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REVIEW

The Removal of Lead from Gasoline: Historical and Personal Reflections

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Tetraethyllead (TEL) was first fabricated for use in gasoline in 1923. Shortly after manufacture began, workers at all three plants began to become floridly psychotic and die. A moratorium on TEL production was put into place, but was lifted in 1926. Between 1926 and 1965, the prevailing consensus was that lead toxicity occurred only at high levels of exposure and that lead in the atmosphere was harmless. Most of the data on lead toxicity issued from a single source, the Kettering Laboratory in Cincinnati. In 1959, the first warnings of adverse health effects of lead at silent doses were raised by Clair Patterson, a geochemist. In hearings before the Senate Committee on Public Works, Senator Edward Muskie raised the question of adverse health effects from airborne lead. As new data accumulated on health effects of lead at lower doses, the movement to remove lead from gasoline gained momentum, and the Environmental Protection Agency examined the question. The removal of lead would take place over the next 25 years, and its accomplishment would require a severe change in the federal stance regarding its hazard. This article details the interaction of various forces, industrial, regulatory, judicial, public health, and public interest, that were engaged in this contest and estimates the value of this step. © 2000 Academic Press

INTRODUCTION

E.I. DuPont and General Motors formed the Ethyl Gasoline Company in 1922 and began to make commercial tetraethyllead in 1923. Standard Oil began production of in 1924. Shortly after production began, workers in three plants, Dayton, Ohio, Bayway, New Jersey, and Deepwater, New Jersey, began to die, and many more became floridly psychotic. A moratorium on production was imposed, and the Surgeon General convened a meeting of scientists and industry officials. Shortly after the Surgeon General's committee pronounced TEL safe for general use in 1926, the Public Health Service recommended that the allowable concentration of tetraethyllead be set at 3 cc per gallon. Ethyl quickly agreed to comply, relieving the government of any pressure to regulate lead in gasoline. For the next 35 years lead toxicity as a health issue virtually disappeared from sight (1).

The struggle to remove lead from gasoline, which began in 1959, would occupy the next three decades. Its removal would require a rearrangement of both the scientific and the public perception of its toxicity and a realization that children's brains were the most sensitive targets. In the process, a fledgling environmental movement would gain strength in contest with the lead industry, while responsible government officials would be forced to jettison their own complacent picture of lead's dangers and realign their long held proindustry bias.

ARRANGING A LEAD CONSENSUS

After the Surgeon General's report, a single figure, Robert Kehoe, was cultivated by the industry as the dominant authority on lead. Data on the health effects of lead were sparse, and the only source of funding for research came from industry treasuries. What little research there was issued almost exclusively from Kehoe's group at the Kettering Laboratory in Cincinnati.

C.F. Kettering established the laboratory that bore his name with an initial gift of $130,000 from Ethyl, E.I. DuPont, and General Motors (GM). He had tapped Kehoe, a young toxicologist at the University of Cincinnati, to study the deaths at the Ethyl plant in Dayton and later to direct the laboratory. Kehoe's early studies compared lead

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concentrations in workers in direct contact with tetraethyllead to men in the same plant with other assignments. He designated this second group "unexposed" controls. When he found lead in the excreta of his unexposed group, he concluded that lead was naturally present in everyone. The presence of it, he argued, could not be taken by itself as an indicator of poisoning. This was a fundamental error, and it was vigorously attacked by David Edsall, Yandell Henderson, and others at the Surgeon General's 1925 meeting, who argued that potentially all workers in the Dayton plant were exposed to TEL fumes. After that meeting, criticism of Kehoe subsided; he had data and few others did. He became a corporate officer at GM and a consultant to DuPont.

Kehoe eventually came to see the merit in his critics' assertions: clearly he had chosen the wrong control group. To answer them, he searched for an unquestionably unexposed group. He visited a remote farming village outside Mexico City, removed from industry or urban pollution. There he sampled food, utensils, and the excreta of the residents. The farmers in this remote area had lead in their excreta. Kehoe concluded, once again, that the lead in these farmers showed that the metal was a "natural" constituent of body chemistry. This observation of natural lead levels in Mexican farmers became the nucleus of Kehoe's position throughout his career. From this he constructed a case that lead in gasoline presented no danger and that the general concern about lead as a health threat was overstated.

Once again Kehoe overlooked a glaring flaw in his conclusions. His Mexican farmers also had increased amounts of lead in their clay dishware. Kehoe's analyses showed this, but he dismissed his own finding. It is difficult to understand how Kehoe, the lead industry, and the public health community could have overlooked such a fundamental mistake.

FLUCTUATIONS IN THE TETRAETHYLLEAD MARKET

At the end of World War II, automobile production expanded and TEL sales swelled. Then the market began to change. Ethyl's patent expired in 1947, and other chemical companies competed for TEL sales. Oil companies used improved fuel stock that required less TEL to raise octane levels, and jet aircraft, which did not require high-octane fuel, began to replace piston-driven planes (2). In the late 1950s, Ethyl laid off part of its workforce. Facing lowered revenues, the company sought permission from the Public Health Service to raise the amount of lead in gasoline to 4 cc per gallon.

STATE OF KNOWLEDGE IN THE PUBLIC HEALTH SERVICE

Ethyl's request was made at a time of growing public concern about the environment. Before World War II, environmental attention had focused on conservation of resources in the service of an industrial economy. Living standards improved after the war ended, and people turned to outdoor recreation. Americans began to regard the environment as an asset with intrinsic value apart from utilitarian purposes. Citizens began to regard the air they breathed and the water they drank (3).

The Public Health Service had in the past displayed a distinct proindustry bias on lead. Its Medical Director was R. R. Sayers, who had authored the 1925 Bureau of Mines study and had served as the president of the business-oriented American Association of Industrial Physicians. At that time the Environmental Investigations Branch was headed by H. H. Shrenk, who would later become the director of the Industrial Hygiene Foundation at the Mellon Institute.

In 1959 the Lead Liaison Committee was created by the Surgeon General to coordinate research on the health effects from atmospheric lead. Government was represented by the National Air Pollution Control Administration, the Department of Health, Education and Welfare (DHEW), and the California Department of Health. Industry's viewpoint had an abundance of weight. It was represented on the committee by the International Lead Zinc Research Organization, E. I. DuPont, the American Petroleum Institute, the Auto Manufacturers Association, Ethyl Corporation, and the Kettering Laboratory. The Liaison Committee concluded that contemporary levels of lead in the atmosphere presented no hazard. The Committee would occupy a strategic position in regulatory activity that held until the public was given access to minutes of their meetings. Shortly after the proceedings were opened up to public scrutiny the industry's interest in the committee waned, and it was disbanded (4).

The same year the Surgeon General convened a meeting to evaluate Ethyl's request to increase the amount of TEL in fuel. Testimony was taken only from Ethyl Corporation and E. I. DuPont, and the only witness on the health effects of lead was Kehoe (5). The Surgeon General's report acknowledged Kehoe's Mexican study as evidence demonstrating the "contribution of natural sources." While lamenting the sparse data on body burdens of lead, the report concluded that there was no reason not to permit an increase in lead added to gasoline.

A CHALLENGE TO THE CONSENSUS

In 1965, Kehoe's monopoly on lead science was threatened by a geochemist. Clair Patterson was a research associate in geology at the California Institute of Technology. His measurements of the isotopic ratios of certain minerals convinced him that the long-held consensus of geologists that the age of the earth was 3 billion years old was wildly wrong—by 1.5 billion years. Patterson's studies placed the age of the earth at 4.5 billion years (6). At the time he did this, he swam against a tidal wave of orthodox scientific opinion. His findings were confirmed, his skeptics silenced, and the geology textbooks revised.

Patterson discovered this error because he employed extraordinary measures to avoid contamination while collecting and analyzing his specimens. As a result the isotope ratios were vastly more accurate than those of earlier workers. As he measured the concentration of mineral isotopes, he observed that the lead levels in soil and ice were much higher than would be expected on the basis of natural fluxes. He realized that human activity had severely raised environmental levels of lead.

Most scientists would have treated the contamination of his reagents as a technical annoyance to be overcome and then forgotten. To Patterson it not a nuisance but a clear signal of the contamination by lead of the biosphere. This, he realized, was an unrecognized danger of major proportions to everyone. His conclusions validated the warnings 40 years earlier of Yandell Henderson, David Edsall, and Alice Hamilton that inserting lead into gasoline would contaminate the entire biosphere.

He began to divert a considerable proportion of his extraordinary mind and energy away from the pure science of geochemistry to the study of lead contamination. If Kehoe ignored contamination, Patterson was obsessed by it. He conducted his experiments in an ultraclean chamber entered through an airlock in which the air was filtered, the experimenters gowned and masked, and the reagents and water supply purified of any trace of lead. By these measures he established the true concentrations of lead in his samples.

From the depths of the Pacific Ocean he brought tuna to the surface with extreme care to avoid taint. He studied pre-iron age mummies buried in sandy soil and cores of the Greenland ice pack. By slicing the ice cores he was able to precisely date the specimen and show the time course of lead in the atmosphere (see Fig. 1).

The techniques that he developed to obtain clean specimens and taught to scientists around the world would produce for the first time unimpeachable and valuable data on people's contamination of the biosphere by lead and other elements. Patterson and his colleagues showed that technological activity had raised modern human body lead burdens to levels 600 times that of our pretechnologic ancients.

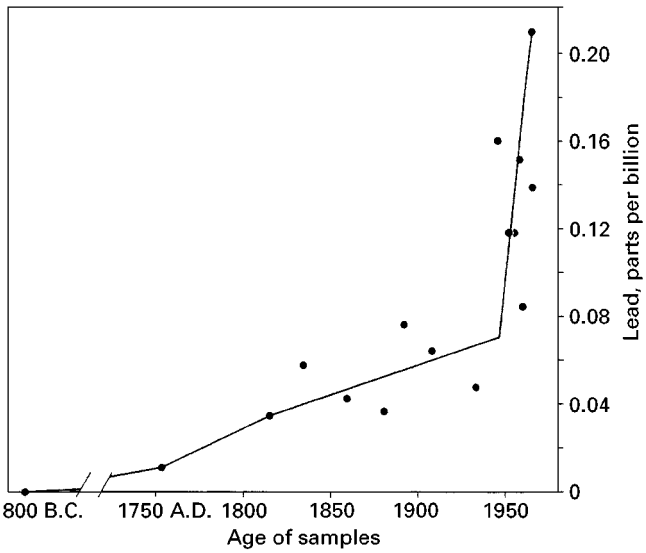

FIG. 1. Lead concentrations in Greenland snow cores since 800 BC. From Morozumi *et al*., 1969.

His work began to attract attention outside of the field of geochemistry. In 1965 in response to an invitation by the editor of the *Archives of Environmental Health*, he submitted a long article titled "Contaminated and Natural Lead Environments of Man" based on his findings and speculations (7). Kehoe was asked to referee the manuscript and decide whether it should be published. Irritated because Patterson did not pay him homage, Kehoe argued for the paper's publication so that Patterson could be offered up for demolition.

> I should let the man, with his obvious faults, speak in such a way as to display these faults …
> The inferences as to the natural human body burden of lead, are I think, remarkably naive … It is an example of how wrong one can be in his biological postulates and conclusions, when he steps into this field, of which he is so woefully ignorant and so lacking in any concept of the depth of his ignorance, that he is not even cautious in drawing sweeping conclusions. This bespeaks the brash young man, or perhaps the not so young [Patterson was 43 at the time] passionate supporter of a cause. In either case hardly the mark off the critical investigator.
> We have been working with the physiological aspects of this problem carefully and step by step for more than thirty years … The virtue of the paper is its examination of the manner in which man has altered "the face of the earth" in a variety of ways, and has disturbed the composition of the

> human internal milieu in so doing. It is strange that Dr. Patterson does not realize that this has happened to the large proportion of mineral components of the earth, and that this is one of the outstanding physiological problems of our time. Can we adapt to these changes, individually and collectively? Are our physiological mechanisms flexible enough to cope with them? It appears, in the case of lead, that they are, and also that we are very nearly able to define the limit beyond which we shall not be able to cope with them .... It is disappointing that our work has not been viewed in this manner by Dr. Patterson, but the issue which he has raised, in this article and by word of mouth elsewhere, cannot be "swept under the rug." It must be faced and demolished, and therefore, I welcome its "public appearance." (8)

In this letter Kehoe displayed the second part of this basic argument: humans have achieved a biological adaptation to lead. Patterson's precise point was that human's exposure to lead was new, and that a few thousand years of lead exposure, a Darwinian moment, was nowhere near the time needed to develop adaptive responses.

Patterson's *Archives of Environmental Health* paper fundamentally altered the vocabulary of the debate over the health effects of lead. Kehoe and his partisans had commonly referred to average population values as "normal" levels of lead in blood. Normal also conveys some of the meaning "natural". Patterson understood that because a certain level of lead was commonplace did not mean it was without harm. He argued that normal should be replaced by "typical." Natural should be reserved for those concentrations of lead that existed in the body or environment before contamination by people. Other workers had missed this distinction because their reagents and instruments, the very air they breathed in their laboratories, freighted with lead, swamped their measurements. The so-called "unexposed" subjects in Kehoe's studies in the Dayton plant who did not directly handle TEL breathed it, and the food of Kehoe's "unexposed" Mexican farmers had been cooked in and served from leaded ceramic pots and plates.

The *Archives of Environmental Health* paper released a fusillade of angry responses from the toxicology orthodoxy. They included the editor of the journal in their attacks for publishing it. The fury of toxicologists focused on Patterson for his hubris in stepping outside his field to talk about people instead of rocks.

While Patterson seemed to thrive on the controversy, there were other, more serious effects. A group from Ethyl Corporation visited him and tried to (in his words) "buy me out through research support that would yield results favorable to their cause." He responded with a lecture in which he predicted that future scientists would show that Ethyl's activities were poisoning both the environment and people, and their operations would eventually be shut down. Following this meeting, his longstanding contract with the Public Health Service was not renewed, and his substantial contract with the American Petroleum Institute was terminated. Members of the Board of Trustees at California Institute of Technology visited the chairman of his department asking that he be fired (9).

The paper and the attendant controversy crystallized the polar positions embodied by Patterson and Kehoe and exposed the question of lead effects at low or silent doses. Those who adhered to Kehoe believed that lead poisoning occurred only at high doses with obvious signs of severe illness. Patterson clearly spelled out the other position: elevated levels of lead found in all humans were associated with sometimes-silent disturbances in body chemistry. Perhaps, he argued, everyone was to some degree poisoned. Complacency over lead would never be the same.

Publicly vilified and professionally threatened, this contentious, unmovable man, who was content to work as an outsider, would eventually be recognized by the scientific establishment for his extraordinary contributions. He would win the Goldschmidt Medal, the equivalent of the Nobel Prize in geochemistry, be elected to the National Academy of Sciences, and have a mountain peak in Antarctica and a large asteroid named after him. His friend Saul Bellow would use him as a model, Professor Sam Beech, in *The Dean's December*.[1]

[1] In *The Dean's December*, Saul Bellow described Professor Sam Beech, a character easily recognized as Clair Patterson.

> These scientists were diapered babies when they went public with a cause. But Beech somehow inspired respect. There was a special seriousness about him. He was physically, constitutionally serious. His head, for a body of such length, was small. His face was devoid of personal vanity ... He was indeed an eminent man of science. That was unanimous. He had authoritatively dated the age of the earth, had analyzed the rocks brought back from the moon. Corde was beginning to think that with pure scientists, when they turned their eyes from their own disciplines, there were occasionally storms of convulsive clear consciousness.

Bellow then describes "Beech's theories about the relationship between lead and social disorder, and the chilly reception they received from the orthodoxy.

> Here science which itself was designed for deeper realization, experienced a singular failure. The genius of these evils was their ability to create zones of incomprehension. It was because they were so fully apparent that you couldn't see them.

THE MUSKIE HEARINGS

For any regulation of lead in gasoline to thrive, it would have to originate outside of the Public Health Service (PHS). In 1966, Senator Edward Muskie, Chairman of the Senate Subcommittee on Air and Water Pollution, presided over hearings on the Clean Air Act (10). He gave considerable attention to the status of lead in the air and in gasoline.

The Surgeon General, William Stewart, one of the first to testify, gave testimony that declared the government's concern, perhaps for the first time, about the effects of lead at low doses, particularly in children and pregnant women:

> Existing evidence suggests that certain groups in the population may be particularly susceptible to lead injury. Children and pregnant women constitute two of the most important of such groups. Some studies have suggested an association between lead exposure and the occurrence of mental retardation among children.

Muskie asked why the PHS was rushing once again to increase in lead in fuel without testing for hazard. With unusual frankness, Dr. Richard Prindle of PHS explained the pressure on PHS to raise the TEL limit.

> I think the situation was one of tremendous pressure, frankly, to move forward in what amounts to an economic problem as far as the industry was concerned … This was attempted in light of the knowledge.
>
> Muskie: If I am out in the woods hunting deer, I don't shoot at a moving leaf but wait until I see something more.
>
> Prindle: I think you are probably correct, Senator.

Prindle also cited a recent PHS study of air and blood lead in Los Angeles, Cincinnati, and Philadelphia (the Three Cities Study) as showing increases in blood lead levels:

> We noted a general trend toward an increase in concentration of lead in the blood of various groups of persons as the vary from rural to central urban areas …

Once again Kehoe was the industry's principal witness. Two years earlier he had gone on record that there was no health risk from airborne lead and no need for an ambient air lead standard (11). The Ethyl Corporation was jittery; Kehoe's testimony was critical to the fate of their company. "… If he had wavered the company would have been faced with disaster," said a member of Ethyl's defense group (2).

Taking a hand in such a high stakes game in the Senate chamber did not induce a trace of retraint in Kehoe. He began by telling Muskie that he knew so much about the subject that he was forced to abridge his presentation: "I am afraid we would be here the rest of the week if I were to undertake to do this [tell all that he knew]."

Although science ordinarily recognizes the provisional nature of any research finding, and scientists are expected to display some modesty or tentativeness about the conclusions they draw, Kehoe, with almost every sentence, stepped on this convention. He said that enough was known about TEL toxicity to allow the amount of TEL to be increased without risk:

> The fact is, however, that no other hygienic problem in the field of air pollution has been investigated so intensively, over such a prolonged period of time, and with such definitive results.

An edginess between Kehoe and Muskie quickly became obvious. When Muskie pointed out that the Public Health Service and others disagreed with Kehoe and that many felt that there were unanswered questions and need for more research, Kehoe responded:

> … I would simply say that in developing information on this subject, I have had a greater responsibility than any other persons in this country ….the evidence at the present time is better than it has been at any time that this is not a present hazard.

Muskie pressed on about finding a substitute for TEL:

> … would it be desirable if a substitute for lead in gasoline could be found?
>
> Kehoe: There is no evidence that this has introduced a danger in the field of public health … I may say the work of the Kettering Laboratory in this field, that lead is an inevitable element in the surface of the earth, in its vegetation, in its animal life, and that there is no way in which man has ever been able to escape the absorption of lead while living in this planet.

Kehoe went so far as to state that air lead levels in Cincinnati had decreased. When Muskie pointed out what appeared to be a paradox, Kehoe had a novel explanation:

> Muskie: Over the past 30 years I assume there has been a tremendous growth in automobiles and in the amount of traffic in Cincinnati, and yet as I understand it, you say that there has been no increase in the concentration of lead in the ambient air?

Kehoe: That is a fact. There has been a change *downward*, since the period of the Second World War … we had difficulty in Cincinnati getting the kind of coal that we would like … During this period we had to take the coal that could be obtained … In 1945 this whole situation was changed and in the period immediately following this the lead content of the atmosphere of Cincinnati went significantly downward.

Muskie: What you have just said is that the decrease in the concentration in the atmosphere is due to better control of stationary sources of air pollution?

Kehoe: That is right.

Muskie: Have you drawn any conclusions as to whether or not the concentration of lead in the atmosphere has gone up, gone down, or remained stationary?

Kehoe: We conclude that there has been no increase.

Kehoe neglected to reveal the whole story, failing to mention two sources of bias in the Cincinnati data. In the early years, different analytic methods were used to measure lead, and more samples were taken from industrial sites, while fewer industrial sites were sampled later. Later, a scientist from Kehoe's own laboratory would publish data showing that lead levels in Cincinnati's air had in fact increased between 1961 and 1968 (12).

Muskie: Is it your conclusion that in 1937 to the present time, on the basis of that data, that there has been no increase in the amount of lead taken in from the atmosphere by traffic policemen, by attendants at service stations or by the average motorist?

Kehoe: There is not the slightest evidence that there has been a change in this picture during this period of time. Not the slightest.

Nothing could jostle Kehoe's limitless confidence and optimism. When Muskie again returned to Kehoe's guarantee that there was no harm to be expected from atmospheric lead, he received a characteristic response.

Muskie: Does medical opinion agree that there are no harmful effects and results from lead ingestion below the level of lead poisoning?

Kehoe: I don't think that many people would be as certain as I am at this point.

Muskie: But you are certain?

Kehoe: … It so happens that I have more experience in this field than any one else alive.

One week later Clair Patterson testified. He began by attacking the belief that natural lead cycling and human activity each contributed about the same amount of lead to the environment. About 10 thousand tons of lead were naturally recycled each year, he said, while millions of tons were emitted due to industrial emissions. Large numbers of people are sickened, he believed, as a result of this unnatural load, and the brain is the most significant target. Patterson attacked the PHS for relying on industry-furnished data:

It is not just a mistake for public health agencies to cooperate and collaborate with industries in investigating and deciding whether public health is endangered—it is a direct abrogation and violation of the duties and responsibilities of those public health organizations. In the past, these bodies have acted as though their own activities and those of the lead industries in health matters were science, and they could be considered objectively in that sense.

Whether the best interests of public health have been served by having public health agencies work jointly with representatives of the lead alkyl industries in evaluating the hazards of lead alkyl to public health is a question to be asked and answered.

When Muskie asked him if his classification into natural, typical, and "contaminated" concentrations of lead in food and humans was a logical approach to follow, Patterson's response was pointed:

"Not if your purpose is to sell lead"

Muskie: "Well, I don't think it is the purpose of the Public Health Service to sell lead."

Patterson: "That is why it is difficult to understand why the Public Health Service cooperated with the lead industry in issuing this report which fails to make this distinction."

Muskie was determined to throw Kehoe's industry perspective into contrast with the public health witnesses' position:

… those representing the industry, the American petroleum industry and others, have told us that there is no evidence of increase in the past since sometime in the 1920s that create any cause for concern as to hazards from lead … Now what do you say on this and where is their analysis faulty?

Patterson: The evidence for an increase in concentration the blood of people in American cities is clear. The difference, as I said, between the concentrations of lead in blood of people living in cities and outside of cities is that between 0.17 and 0.11 parts per million. The difference is not due to food … As I say from these known things we can predict that the people in the cities will have higher concentrations of lead in their blood as a consequence of their absorbing the greater amounts of lead and the difference is due to the greater concentration of lead in the air.

He attacked Kehoe's claim that levels that dropped in Cincinnati:

> …there is given on the back side of the page of data from which Dr. Kehoe quoted, another figure which shows that concentrations of lead in that very same city increased. This is data gotten from the National Air Sampling Network which is not the same organization that Dr. Kehoe represents. It shows an opposite trend. The point here is that kinds of data which purport to show that the concentrations of lead in the atmosphere of American cities is decreasing is rather invalid.

Industry had traditionally measured the prevalence of lead toxicity by counting deaths, or at least severe damage to the brain. Muskie raised the question of a larger pool of unrecognized toxic illness:

> Is it conceivable that there is something different in the deleterious effects on health from low-level exposure than from more concentrated exposure leading to classical lead poisoning?
>
> Patterson: … when you expose an organism to a toxic substance it responds in a continuum, to continuously changing levels of exposure to this toxic substance. There is no abrupt change between a response and no response. Classical poisoning is just one extreme of a whole continuum of responses of an organism, human organism, to this toxic metal. There is no reason why this should't be so."

Muskie's aggressive inquiry marked the government's shift away from complacency towards lead. The hearings established a new premise: that lead poisoning was not only a florid disease of workers, it could be an insidious, silent danger. The notion that lead poisoning was an all-or-nothing phenomenon was discredited and replaced by degrees of disease spread gradually across a continuum. Patterson had inserted the concept of the dose–response relationship into the debate. This was a concept that the PHS could no longer casually disregard, and it would from then on play a central role in regulation of lead in gasoline.

SILENT LEAD POISONING

In the late 1960s, the question of "silent" lead poisoning drew the attention of the civil rights and antipoverty movements, urban advocates, and environmentalists. In an important move, the PHS shifted responsibility for management of childhood lead poisoning to the Centers for Disease Control and in 1974 placed the lead program under Dr. Vernon Houk. The definition for lead poisoning was a level of lead in blood equal or greater than 60 μg per 100 ml of blood. Screening studies of ostensibly normal children in Chicago, New York, and other cities reported that between 20 and 45% of children considered normal had blood lead levels in the range of 40–50 μg/dl. Dr. Jane Lin Fu of the Department of Health, Education, and Welfare, who first raised the question of asymptomatic lead toxicity, reviewed these studies (13). Some pediatricians began to think that if 60 μg/dl was toxic, it was dubious that 50 μg/dl was harmless.

In 1970, the Surgeon General called for early identification of children with "undue" lead exposure, the best locution the government could summon. His statement avoided the loaded term "poisoning" but indicated that this was probably more lead than a child should have. It also indirectly suggests that there was a "due" level of lead in blood. For the first time, research funds were allocated from federal sources to study the health impacts of lead on children. The industrial monopoly on scientific data was drawing to an end.

Ethyl's anxiety about sales was exacerbated by the new perspective on lead toxicity. This was not helped by an inning or two of corporate hardball. In 1962 Ethyl was bought by Albemarle Paper Manufacturing, and GM's interest in the Ethyl was liquidated. In 1970 GM announced that it would begin installing catalytic converters in its new models, and as a result, GM stated, it would be necessary to phase out lead in gasoline. To Ethyl's management this was a betrayal: "…it struck some people as incongruous—not to use a harsher word—for General Motors to sell half of what was essentially a lead additive firm for many millions and then to advocate annihilation of the lead antiknock business," wrote Ethyl's official biographer (2).

Badly shaken, Ethyl resolved to fight the growing environmental spirit in the United States, stating that it was "fully justified in speaking out for this additive, which had saved billions of dollars for the American economy and helped make possible the modern automobile." To combat lead regulation, it formed a defense team, titling it, with unconscious irony, the "Ethyl Air Conservation Group." The Group was staffed with Ethyl officials and members of the Hunton and Williams law firm. Lawrence Blanchard, a partner in Hunton and Williams and board member of Ethyl, headed the group. Ethyl's biographer captured this step in apocalyptic terms: "Blanchard, in effect, was appointed general in a war…"

THE SEVEN CITIES STUDY

In 1968 the PHS commissioned a large epidemiologic study of lead in the atmosphere, directed

by Lloyd Tepper of Kettering Laboratory. Once again, questions were raised about the objectivity of the study, because of industry's participation and the fact that inner-city children were excluded from its sample. The planning group at the outset agreed that the results of this study would be withheld from the public until it was completed and reviewed.

Dr. John Goldsmith, Director of Epidemiology in the California Department of Health, and member of the California Air Resources Board (CARB), requested access to the data from Robert Horton, of the Environmental Protection Agency (EPA), to be used in open hearings on airborne lead by the CARB. Horton denied the request, even though some of the data Goldsmith wanted were from California and had been furnished to the EPA by Goldsmith's own group. Then, at the Air Resources Board hearings, Tepper rose to testify on behalf of industry, using his version of the proscribed Seven Cities data to argue against the hazards of airborne lead. Tepper was followed by testimony from Ethyl Corporation, Kettering Laboratories, and Nalco, another TEL producer. All of them used Seven Cities data. Despite this, in 1976 the CARB set a standard for air lead in California of 1.5 $\mu g/m^3$. California's action put increased pressure on EPA to develop a federal standard.

THE NATIONAL ACADEMY OF SCIENCES: AIRBORNE LEAD IN PERSPECTIVE

The Clean Air Act of 1970 directed the Environmental Protection Agency to name each pollutant known to be dangerous and widespread and then, within 2 years, issue a standard that would define a safe level of exposure. Constructing a lead standard exposed the agency to its first encounter with serious controversy in rule-making. Kenneth Bridbord, an EPA physician and epidemiologist, quickly sent the EPA's administrator a report indicating that millions of Americans were breathing air with lead in excess of what was thought to be an acceptable threshold of 2 $\mu g/m^3$. EPA recoiled from issuing a standard for lead in air. Instead of writing a standard, it deferred to the National Academy of Sciences (NAS), contracting with them to conduct a survey of airborne lead, hoping that NAS would provide both guidance and authority the agency felt unwilling to supply (14).

From the beginning, NAS relied on its informal network of associates and colleagues to select committee members and, as a result, drew criticism from the public health community. Four well-qualified choices, eminent scientists with long experience in lead, were overlooked. Clair Patterson, Harry Schroeder at Dartmouth, who had conducted some of the only transgenerational studies of lead at low dose, and T. J. Chow, who had published fundamental studies of atmospheric lead deposition in Greenland ice cores, were excluded. John Goldsmith, head of the California Health Department's Division of Epidemiology, who had published a groundbreaking study of the relationship between air lead levels and blood lead levels in *Science* (15) was omitted from the panel. All of these established scientists were seen by the NAS as alarmists.

The lead industry, in contrast, was handsomely represented on the panel of consultants. Kehoe and Lloyd Tepper came from the Kettering Laboratory. Kamran Habibi and John Perrrard were from E. I. Dupont, and Gary Ter Haar came from Ethyl Corporation. Industry scientists were also granted major responsibility for writing sections of the draft. Gordon Stopps of DuPont, who was a member of the oversight committee on Biological Effects of Atmospheric Pollutants, was neither a member of the committee nor an appointed consultant. Nevertheless, he was assigned to write two critical sections in the report: adult epidemiology and lead alkyls. His earlier position on lead was a matter of record: in numerous earlier publications Stopps had stated that TEL was harmless (16).

Harriet Hardy, a widely respected expert in metal toxicity, complained about the imbalance and bias of the panel. T. J. Chow wrote about the propriety of asking industry employees to write chapters on their products. The Academy staff became defensive when questioned about the fairness of the selection process. One staff member told the *Science* magazine reporter covering the NAS selection process that Goldsmith and Schroeder were thought to be potentially disruptive to the work of the Committee (16). The Academy staffer responsible for this project responded to the question of industrial bias: "Rosters of committees and panels consist of people with high competence in specific fields regardless of where they work and the appointment is made with the understanding that the person is thought to serve as an individual and not as a representative of his organization … " This same understanding did not, however, extend to Patterson, Goldsmith, or Schroeder.

The NAS report "LEAD: Airborne Lead in Perspective" was a clear failure (17). It spent many pages on discussions of lead in plants and animals, while evading full examination of the specific questions for which it had been commissioned. It virtually ignored the Seven Cities Study, presenting it

in one paragraph as a hasty afterthought. The report said that there were no conclusive data to show that atmospheric lead at concentrations below 2 $\mu g/m^3$ contributed to blood lead levels, nor was there any evidence to support toxicity at low levels of lead. The senior review committee of NAS treated the report with unusual harshness and gave it failing grades. Because of its vagueness and unwillingness to grapple with lead in the air, the review committee chairman stated that the report "failed miserably to form any sort of a precise conclusion … There's no point in being a high priced data collector."

Despite this caustic review, the ambiguities and bias in the NAS report provided the industry with a new instrument. They trumpeted it, proclaiming that the country's most prestigious scientific body had given TEL a clean bill of health and that any regulation of lead in gasoline was unsound and unnecessary. Once again progress in lead control had been damaged. On the day following the release Ethyl's stock increased 20%.

EPA's negligence in monitoring the NAS committee was obvious; the agency was new to this controversial area and had internal conflicts about the need to regulate lead. As a result it failed to press the NAS to produce what it paid for: a clear statement about the dangers of lead in the air. Instead EPA took the equivocal language in the NAS report and used it to justify its failure to write the lead standard mandated by Congress.

A DUAL STRATEGY FOR REGULATING LEAD IN GASOLINE

Congress recognized, when it wrote the Clean Air Act, that to control hydrocarbons and carbon monoxide in the exhaust, a catalytic converter was necessary. The catalyst was made of platinum, and platinum is effectively poisoned by lead. EPA now possessed two separate mechanisms through which to control lead in gasoline: protecting the platinum catalyst and protecting human health. Safeguarding the catalyst was easy work; it needed no evidence of adverse health effects. In 1972 EPA issued rules that each gas station have at least one lead-free pump to protect the platinum catalytic converter on new models.

EPA's medical officers continued to struggle for a separate health standard, fearing that if a substitute for platinum was discovered sometime in the future, lead would be returned to fuel. In 1973, EPA, recognizing that 200,000 tons of lead were blowing out of the exhausts of American cars each year, promulgated a regulation phasing down lead content in all gasoline. Its target was to reduce lead in gasoline to 0.5 g/gal within 5 years (18).

The White House began its own private review of the issue and relied on the Office of Management and Budget (OMB) for direction (19). Within EPA a small staff of doctors and epidemiologists, handicapped on one hand by the NAS report and pressured on the other by the OMB, found themselves entangled in a struggle with a practiced and well-lawyered lead industry. The EPA administrator once again announced a delay in regulating. It appeared that this would go on indefinitely, when a young lawyer from the National Resources Defense Council, David Schoenbrod, filed suit against the EPA. His claim was upheld by the District Court of Appeals, who found that the administrator had illegally delayed and ordered him to set a standard (18).

The Office of Management and Budget, which had gained increased power under Nixon, conducted its own review and was in a strategic position to halt the process. Other intramural politics were at work. DHEW, which bore ill feelings toward the EPA for taking over some of its roles in health protection, expressed them by discrediting the EPA's health analysis before OMB. Meanwhile, the Arab oil crisis threatened (19).

In this setting, John Sawhill of OMB and John Quarles, deputy administrator of the EPA, met in the Executive Office Building to discuss the impact of lead removal on fuel stocks in the face of the looming oil crisis. The additive industry was skillfully exploiting the growing national anxiety about fuel supplies. EPA estimated the oil penalty from phasing lead out at 30,000 barrels per day. Industry's calculations were different and their public relations arm broadcast them. On December 2, 1973, a full page ad appeared in the *New York Times* showing an oil barrel bearing an American flag pouring oil down a manhole. Its headline proclaimed that removing lead from gasoline would have the effect of dumping one million barrels of oil a day. Two days later it was published in the *Washington Post* (20).

Sawhill's deputy at OMB, Richard Fairbanks, threatened to veto the regulations, claiming that Melvin Laird, Council to President Nixon, said "those regulations would go out over my dead body." This turned out to be a bluff. Laird had no position on lead, and after some compromises by EPA on the timetable, the White House signed on (19).

On December 6, 1973, the final regulations calling for a phased reduction of lead in gasoline to protect health were released. Ethyl Corporation and DuPont sued in court, arguing that removing lead would cost an enormous amount of money and crude

oil resources, that no one had been poisoned by lead in air, and that any changes in humans reported at lesser doses of lead were not actual health effects. The court upheld the industry, setting aside the regulations as "arbitrary and capricious." The EPA petitioned for a rehearing. The earlier judgement was vacated and the EPA's regulations were upheld (21). Ethyl, PPG Industries, DuPont, NALCO Chemical, and the National Petroleum Refiners Association appealed to the Supreme Court, where they lost.

SETTING A STANDARD

Still, by 1976, the EPA continued to show reluctance to bear down and enforce the regulations. There was no progress in reduction of lead in gasoline. Schoenbrod again went to court, and the EPA was ordered to set an ambient standard and "end the administrative foot dragging."

The statute specified that the first step in setting a standard is to collect and critically summarize the scientific knowledge about the pollutant. These data are assembled and evaluated is what is called a *Criteria Document*. The EPA staffers assigned to write the first draft had a severe tilt toward industry's position. They met with industry representatives, but refused to meet with Schoenbrod (18). Their draft contrasted strongly with other EPA position papers on airborne lead and concluded that an acceptable standard in the atmosphere was 5 $\mu g/m^3$, considerably higher than that found in most American cities.

David Shoenbrod sent me a copy of that draft and asked if I would review it and discuss it at a public meeting of the EPA's Science Advisory Board (SAB). The chemist on my team, Neil Maher, and I examined it and found its survey of the studies of lead's impact on children badly out of date and biased. To us it read as if written by an industry scientist. We wrote a strong critique and presented it at the SAB meeting in Arlington, Virginia. In addition to our testimony, Sergio Piomelli, a pediatric hematologist with considerable experience in treating lead-poisoned children, made a strong case to lower the permissible level of lead in air to 2 $\mu g/m^3$ or less. Two members of the SAB, Samuel Epstein, a professor of environmental health at Case Western Reserve University, and Ruth Levine, Dean of Graduate Studies at the Boston University School of Public Health, also had strong reservations, but the rest of the Board seemed acceptant of the 5 $\mu g/m^3$ standard.

Almost completely silent during this process were the two academic consultants to the EPA, Dr. Julian Chisolm and Dr. Paul Hammond. Chisolm was the dean of childhood lead poisoning. He had spent his career at the Johns Hopkins University Medical School and, more than anyone, had put the diagnosis and management of the disease on a solid footing. Hammond was a veterinarian and had published on the poisoning of cattle and horses near a smelter in Minnesota. On the strength of this he was appointed to chair the 1972 NAS study.

After 2 days of vigorous debate the tide of opinion slowly shifted, and the SAB told the authors of the document to return to the drawing board, discard the first draft, and submit a new version. The original authors were removed and different writers were assigned. A second draft was completed in 1976. This draft was longer and not as obviously flawed, but it was still far from acceptable.

The SAB recommended that new consultants be appointed to the Criteria Document staff and instructed EPA staff to revise it once again. Piomelli and I were appointed, along with two industry representatives, Emmet Jacobs, a vice president for environmental affairs at DuPont, and Edward McCabe a pediatrician who was a paid consultant to the International Lead Zinc Research Organization. We met with EPA staff in North Carolina in midsummer heat to hammer out the final version. Representing the EPA were two University of North Carolina faculty members: Lester Grant, a neurobiologist who had done some research on lead, and Paul Mushak, a metals toxicologist who had worked on lead and other pollutants. The six of us spent long sweltering days laying out our positions on the critical issue: the effects of lead at low dose on children. Jacobs and McCabe were at a disadvantage; they had less clinical experience in managing lead-exposed children than Piomelli and I and were not as familiar with the clinical literature. The health effects section was brought up to date to include the latest data.

Late one night after a long day's work, we all had dinner together at the home of an EPA staffer. After dinner and a liberal amount of red wine, I asked Jacobs why DuPont, with its wealth of excellent research chemists, hadn't developed a safer gasoline additive to replace TEL. Jacobs, who had matched my intake, told me that their economists had modeled the future sales of leaded gasoline and projected that the consumption of gasoline would soon level off and perhaps decline. Given such a projection, the company would not invest $100 million in research and development funds.

I learned a valuable lesson that night: the entire debate about scientific studies, about the health risks for children, was merely a shadow play. The real decision had been made by DuPont's economists. Their plan was clear: don't budge on TEL and seek medical and environmental arguments to support the choice.

The Criteria Document for lead was published in December 1977 and called for a standard of 1.5 $\mu g/m^3$. In some ways it signaled a minor revolution. It stated that lead in air and in dust was a significant source for human exposure and that brain damage occurred in individuals who showed no symptoms (22). Hearings were held on the document that summer. During the hearings, there was a moment of surprise. The two former EPA consultants, Hammond and Chisolm, testified, but now in a different role. They now appeared as witnesses for the lead industry and testified that the analyses in the Criteria Document that they had worked on were faulty. The new Criteria Document was accepted and was then used by the Air Office of EPA to determine a standard. Another step toward the removal of lead from gasoline had been taken.

THE ATTEMPT TO PUT LEAD BACK INTO GASOLINE

The lead phasedown was by all measures a striking success. With the new standard in place, and the gradual retirement of old cars that run on leaded fuel, air lead levels began to fall. In 1977 air lead levels in Philadelphia ranged between 1.3 and 1.6 $\mu g/m^3$. In 1980 the concentrations were between 0.3 and 0.4 $\mu g/m^3$. Similar trends were observed in most major cities.

In June of 1980, Lead Industries Association petitioned EPA to rescind the regulation, claiming that a study of atmospheric lead in Idaho upon which the regulation relied had contained serious error. The study in question examined the relationship between air and blood lead levels in the vicinity of a large lead mine and smelter in Kellog, Idaho (23). The authors, Anthony Yankel and Ian Von Lindern, originally estimated that a 1 $\mu g/m^3$ increase in atmospheric lead would increase blood lead by 2 $\mu g/dl$. Yankel later claimed to have found an error in calculations that overestimated the air lead effect. When the case was heard in court, the original calculations were upheld. Yankel, it turned out, no longer worked for the Idaho Health Department. He had taken a job with the lead industry. The judge denied the LIA claim and recommended that the Department of Justice investigate Yankel's behavior (24). The standard had withstood another skirmish.

In 1980 Ronald Reagan, who succinctly expressed his environmental concerns by saying "If you've seen one tree, you've seen them all," was elected to the presidency. By executive order, without consulting Congress, he made the OMB the clearinghouse for all government regulations. OMB was given the power to require sweeping analyses of proposed regulations and by doing so delay and halt any that it found objectionable. Reagan appointed Ann Gorsuch to the post of EPA Administrator and assigned his Vice-President, George Bush, a former oil man, to head the Task Force on Regulatory Reform.

Reagan wasted no time. The EPA's budget was cut, and its enforcement section was reorganized out of existence. In 1980, 1300 cases had been referred for enforcement. One year later, 59 cases were referred. The agency was virtually toothless. Many career EPA staffers in middle management positions were squeezed out or forced to resign. Experienced professionals were replaced by political appointees. The agency was in a confused shambles.

OMB canvassed industries to determine which regulatory programs they felt needed revision. Deregulating lead in gasoline was the first item on the Bush Task Force Agenda. Noting that air lead levels were dropping as older cars were replaced by catalyst-equipped vehicles, DuPont representatives called upon EPA to rescind the lead regulations.

OMB increased the pressure on EPA to do something about the complaints of the small refiners. Boyden Gray, counsel to Bush and to the Regulatory Task Force, promised that EPA would reexamine the phasedown and consider relief. Richard Wilson, EPA's acting director of enforcement for air, held 32 meetings with refiner representatives to discuss their problems, but none with public health of public interest officials.

The definition of a *refiner* included those who bought low-lead fuel and mixed it with high-lead-content gasoline. These were refiners without refineries; they made large profits simply by blending fuel stocks. The adjective "small" was also misleading. It referred to those who processed less than 50,000 barrels per day. An EPA staffer defined a "small refiner" as "a short man with pockets full of $1000 bills" (25).

In December of 1981, Senator Harrison Schmitt arranged a visit of officials of a New Mexico oil refinery, Thriftway, with Administrator Gorsuch. Thriftway executives complained that lowering the amount of lead in gasoline was producing losses of $100,000 a month for them and that they faced

eventual bankruptcy. They requested an individual waiver of the regulations on the basis of financial need. Gorsuch told them that if she granted it, she would be forced to give the same dispensation to other refiners. But, she said, a relaxation of the lead phasedown regulations was in the offing, and that it did not make sense to use EPA's limited enforcement powers when the lead regulations were to be changed. The Thriftway people then asked for written assurances that they would not be prosecuted for exceeding the standard. Gorsuch demurred, but told them that they had been assured by the Administrator of the EPA (26). As she left the room, she said to Senator Schmitt's administrative assistant, "I can't tell your client to break the law, but I hope they got the message" (25).

A firestorm ensued over the Administrator's statement that she would not enforce her agency's own regulations, and the episode became the subject of wide publicity capped by a *Doonesbury* cartoon. Congressman Toby Moffet asked the Inspector General to investigate whether any laws had been violated. In February of 1982, EPA bent to OMB and announced the projected relaxation of the regulations that Gray had promised and Gorsuch predicted.

Congressman Moffet, chairman of the Subcommittee on the Environment and EPA, held hearings on the lead phasedown in April 1982. Public health professionals and private physicians, including Vernon Houk, Sergio Piomelli, and myself, turned out to testify on the unsoundness of such an action. The EPA hearings also marked the debut of Dr. Claire Ernhart as a lead industry spokesperson, testifying that the evidence for lead's threat to child health was exaggerated.

The Gorsuch–Thriftway episode had the effect of waking up EPA's demoralized staff. In some ways this became one of EPA's finer moments. EPA's own data indicated that 200,000 children would be poisoned if the rules were relaxed. Despite the purges of their ranks, the deep cuts in their budget, and their damaged morale, EPA's professionals could not countenance inflicting such harm on the nation's children. They took a stand against rescinding the regulations.

Considerable antagonism grew between the large and the small refiners on the need to regulate. Many large fuel companies, including Exxon, Amoco, and Phillips Petroleum, supported the continuance of the phasedown. They pointed out that they had fought against regulation, but, faced with the inevitable, had invested hundreds of millions of dollars to retrofit their refineries. They were now in compliance and strongly protested granting any competitive advantage to those who had not spent the money to retool.

Congressman Moffet demanded that the president discipline Gorsuch for encouraging refiners to break the law. While the hearings were taking place, Jack Anderson reported that a tanker load of high-lead gasoline purchased from China by a California refiner was on the high seas approaching the West Coast. The lawyer for the refiner who had chartered the ship, and who had served as chairman of Reagan's fundraising committee in California, had visited him in the White House to press for relaxed regulations.

A bipartisan group of 31 congressmen joined by 13 senators from both parties petitioned the White House to hold the line on the phasedown. On August 15, 1982, Anne Gorsuch seemed to have experienced a conversion. The *Environmental Health Letter* carried this headline "EPA Reverses Position, Toughens Regulations on Lead in Gasoline."

OMB's move on EPA served to highlight industry's role in influencing health-based regulations and sharpen the focus on the health impacts of airborne lead. In the wake of the administration's embarrassment, the relaxation of the phasedown was quietly buried. The president of the National Petroleum Refiners Association complained bitterly that "EPA is reneging on an implicit promise in the present regulatory scheme." Lawrence Blanchard, vice chairman of Ethyl, and "general" of the company's antiregulatory campaign, who had called EPA "novelists" and "bastards" at an Ethyl stockholders meeting (27), fired another of his smallbore expostulations at the EPA hearings:

> It was misleading at best and fraudulent at worst to talk about symptoms and horrors of lead poisoning. That is just like talking about the horrors of gassing World War I soldiers with chlorine at a hearing as to whether we should chlorinate to purify drinking water (28).

Between 1976 and 1980, the amount of lead consumed in gasoline production dropped by 50% (see Fig. 2). The blood lead level of the average American dropped by 37%. In 1984 EPA's analysts calculated that the benefits of the phasedown exceeded the costs by $700 million.

THE SECOND CRITERIA DOCUMENT

In 1982, the EPA was mandated by statute to update and revise its 1977 airborne lead regulations. By this time, a separate Criteria office had been created to write these documents. Lester Grant, a consultant to EPA in the first lead document, was

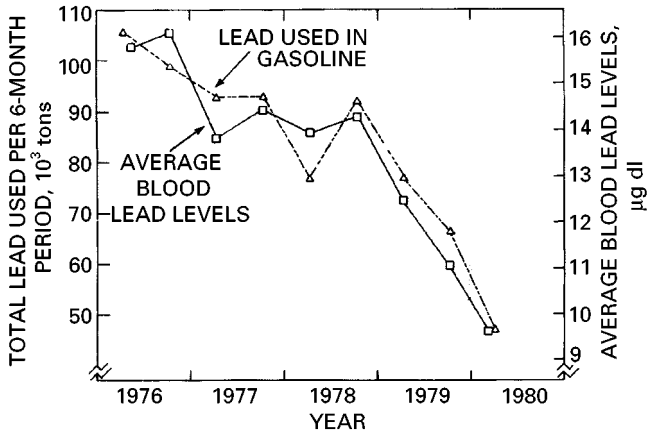

FIG. 2. Parallel decreases in blood lead values and the amounts of lead consumed in gasoline between 1976 and 1980. Source: USEPA/Environmental Criteria and Assessment Office (1986).

appointed director. A substantial increase in the budget for the lead document was allotted, a panel of external writers was appointed, and a greatly enlarged group of consultants and reviewers was appointed.

Important changes had taken place since the publication of the first document. Air lead levels had come down quite sharply, and considerable data had been collected correlating air lead levels, gasoline lead emissions, and blood lead levels. At the time the first Criteria Document was written, there were only hints that lesser levels of lead were toxic to children. In the 5 intervening years, a number of studies had been published showing that children with lower levels of lead had lower IQ scores, language and attentional problems and behavioral disturbances. The work of my group at Harvard was one of these (29), and it was followed by data from England showing similar changes. Claire Ernhart, who had published an early study showing that lead decreased (30), and who now was supported by International Lead Zinc Research Organization, tried to recant her earlier conclusions that low-dose lead was toxic.

The EPA now had a growing health database. The National Academy of Sciences had convened a new committee, which came to much stronger conclusions about the hazards of lead in the atmosphere (31):

To the lead industry this new standard was another crucial battle, and they planned their attack around three salients: (1) The decline in blood lead levels was not due to removing lead from gasoline; the close correlation between gasoline sales and blood lead levels was not causal. (2) While lead at high doses was toxic, there was no solid evidence that at lower doses, humans suffered any effects. The studies of lead in humans were flawed, and the animal work was irrelevant. (3) Not only was lead toxicity overrated, lead was probably an essential trace element.

After thorough review of the literature and the many submissions from external authorities, EPA concluded that the relationship between gasoline production and air lead levels was causal. "The contribution of gasoline lead to total atmospheric emissions has remained high, at 89% ... Between 1975 and 1984, the lead consumed in gasoline has decreased 73%, while the corresponding composite maximum quarterly average of ambient air lead decreased 71%." See Fig. 3. Industry arguments that this was a spurious relationship were futile.

In the meetings of the EPA Criteria Committees, Ernhart and I represented the two polar positions on health effects in children. We were asked to critique each other's papers before the hearing panel. Ernhart raised the now traditional criticisms: that I had not controlled for other factors that affect development and that causality worked in the other direction: children with low IQ may ingest more lead. I pointed out that complete covariate control is impossible to achieve, but that many studies controlling for differing factors found a lead effect. This

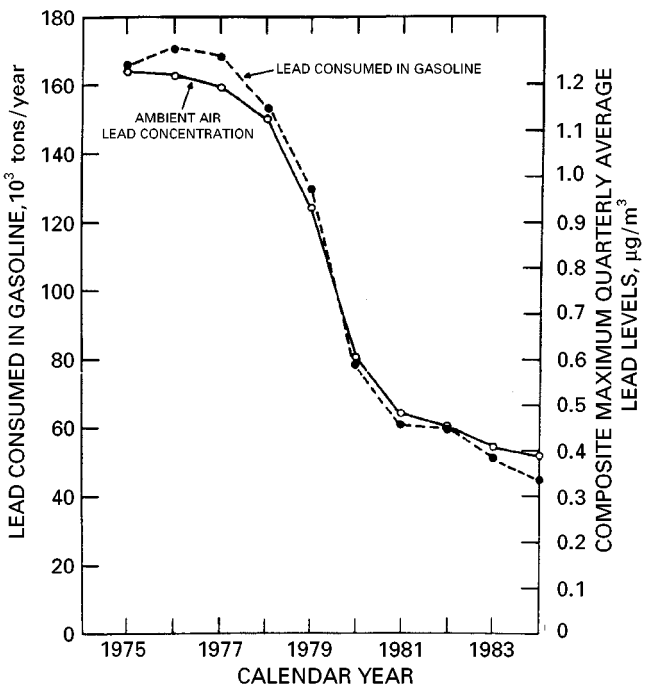

FIG. 3. Relation between lead consumed in gasoline and air lead concentrations. Source: USEPA/Environmental Criteria and Assessment Office (1986).

consistency among the many studies published at that time was strong evidence that the lead effect was real and not produced by confounders, and this was strongly buttressed by animal studies, which showed similar changes and effectively destroyed the reverse causality hypothesis.

Ernhart had criticized me for incomplete control, but in her 1974 study she had not controlled for an important factor, socioeconomic status. I pointed this out. She responded that this was because all her subjects were from a single class, welfare parents. I had brought her paper, along with others, with me to the hearing and was able to quote it to her: "They [the parents] ranged from managers, clerical workers, skilled and unskilled workers to service workers and welfare recipients (30).

Lester Grant then appointed a special committee to review both our studies in depth. The committee consisted of three psychologists, including Sandra Scarr, Lawrence Kupper, a statistician, Paul Mushak, a toxicologist, and Lester Grant. Their draft report asserted that no conclusions could be drawn from either study about the health effects of lead at low dose. I received my copy and counted 11 errors in the committee report, all of which biased it against my study. I wired Grant that if he did not correct them, I would insist that he send an errata sheet to everyone who received a copy of the draft. The errors were corrected, but the conclusions were allowed to stand. With financial and statistical support from EPA, I reanalyzed the data to address the special committee's criticisms that had been the source of their assertion of no conclusion. The reanalyses, using EPA's suggestions, showed an even stronger lead effect than I had published earlier. I published this as a letter to *Science* (32). On April 27, 1984, I presented these reanalyses to the Clean Air Advisory Committee (CASAC), the highest level of peer review in the EPA.

After CASAC heard my presentation, they declared that my paper was sound and qualified to be included in the Criteria Document and used in the standard setting. Ernhart's paper recanting her earlier findings was also included, but EPA's conclusions differed from her interpretation: "…it is notable that an association [in Ernhart's paper] between lead and lower Verbal Index scores was nevertheless observed across several of the analyses (at p values ranging from 0.04 to 0.10) and that an association between preschool lead levels and General Cognitive Index scores approached significance at $p < 0.09$." EPA concluded that her study continued to show a lead effect, despite her persistent efforts to discredit it (33).

The sum of data on human health effects dwarfed what had been known in 1977, when the first Criteria Document was issued. The second (1980) NAS report this time was much more declarative about the health effects of lead at low dose.

> The evidence is convincing that exposure to levels of lead commonly encountered in urban environments constitutes a significant hazard of detrimental biological effects in children, especially those less than 3 years old. Some small fraction of this population experiences particularly intense exposures and is at severe risk.

The EPA's Criteria draft of 1986 firmly agreed:

> …lead has diverse biological effects in humans and in animals… the developing organism seems to be more sensitive than the mature individual.

The lead industry drew its last arrow and in doing so exposed their desperation. In the 1970s they had supported a series of investigations attempting to demonstrate that lead was an essential trace element. This was done by growing rodents in lead-free environments on synthetic diets made to contain no lead and comparing them to animals raised on an ordinary lead-containing diet and comparing growth (34). These studies had little credibility. This time they brought two German investigators to EPA to argue their claim for lead's essentiality. This position simply did not withstand investigation by an independent review committee. They criticized the statistical analysis and noted that the method of obtaining blood for analysis was open to contamination and that the animals may have suffered other deprivations. In order to achieve a lead-free diet, the investigators may have deprived the animals of other essential trace elements such as selenium and chromium. They added calcium EDTA to the rat chow. EDTA is an agent long used to treat lead toxicity. This drug also removes other minerals along with lead, resulting in other dietary deficiencies (35).

EPA had traveled a long way since the first *Criteria* draft of 1972. The evidence documenting lead toxicity was now strong enough that the agency, citing the "overwhelming evidence of the threat to humans," proposed to cut the lead in gasoline by 91% in 1986 and achieve a total ban by 1995.

Long accustomed to having their way in regulatory proceedings, the industry was ill equipped to lose. In a plaintive tone, they blamed a conspiracy of a small group of scientists, environmentalists, and the press. "Ethyl vowed to fight the EPA goals 'in every appropriate manner'" related the *New York Times* (36):

> "We feel wronged at this stage of the game," said Jerome Cole, president of the International Lead Zinc Research Organization. "Five or six scientists, together with the rabid environmentalists, have used the media very skillfully putting over their views, but there's a lot of responsible opinion that doesn't support that." According to Donald R. Lynam, the director of air conservation at Ethyl Corporation:
>
> "Unfortunately, the atmosphere we're now in prohibits objective scientists from coming forward. And why should they, when they would be crucified by the press, the EPA and the environmentalists."

The payoff for taking lead out of gasoline exceeded the predictions of the most convinced lead advocate. Lead levels in children's and adults' blood continued to drop in direct relationship to the reduction in lead in gasoline. The average American child's blood lead level in 1976 was 13.7 μg/dl. In 1991 it was 3.2 μg/dl. In 1988 the Government estimated that 3–4 million American children had blood lead levels greater than 15 μg/dl, the level then assumed to be toxic (37). Six years later, in 1994, it was estimated that 600,000 children had blood lead levels in that range (38). The removal of lead from gasoline spared as many as 3.4 million children from growing up with hazardous concentrations of the toxic metal in their bodies.

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