Philadelphia Story

By Kay H. Jones
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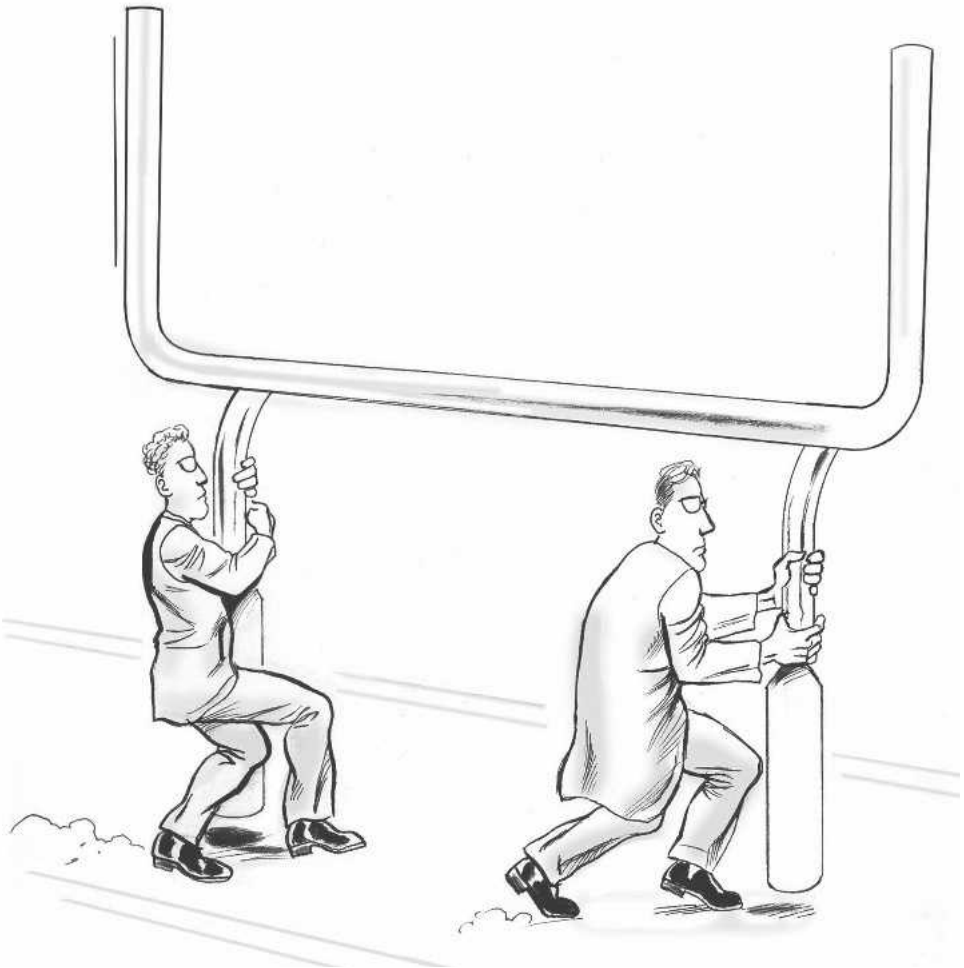
In June 2007, the U.S. Environmental Protection Agency proposed a further reduction of the National Ambient Air Quality Standard (NAAQS) for ozone. The original standard was set in the wake of the 1970 Clean Air Act. It has been revised twice in the intervening 37 years in response to ongoing research on the health effects of ozone exposure; the standard was relaxed in 1977 when research suggested the original standard was a product of flawed science, and then tightened in 1997 when new research suggested ozone exposure was more risky than previously thought. Though the standard itself has shifted back and forth, the EPA has constantly tightened its regulatory requirements so as to achieve compliance with the standard.

I suggest that the EPA's efforts to tighten the standard amount to little more than moving the goal posts at a time when the nation (outside the troublesome Los Angeles Basin and Houston) is close to being in compliance with the current standard. That is, the new standard is not about promoting health, but about maintaining the EPA's command-and-control regulatory position in perpetuity. To understand why I make this claim, consider the nation's ozone regulation history.

AS GOES PHILADELPHIA In 1979, I retired from the U.S. Public Health Service and at the time was serving as the senior adviser on air quality at the President's Council on Environmental Quality (CEQ). In that role, I was responsible for reporting on the status and trends of the nation's air quality in the *President's Annual Environment Report to Congress*. A professorship at Drexel University in Philadelphia followed. My first lecture to the faculty and students in the civil engineering department was entitled "As Goes Philadelphia, So Goes the Nation's Smog Problem." Based on my CEQ assessment, the smog problem in Philadelphia represented the upper bound of the measured ozone impacts in the nation, except for the L.A. Basin and Houston. Philadelphia is in the heart of the East Coast smog corridor that stretches from Washington to Boston. This relationship has held true over the last 30 years, so I considered Philadelphia an indicator of the nation's ozone air quality regulation.

The Clean Air Act of 1970 set the framework for establishing NAAQS for five major air pollutants, including ozone. The legislation also set the timetable for achieving the standards. The original ozone NAAQS was set at 85 parts per billion (technically, 0.08 parts per million) for one hour, not to be exceeded on more than one day per year. That is, for only one day a year could ozone concentration levels persist at 85 ppb or more for one hour. The attainment target date for this standard was — unrealistically — 1975.

The actual baseline (or "design value") ozone level in the Philadelphia metro area in 1975 was 199 ppb. Hence, to comply with the ozone standard, Philadelphia had to reduce its



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ozone level by 57 percent. As shown in Figure 1, the city's ozone level began to decline, mainly because of the infusion of auto emissions controls.

MOVE FORWARD, MOVE BACK In 1977, the standard was revised upward to 125 ppb because the single study upon which the original 85 ppb standard was based was discredited by the EPA. That study had indicated supposed adverse health effects at 100 ppb for a one-hour exposure. The EPA had taken that number, applied a 20 percent safety margin, and established the 0.08 ppm standard (85 ppb after rounding). In 1977, the baseline study was found to be faulty scientifically, so the EPA turned to another study that showed respiratory stress in exercising adults at a one-hour exposure of 150 ppb of ozone. Again applying a 20 percent safety margin, the EPA set the new standard of 125 ppb.

By 1986, the ozone level in Philadelphia had dropped to 156 ppb, a reduction of 22 percent from a decade earlier. Though the city was still far away from the original 85 ppb standard, it was slowly growing close to the revised 125 ppb standard.

In 1990, Congress passed a new Clean Air Act that amended the earlier legislation. The new law required that all metro areas, as well as some remote non-metro counties, be categorized based on their ozone levels over the previous three years. The inclusion of 1988 data (which was clearly an atypical meteorological year — Jonathan Adler and I offer a detailed analysis of the bias associated with the use of these data in Cato Policy Analysis #233, published July 1995) caused Philadelphia's design value to inflate to 187 ppb. This classification scheme resulted in some 98 metro areas (outside of California) being labeled as non-compliant with the ozone NAAQS.

But, just as with Philadelphia for the previous decades, national progress was being made to achieve the ozone standard. By 1994, there were only 17 metro areas (outside California) out of compliance with the NAAQS. The design value for Philadelphia, itself, fell to 139 ppb, only 10 percent above the 125 ppb standard. By 1997, Philadelphia's design value was only 131 ppb, or 4.5 percent above the goal.

MOVE THEM BACK (AGAIN) The ozone air quality in Philadelphia and the rest of the nation was improving rapidly. So what did the EPA do? They moved the goal posts. In 1997, they moved the standard back to 85 ppb, though the persistence timeframe was increased to eight hours. The Clean Air Science Advisory Committee, which acts as the external review body on EPA standard-setting, agreed that changing the standard from 125 ppb to 85 ppb was appropriate in light of a 1997 study indicating that children at a summer camp showed respiratory effects when ozone was in the range of 70 to 90 ppb during an average exposure of six to eight hours. Though the committee backed the new, lower standard, it also advised the EPA that regulatory enforcement should be no more stringent than what it had been previously — that is, the allowable exceedance rate of once per year under the old standard should be recalibrated to fit the new standard.

In general, one day of ozone above 125 ppb would equal about nine days of ozone above 85 ppb in most urban areas. But the EPA ignored the committee's recommendation and set the limit at about four days per year above 85 ppb. The design value for Philadelphia was now 101 ppb, or 16 percent above the new ozone NAAQS. The goal posts had moved 11 percent further away.

But Philadelphia's ozone level continued to improve. By 2005, the city's design value was 86 ppb, only 1.2 percent above the current ozone NAAQS. The endzone was in sight! It would thus seem an appropriate time for the EPA to take a bow for its efforts and hand the air-quality regulatory baton over to state and local governments so that they could establish and pursue local air quality policy as appropriate. Not a chance.

The EPA is trying to move the goal posts once again, proposing a new standard in the range of 65 to 75 ppb — 65 ppb is arguably close to background. If the 65 ppb standard were adopted, 575 counties — that is, 91 percent of the nation's monitored counties — would be non-compliant. Further, there are no reasonable control strategies for achieving a further 13 percent to 24 percent reduction in ozone precursor emissions to meet the two proposed standards. Despite reams of support documentation, there is no new scientifically valid information to suggest that the ozone NAAQS needs revision to enhance public health protection.

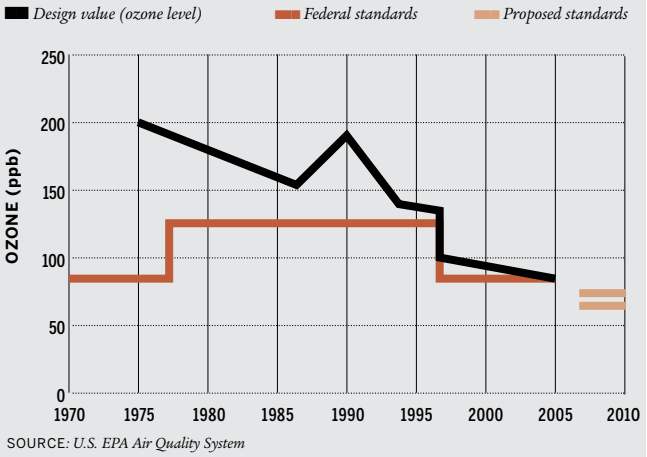
Is there a public health benefit here? The EPA claims that lives will be saved. For Philadelphia County (one of the 12 EPA test cases), the ozone-related death rate estimate is 0.20 percent of the current total observed death rate. The projected death rate, assuming the 65 ppb standard would be met, is 0.15 percent of the total. That is a 0.05 percent net benefit. If we run the EPA risk model backwards to 1980, the ozone-related death estimate would be 0.27 percent of the total. In comparison, the all-cause mortality rate in Philadelphia has dropped by some 20 percent since 1980 because of advances in medical care, while a drop of 33 percent in Philadelphia's ozone level produced only a 0.07 percent relative mortality reduction.

The EPA surely needs to put the nation's smog problem in perspective and stop moving the goal posts. R

Figure 1

Moving the Goal Posts

Philadelphia ozone levels compared to federal standards



SOURCE: *U.S. EPA Air Quality System*

A Gene-Splicing Contrivance

By Henry I. Miller
Hoover Institution

"If you put the federal government in charge of the Sahara Desert, in five years there would be a shortage of sand," Milton Friedman once quipped. That is certainly true of the international bureaucrats I rubbed elbows with in September during the meeting of a hapless United Nations task force charged with setting regulatory standards for foods obtained through biotechnology. They are making it harder for anyone, anywhere, to produce more varied, safe, and nutritious foods economically.

The task force was organized under the auspices of the Codex Alimentarius Commission, which sets food standards on behalf of the UN's Food and Agriculture Organization and the World Health Organization. Unfortunately, the task force's work is a long-term exercise in self-indulgent irresponsibility on the part of government bureaucrats and industry lobbyists. Now in its eighth year, the mission of the task force is to create new regulatory requirements that apply only to foods made with the newest, most precise, and most predictable techniques of biotechnology — gene-splicing, or "genetic modification" — while exempting others made with far less precise and predictable conventional technologies. Having already stifled innovative research on food plants and microorganisms in past years, it is now metastasizing to other areas, such as animals and even animals immunized with high-tech vaccines.

It is one thing to regulate new foods with *traits* that are of potential concern. It is quite another to regulate merely because a certain technique has been used, especially when the technique is state-of-the-art and superior to its predecessors. It is rather like circumscribing for extra regulation only cars outfitted with disk brakes, radial tires, and air bags — and then limiting only those vehicles to a lower speed. The task force's regulations impose various arcane and highly sophisticated requirements for food from gene-spliced organisms merely because it is possible (often at great expense and effort) to meet them. This unscientific and illogical approach is the antithesis of the quest for the degree of regulation that is necessary and sufficient.

The members of the task force — including the U.S. delegation — have systematically ignored scientific principles as well as the basic axiom that the degree of regulatory scrutiny should be proportionate to risk. They disregard the scientific consensus that gene-splicing is an extension or refinement of older, traditional techniques of genetic modification and that it does not warrant discriminatory, excessive regulation. They overlook the fact that during two decades of widespread use, the performance of gene-spliced crops has been spectacular, with farmers enjoying increased yields, decreased use of agricultural chemicals, lower occupational exposures to pesticides, and decreased release of carbon dioxide — and that there has not been a single consumer injured or ecosystem damaged.

Henry I. Miller, a fellow at the Hoover Institution, was the founding director of the Office of Biotechnology at the FDA, 1989–1993. His 2004 book *The Frankenfood Myth* was selected by Barron's as one of the 25 best books of that year.

ENTRY BARRIERS Much of the September task force meeting was devoted to the drafting of a guideline for a "food safety assessment" of gene-spliced foods that have been "modified for nutritional or health benefit." The new guideline ensures that almost any important nutritional advance could be blocked by a country for reasons of ideology or trade protection. Suppose that plant breeders use gene-splicing techniques to construct a peanut with deletions in the genes that express allergens, or a new variety of low-gluten wheat appropriate for the sufferers of celiac disease (dietary gluten intolerance). The new guideline requires regulators to consider whether the alterations, which are obviously beneficial to persons with peanut allergy and celiac disease, respectively, could somehow be detrimental to other sub-populations. Could their very slightly lower concentrations of protein cause malnutrition in people who normally consume large amounts, for example? This is an absurd question. Would they expect food producers to perform feeding studies in rodents or monkeys — or humans? (There is no remotely similar requirement for conventionally produced new plant varieties, which are more crudely constructed and less predictable but are completely unregulated.) But a regulator could simply say the requirement is in the Codex guideline, you haven't met it, tough luck.

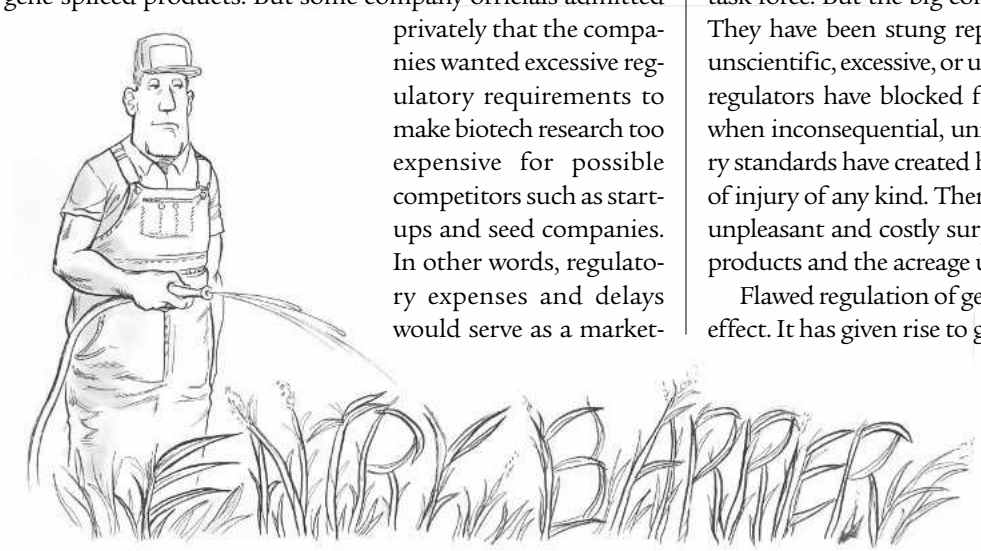
The major agribusiness companies (whose lobbyists flock to the task force's meetings) endorse and collude in the Codex process. During the meetings, industry lobbyists literally whisper in the ears of the U.S. government representatives, trying to eke out small concessions for their own narrow interests. At the end of the previous meeting of the task force, Michael Phillips, vice-president of the Biotechnology Industry Association, conceded to me that the outcome in Chiba "is as stupid as you think it is, but we got what we needed." His organization is perhaps the prototype of an organization with plenty of money but little integrity.

Big companies like stringent regulation if it hurts their competitors and confers on their products a sort of Good Housekeeping seal of approval. Long before the first gene-spliced plants were ready for commercialization, a few agrochemical and biotechnology companies, led by Monsanto and Calgene, approached senior policymakers in the Reagan administration and requested that the Environmental Protection Agency, Department of Agriculture, and Food and Drug Administration create a regulatory framework specific

to gene-spliced products. The policies recommended by the biotechnology industry were predicated on the myth that there is something fundamentally novel and worrisome about gene-splicing techniques, and the proposed policies were far more restrictive than could be justified on scientific grounds. Often, the industry's recommendations were even more burdensome than those proposed by regulators.

The over-regulation sought by the big agribusiness/biotech companies in the United States and abroad also served to placate the packaged food industry. Food companies see great potential value in gene-spliced food crops but, cognizant of anti-biotech consumer sentiment in Europe, they are willing to pay a high price to obtain what would amount to a federal government endorsement. Because competition in the food industry is intense and profit margins are very small, individual companies and their trade associations fear the effects of anti-biotechnology activism and its resulting negative publicity. These companies, too, have supported stultifying regulation in order to preempt activists' condemnation of foods that contain gene-spliced ingredients.

CONSPIRACY AGAINST THE PUBLIC The agbiotech industry said early on that this excessive regulation was intended to placate anti-biotech activists and provide reassurance to consumers that government regulators had evaluated and cleared gene-spliced products. But some company officials admitted privately that the companies wanted excessive regulatory requirements to make biotech research too expensive for possible competitors such as start-ups and seed companies. In other words, regulatory expenses and delays would serve as a market-entry barrier. But even the industry's ostensible reason for demanding excessive regulation was not credible. As the then-president of the consumer advocacy group Consumer Alert testified to a federal investigative panel, "For obvious reasons, the consumer views the technologies that are *most* regulated to be the *least* safe ones. Heavy involvement by government, no matter how well intended, inevitably sends the wrong signals. Rather than ensuring confidence, it raises suspicion and doubt." Surely, a better philosophy is to choose progressive, rational public policy that defies the myths and then to vigorously educate the public as to its appropriateness.



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If the industry's plan was to roll back regulation after competition from agbiotech startups and seed companies had been eliminated by high barriers to entry, that "regulatory rescue" strategy has failed dismally. If anything, regulation is becoming progressively more stringent and product development more expensive. (It is no coincidence that more than 99 percent of the acreage of gene-spliced crops is accounted for by five huge-volume commodity crops.)

This is not a new phenomenon. In the 18th century, the patron saint of capitalism, Adam Smith, was wary of the motives of some capitalists. Acutely aware of the potential conflict between self-interest and the public interest, he warned that any policy advocated by businessmen should be viewed with the greatest suspicion and that special interests often urged the government to interfere with free markets. Past examples include tariffs on steel and limits on imports of Japanese automobiles, lending support to Smith's observation that "people of the same trade seldom meet together, even for merriment and diversion, but the conversation ends in a conspiracy against the public, or in some contrivance to raise prices."

But in the end, encouraging unscientific, excessive regulation is like eating your seed corn: a short-term expedient but a long-term catastrophe, especially for smaller farmers, plant breeders, and academic researchers (who are not represented at Codex). The representatives of the major agribusiness companies at Codex are unapologetic about the burden that the regulations place on academia, and they freely admit that there is little prospect of revisiting the flawed assumptions that drive the work of the Codex task force. But the big companies are themselves not immune. They have been stung repeatedly, and often unexpectedly, by unscientific, excessive, or unwise regulation — for example, when regulators have blocked field trials of innovative products or when inconsequential, unintentional failures to meet regulatory standards have created huge legal liability even in the absence of injury of any kind. There will be additional examples of such unpleasant and costly surprises as the number of gene-spliced products and the acreage under cultivation grows.

Flawed regulation of gene-splicing exerts a pernicious ripple effect. It has given rise to governmental cottage industries that are devoted not just to performing unnecessary case-by-case reviews but also to creating and maintaining databases and mechanisms to share their contents. Flawed, worthless "risk assessment" studies have been funded and performed and international conferences convened on subjects from biosafety and liability for mishaps to "ethics." Public policy toward gene-splicing is one of the most monumental hoaxes of all time and all Americans are paying for it.

Worst of all, the Codex task force represents only the tiniest tip of a vast iceberg of international organizations — many of which, including other UN agencies and programs and the Organization for Economic Cooperation and Development, are liberally funded by the United States and supported by American industry. Those organizations, their agencies, programs, and projects often ignore scientific principles and the fundamental principles of regulatory policy in order to promote hugely debilitating and unnecessary regulation. Politics trumps all. And quite often, industry is a fellow-traveler. R