trans fat was manufactured.¹⁸ She observes:

It was not like red meat and milk, that everybody loves and has for dinner. Nobody goes and says, 'Can I have some trans fat, please?' Or, 'Honey, would you like trans fat for dinner?' It's not that kind of thing. It's more like lead in paint, something that somebody added to something for some purpose, but it ended up causing significant harm and it didn't really need to be there, it was replaceable. You can still paint your walls and have great new yellow walls without lead, and you can still make cannoli without trans fat.

At the time, the only place in the world that had banned or restricted trans fat was Denmark, which had done so in 2003. So the team began by compiling the scientific literature and data to determine whether a public health initiative around trans fat made sense. Goldstein remembers:

There was a lot of internal discussion about it. There was certainly a feeling that perhaps we should just restrict this product, since we knew it was bad for everybody. But we also felt like this was a potentially charged issue. And we needed to start with educating people, because we felt like no one really knew what trans fat was at the time.

¹⁷ The risks of smoking had already been widely publicized.

¹⁸ The bureau did tackle saturated fat in other settings, like day care centers and schools.

They looked not just at scientific data about the dangers of trans fat, but also at the ways restaurants were using it, what fats manufacturers were making, and to see what its role was in the food supply and cooking. McDonald's had set a precedent when it announced in 2002 that it would stop using trans fat (although it had not yet done so).

By the beginning of 2005, they had created a packet with articles and scientific studies about trans fat and its link to heart disease. Trans fat, for example, increased LDL "bad" cholesterol, and lowered HDL "good" cholesterol. Studies showed that it caused at least 500 deaths a year from heart disease in New York City. Moreover, there were healthier, inexpensive substances available, such as vegetable oils or those made from soybeans or sunflowers. There was no discernible difference in taste. Silver and Bassett reviewed the packet and the team sent it to Commissioner Frieden.

Mandatory or Voluntary?

The information packet started a lively debate inside the department: should they mandate restricted use of trans fat by restaurants, or ask for voluntary efforts? Silver favored a legal mandate. Before coming to the Department of Health and Mental Hygiene, she had spent 20 years working and teaching on food and drug regulation, amongst other issues. She had worked as a consultant to the World Health Organization, and at the Karolinska Institute in Sweden. Her experience led her to think that restaurants would not voluntarily give up using trans fat. In her first months at the Department of Health, for example, she had tried in vain to persuade McDonald's—at least in New York City—to make fast food healthier by making portions smaller or creating better children's meals. She notes:

It's hard to get people to invest time and money and attention to making changes that they don't necessarily see the need for, in relation to their business. Most people think that combating heart disease is a doctor's job, not a cook's. It's not that they're bad or lazy, it's that they're busy bakers and cooks, and in the food business, they're worried about making food that tastes good and that people want to buy as opposed to health.¹⁹

Silver had been impressed by an informal introduction to public health law she attended when she started at the department in 2004. "Wilfredo Lopez, who was one of our general counsel, gave us what he used to call Public Health Law 101, where he would introduce the new staff to our public health law framework," she says. As part of the session, Lopez talked about the department's authority over food service establishments. At the time, the department was in the process of revising New York City health codes, and Commissioner Frieden asked Silver which

¹⁹ Author's telephone interview with Dr. Lynn Silver on January 27, 2012.

codes the city should have on the books for chronic diseases. “Mostly, the initial concern was about cleaning up old archaic chapters,” says Silver.

I was much more interested in saying, “How can we use health law to prevent chronic disease?” which was not a traditional application of our legal framework. Our legal framework had been much more used to address infectious disease, particularly in the food-borne setting.

Silver realized that, in theory, the department had the legal authority to require restaurants to restrict trans fat. But such regulation, she knew, would be very controversial. “Food safety authority in the United States has not really been used to address non-communicable disease. [But] we thought that this was an essential way for food safety to move and to address the problems of the 21st century,” says Silver.

Silver’s cardiovascular staff, Angell and Goldstein, favored a voluntary approach, combined with a public education campaign. “[The American Heart Association] actually did an Internet-based survey of consumers to understand what they knew about trans fat. And they found fairly low knowledge about trans fat,” says Goldstein.

People had heard of it, they knew it was bad, but they didn’t know what it was in. As I was starting to talk to people, I realized, people don’t even know what this stuff is. How can you restrict it if you don’t even know where it is or what it is and why? It just seemed like we needed to educate people first.

Over the first few months of 2005, “we had a lot of internal discussion with Commissioner Frieden, Sonia [Angell], myself, our general counsel, Elliot Marcus and Robert Edman who led our food safety team,” recalls Silver. The food safety staff specifically questioned the department’s capacity to monitor restaurants, as well as the associated costs. Silver recalls:

Our food safety folks were actually very skeptical that restaurants would change unless it was regulated. They were also hesitant to use their regulatory authority to that end and they were concerned about the burden on the inspectors who were already overloaded, to have to enforce these types of things, and the financial burden. Anything you add to the law that people have to enforce [means] additional time and energy, and that’s a legitimate concern, because they still had to watch out for E. Coli and all those other things, like rats and cockroaches.

By April, Commissioner Frieden decided that it was best to try voluntary efforts first. The team decided to design a program to educate the public on the dangers of trans fat, and simultaneously persuade restaurants to restrict its use on a voluntary basis. “By that time, I agreed with the voluntary campaign; it felt like it was a reasonable way to do it. With the plan, we would

reassess progress [after a year], evaluate where we were, and decide what to do then,” says Silver. Before they could launch, however, they would have to establish a baseline.

Measures and Partners

Silver asked Elliott Marcus, associate commissioner of the Bureau of Food Safety and Community Sanitation, to send inspectors to survey current restaurant use of trans fat. She explained that they would need to re-survey a year later to see if there had been any progress. At first, Marcus was hesitant. Goldstein says: “The first time [Dr. Silver] went to him and asked, ‘Can we use your restaurant inspectors to survey the restaurants and see what they’re serving?’ he said no. I think he said no twice. [But] Lynn doesn’t take no for an answer and went back again.”

Traditionally, food safety inspectors ensured that restaurant workers used proper sanitary measures and that restaurants were clean. Silver was asking inspectors to address an issue that was not part of their normal domain. “A lot of the work we’ve done recently has focused on re-conceiving that area and saying that our control of food safety should also address illness,” says Silver. “That was new for Elliott [Marcus], and new around the country, and they already didn’t have enough inspectors.”²⁰

Marcus worried that measuring trans fat would take too much time. “I wanted to make sure that the time it would take to administer the survey would be minimized,” he says, “and integrated in the inspectors’ use of handheld computer technology, so as not to add to the weight of packs inspectors lug around all day.” He adds:

These are small things to others, but integral considerations for a field operation unit with specific mandates and union concerns. There is a tendency to believe that, because we visit every food service establishment in the city, it is easy and inconsequential to add activities to the inspection. But adding even five minutes to an inspection, when you inspect 26,000 facilities, results in sizable productivity concerns.

But over several meetings, Silver and her team presented scientific evidence of the dangers of trans fat. Silver also met with an advisory group of restaurants. Once Marcus saw that restaurant owners seemed interested in using trans fat-free products, he came around.

Baseline. In May and June 2005, the department’s restaurant inspectors conducted a baseline survey of 500 restaurants during their regular inspections to estimate how many were using trans fat. The answer was: about half.²¹ The high percentage of establishments already not

²⁰ Author’s telephone interview with Dr. Lynn Silver on January 27, 2012.

²¹ Goldstein clarifies that inspectors were not always able to determine the incidence of trans fats because a third of NYC restaurants did not have labeling for their food. So of those restaurants where trans fat use could be measured, half were using them.

using trans fat products provided persuasive evidence that there were viable alternatives to partially hydrogenated oils. The cardiovascular program staff then visited bakeries, kosher bakeries, and ethnic restaurants to understand if there were issues specific to the preparation of bread products or ethnic foods. Goldstein also talked to cooking oil companies and their research branches to learn more about non-hydrogenated oil blends that were either currently in production or under research.

The department developed a working partnership with the American Heart Association (AHA), which had just received a \$7 million settlement from McDonald's. In 2003, the consumer advocacy group bantransfats.com had filed a lawsuit against McDonald's, claiming that the restaurant chain had failed to inform customers that it was still using trans fat despite its highly publicized 2002 announcement that it would stop.²² Bantransfat.com won and donated the money to AHA, which took a new interest in trans fat. "They came out to hear about our plans to do an education campaign," says Goldstein.

We decided to develop a three-pronged approach, where we would educate consumers about trans fat and ask them to ask their restaurants to not serve trans fat; educate the restaurants about trans fat, and ask them to ask their suppliers for trans fat-free products; and educate the suppliers about trans fat, and encourage them to provide 0 grams trans fat products to their restaurant customers. The idea was to use a market-based strategy, where supply and demand would change the food environment.

Campaign launches

In August 2005, the New York City Department of Health and Mental Hygiene officially unveiled its trans fat public education campaign. The program developed and distributed posters, brochures and a health bulletin on trans fat and sent this information to the 30,000 licensed food outlets in the city, 15,000 suppliers and supermarkets, and hundreds of thousands of consumers through the City's 311 information system and other routes. Mailings urged restaurants to remove artificial trans fat from food, suppliers to promote products with 0 grams of trans fat, and patrons to ask about oils used.²³ An August 10 press release quoting Commissioner Frieden said: "To help combat heart disease, the No. 1 killer in New York City, we are asking restaurants to voluntarily make an oil change and remove artificial trans fat from their kitchens."²⁴ He compared trans fat to asbestos and lead.

²² "McDonald's To Pay \$8.5 Million For Misleading Public About Use of Trans Fat," *Democracy Now*, PBS, February 16, 2005. See: http://www.democracynow.org/2005/2/16/mcdonalds_to_pay_8_5_million

²³ Angell et al, "Cholesterol Control Beyond the Clinic: New York City's Trans Fat Restriction," *Annals of Internal Medicine*.

²⁴ Marc Santora, "Hold That Fat, New York Asks Its Restaurants," *New York Times*, August 11, 2005, p.A1.

To help restaurants, the department added a module on trans fat to its mandatory food handler's course. Over the next half year, more than 7,800 restaurant food handlers received the training. Restaurants seemed in favor of the campaign and eager to make the switch from partially hydrogenated oils to less harmful products. "Working together to reduce trans fat from our kitchens will be one more way to ensure an enjoyable and healthy experience," said E. Charles Hunt, executive vice president for the New York State Restaurant Association, which, at the time, represented 7,000 restaurants statewide.²⁵

No change. Eight months later, in April and May 2006, the department sent its inspectors back to city restaurants to gauge the effect of the voluntary program. Using the same methodology as the previous year, they surveyed 1,021 restaurants. The results were dispiriting. Despite the education campaign, extensive press coverage and fanfare, artificial trans fat use in the surveyed restaurants remained virtually unchanged at 51 percent.²⁶ Says Marcus: "When we said to [restaurant owners] look, trans fat kills people, it's not necessary, you can replace it, they said, 'Yeah, okay, fine.' And they kept serving it."²⁷

Preparing to regulate

Like Assistant Commissioner Silver, Associate Commissioner Marcus had been skeptical that restaurants, particularly large chains, would give up using trans fat on their own. "It's costly for them," says Marcus. "For McDonald's, for the fries, they told us that they needed like a nine month lead-in so that they could have the people that grow the corn from which they make the oil change the formulation. For them it's a sea change, it's like turning the Titanic." Silver chose to look on the bright side: at least the educational campaign had been beneficial. "I wouldn't say it was entirely unsuccessful," she comments.

The guy who has a *cuchifrito* stand in the Bronx, you can't expect him to know that partially hydrogenated vegetable oil is trans fat. Half the people in the health department didn't know that. It was complicated stuff; people don't have PhDs in biochemistry when they're working in a restaurant, or at the health department. So making it comprehensible to people, raising consciousness about it, creating educational tools so people could look at a product and even understand whether it had trans fat in it or not was important.

²⁵ Ibid.

²⁶ Angell et al, "Cholesterol Control Beyond the Clinic: New York City's Trans Fat Restriction," *Annals of Internal Medicine*.

²⁷ Author's interview with Elliott Marcus in New York City, on November 30, 2011. All further quotations from Marcus, unless otherwise attributed, are from this interview.

Labeling? But now Silver and her colleagues faced a dilemma. Volunteerism had not worked; it would have to be regulation. But what kind? She, Angell, Goldstein, Marcus, lawyer Martha Robinson, and the department's general counsel Lopez spent hours discussing the range of options. Would it suffice simply to label trans fat, or should they be actively restricted? Were there enough trans fat-free options for both frying oils and baking shortening?

Labeling, they decided, was not a viable option because it would benefit only those consumers who knew enough about trans fat to avoid it. That excluded several populations, including children, and left them still at risk of consuming too much trans fat. Moreover, the department was already lobbying for restaurants to display the number of calories in different dishes on their posted menu boards. They felt listing the number of calories as well as grams of trans fat on menus might be confusing for consumers. Moreover, they considered it wrong to allow restaurants to continue using trans fat, even with labeling, knowing it was harmful and that there were alternatives. "You should have zero artificial trans fat in your food," says Goldstein.

So we felt like labeling was not the answer for trans fat. This was something that you simply don't need to have and you shouldn't have in your food... It's kind of like labeling for arsenic. Why would you do that, why wouldn't you just take it out?²⁸

Replacements? By early summer, they had decided that the only sensible course of action was to restrict restaurants from using trans fat. But first, they had to educate themselves on what to recommend in its place, and whether there was a sufficient supply of alternatives. "We had some concerns about what would replace trans fat," says Goldstein.

One alternative to trans fat-containing products are products made with interesterified oil, which is a process involving enzymes. But nobody knows how an interesterified fat might affect the body. It makes a nice solid fat and works well in baked goods. But it hasn't been studied much, although supposedly they'd been using it in Europe forever... At the time there were some crude versions of blended oils, which didn't work as well for baking. And then there's palm oil. Palm oil has environmental implications, doesn't have the same technical properties as other shortenings and it's also high in saturated fat. Now there are many viable 0 grams trans fat free options that work as well or better than the items they replaced.

The team had learned, when they accompanied the food safety inspectors on restaurant visits, that they would have to evaluate frying and baking products separately. While there were several trans fat-free options for fry oils, there weren't as many for baking shortenings.

²⁸ Author's telephone interview with Gail Goldstein on January 27, 2012.

“Shortenings are tricky because shortening has very specific properties that allow a crust to puff and flake and be tender and all sorts of things, or to make a frosting stick,” says Goldstein. The team debated whether the proposed restriction should therefore apply only to fry oils. But they concluded that to restrict trans fat exclusively in cooking oils and spreads would be insufficient, as baked goods were the largest dietary source of trans fat.²⁹ Says Silver:

The largest portion of trans fat in the diet came from baked goods. So even though it was harder to reformulate them, I felt that the public health impact of the law would be greatly diminished if we didn’t cover them.

The team also considered whether the taste of foods would be altered. “The Commissioner even surprised us one day, organizing a tasting of trans fat-free donuts from a local bakery to see if they were good. They were delicious,” says Silver. “We didn’t want to take away people’s pleasure in food and give them something that tasted awful.”³⁰ The other question was supply. Would there be enough alternatives available? “The American Heart Association and others were raising concerns about whether the supply of trans fat alternatives would be sufficient, so we researched that very carefully,” says Silver.

We went to the conferences, we listened to the industrial projections from the companies. They were basically saying that by 2009, the supply would be sufficient for the nation. We were only about 3 percent of the US population... We concluded, based on these conversations, that with the timeframe we were providing, that the supply for New York City would be adequate.

Clear and enforceable?

The team spent the most time devising regulatory language that would be relatively easy for restaurant owners to comply with, and for the department to enforce. “Mostly it was about feasibility,” says Goldstein.

Everyone wanted to do it, but it took a really long time for us to figure out how. You can’t just say ‘You cannot serve products with artificial trans fat,’ because there’s no way to [enforce] that. They weren’t heated discussions, they were just long. We all sat in a room and looked at each other and said, how are we going to write this regulation?³¹

The first issue was measurement. The team planned to ask restaurant inspectors to monitor compliance by reading labels on the products used to prepare foods. Restaurants would be asked

²⁹ “Revealing trans fats,” *FDA Consumer*, September 1, 2003

³⁰ Author’s interview with Dr. Lynn Silver on January 27, 2012.

³¹ Author’s telephone interview with Gail Goldstein on January 27, 2012.

to retain original labels for food products that were or contained fats, oils or shortenings, or to provide documentation listing trans fat content for foods that did not come with such labels, since restaurant products, unlike packaged goods in grocery stores, are not required to bear nutrition facts panels on their labeling. But how would inspectors distinguish between naturally occurring trans fat (which would not be restricted) and artificial ones, when the labels did not? The issue literally kept Goldstein up at night. “It was a tricky operational question,” says Goldstein.

There’s naturally occurring trans fat and artificially occurring trans fat. We’re not regulating the naturally occurring trans fat. So if you have a product that contains both butter, which contains natural trans fat, and partially hydrogenated vegetable oil, how do you determine the trans fat content? The label doesn’t distinguish. In fact, it’s very difficult for a laboratory to distinguish the difference between natural and artificial trans fat. So we had to come up with a way to avoid the natural, but identify the artificial.

One night, Goldstein had an “aha moment.” They needed a two-step process. Rather than just looking at the number of grams of trans fat in a product, the restaurant inspectors would first look for partially hydrogenated oils in the ingredient list. If the oils were listed, that would mean artificial trans fat were present and only then would inspectors look at the trans fat content. The team had its wording. Restaurants could use products containing up to 0.5 grams of trans fat (an FDA threshold) per serving.³² The regulation would apply to all licensed food establishments, including restaurants, school cafeterias, caterers, senior centers, and street-food vendors.³³

Then there was enforcement. Silver and Marcus discussed the options. As with every agency decision, the variables were cost, time and personnel. “I said everything is enforceable, given the resources,” says Marcus.

That means that if you want to check on whether or not various products contain trans fat, you need to check labels. That takes time. When you are inspecting 24,000 restaurants, even if it takes an extra 10 to 15 minutes, that’s a considerable amount of fulltime equivalents in people hours. We needed to make sure that we had the resources to carry that out and still meet the expectation that we’d inspect all restaurants at least once a year.

Silver knew that any program that incurred additional costs could raise concern from the commissioner, mayor or Board of Health. She says that, given assurances that the department would consider difficulties in meeting inspectional targets for food service establishments, Marcus was convinced that this issue should not torpedo the initiative. She expands:

³² The FDA threshold provided for the presence of naturally-occurring trans fats.

³³ Angell et al, “Cholesterol Control Beyond the Clinic: New York City’s Trans Fat Restriction,” *Annals of Internal Medicine*.

Anything that you do to add to the time of the inspections means [the inspectors] may get fewer inspections done. So we had to win them over and talk to them many times... We didn't have any specific funding, so Elliott [Marcus] and his team of inspectors had to do some extra work with no extra money. But it wasn't so much extra work that it wasn't feasible.³⁴

In early August 2006, the team presented its plan to Commissioner Frieden. Their proposal called for a six-month phase-out period for artificial trans fat in fry oils and spreads, and in baking shortenings. It stated: "No foods containing artificial trans fat, as defined in this section, shall be stored, distributed, held for service, used in preparation of any menu item or served in any food service establishment." An exception was made for foods, like potato chips, served directly to patrons in the manufacturers' original sealed package, proposed by Lopez, for legal reasons. Frieden approved the initiative.

But their job was not done. Only if Mayor Bloomberg agreed could they take the proposal to the Board of Health—which would meet next on September 26. "The first step was the health commissioner had to win over the mayor," recalls Silver.

We prepared detailed presentation and briefing materials and a health impact analysis for Mayor Bloomberg, who's a numbers man. He wanted to know, what's the benefit of this, how many lives will it save? And we had to try and do our best estimates of epidemiologic impact, which are difficult in many of these measures, because it's not always entirely clear.

Their briefing packet and slide show detailed the dangers of trans fat, the proposed restriction, and its expected benefits. For example, they noted that in 2004, 23,000 New York City residents had died from heart disease, and that nearly one-third of those were under 75. They also cited scientific studies that estimated as much as 23 percent of coronary heart disease events could be avoided by replacing trans fat with healthier alternatives.

The team tried to anticipate objections from the mayor and members of the Board of Health. No doubt city leaders would ask how the restriction would affect small business owners. What about expected pushback from the restaurant industry? How should the politicians respond? Was the science ironclad? There would also be queries about the "nanny state." Wouldn't a restriction on trans fat smack of paternalistic government trying to dictate to citizens what they should and should not eat? Silver and her team hoped Commissioner Frieden could sell the restriction to City Hall and the Mayor on the grounds that the benefits outweighed the risks.

³⁴ Author's phone interview with Dr. Lynn Silver on January 27, 2012.

APPENDIX 1

Trans fatty acids: definition

Excerpt from *Circulation Magazine*

Trans fatty acids contain at least one double bond in the trans configuration. The carbon/carbon double bonds of fatty acids can exist in either the cis or trans configuration. When the two hydrogen atoms are on opposite sides of the double bond, the configuration is termed trans; when the two hydrogen atoms are on the same side of the double bond, the configuration is termed cis. Lack of rotational mobility precludes interconversion of configurations under normal circumstances. The bond angle is larger for a trans than a cis double bond. Therefore, the presence of a trans, relative to a cis, double bond results in acyl chains that can pack together more tightly.

Trans double bonds occur in nature as such. They are the result of anaerobic bacterial fermentation in ruminant animals and are thereby introduced into the food chain. Humans consume them in the form of meat and dairy products. Trans double bonds are also formed during the hydrogenation of either vegetable or fish oils. Oils are hydrogenated to increase their plasticity and chemical stability, hence their potential use in food products. It is important to note that hydrogenation results in a number of changes in the acyl chain of the fatty acid moiety, all of which can impact physiological parameters: conversion of cis to trans double bonds, saturation of double bonds, and migration of double bonds along the acyl chain resulting in multiple positional isomers."

Source: Alice H. Lichtenstein, "Trans Fatty Acids, Plasma Lipid Levels, and Risk of Developing Cardiovascular Disease. A Statement for Healthcare Professionals from the American Heart Association," *Circulation*, 1997; 95:2588-2590.

See: <http://circ.ahajournals.org/content/95/11/2588.full>