

With the *Best* INTENTIONS

Lead Research and the Challenge to Public Health

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In 2001, Maryland's court of appeals was asked to decide whether researchers at Johns Hopkins University had engaged in unethical research on children. During the 1990s, Johns Hopkins's Kennedy Krieger Institute had studied 108 African American children, aged 6 months to 6 years, to find an inexpensive and "practical" means to ameliorate lead poisoning. We have outlined the arguments in the case and the conundrum faced by public health researchers as they confront new threats to our health from environmental and industrial insults. We examined the case in light of contemporary public health ideology, which prioritizes harm reduction over the historical goals of prevention. As new synthetic toxins—such as bisphenyl A, polychlorinated biphenyls, other chlorinated hydrocarbons, tobacco, vinyl, and asbestos—are discovered to be biologically disruptive and disease producing at low levels, lead provides a window into the troubling dilemmas public health will have to confront in the future. (*Am J Public Health*. 2012;102:e19–e33. doi:10.2105/AJPH.2012.301004)

IN MAY 2012, THE CENTERS

for Disease Control and Prevention officially accepted the recommendations of its Advisory Committee on Childhood Lead Poisoning Prevention and adopted a new, lower standard for "acceptable" blood lead levels in American children. The new standard of 5 micrograms per deciliter of blood halved the older definition of 10 micrograms established 20 years ago and nearly doubled the scope of the lead poisoning epidemic in the United States as the estimated number of at-risk children jumped from about a quarter of a million to nearly one half a million victims.¹

This staggering number of children whose neurologic integrity, intelligence, and behavior have been threatened by lead makes this epidemic among the broadest and longest lasting in American public health history.² As public health professionals have uncovered the negative effects of ever-lower exposures to lead, their frustration with the lack of political will to eliminate lead from the walls, soil, and air has grown. For the past 30 years—since the confluence of documentation of the widespread damage to children from low levels of lead and the growing strength of conservative, antigovernment ideology in the

broader culture and in government—the public health community has been divided on how to proceed in the future: should we demand a massive program to eliminate lead paint on older structures, the major source of lead in the children's environment, or should we reduce exposures through various abatement procedures, knowing that low-level lead exposures still threaten poor children living in decaying, older homes? These questions about how to address this age-old hazard are not new but have gained increasing urgency as we discover that there very well may not be any threshold below which lead does not negatively affect children's neurologic development.

No case encapsulates the tensions that have arisen over the conflicting approaches to the epidemic better than the Johns Hopkins Bloomberg School of Public Health's experience with a lead abatement research project it conducted in the 1990s. That study achieved notoriety because in August 2001, just weeks

before the attack on the World Trade Center and the Pentagon diverted the nation's attention, the Court of Appeals of Maryland, that state's highest court, handed down a strongly worded, even shocking, opinion that goes to the heart of beliefs about what public health should do and what our responsibility to others should be.³

The court had been asked to decide whether researchers at Johns Hopkins University, among the nation's most prestigious academic institutions, had engaged in unethical research on children. The case pitted two African American children and their families against the Kennedy Krieger Institute (KKI), Johns Hopkins's children's clinic and research center, which in the 1990s had conducted a multiyear study in which children were exposed to differing amounts of lead in their homes. The KKI project was designed during the presidency of George H. W. Bush to find a relatively inexpensive and effective method for reducing—though not eliminating—the amount of lead in children's homes and thereby reducing the devastating effect of lead exposure on children's brains and, ultimately, on their life chances. The Johns Hopkins researchers had recruited 108 families with young children to live in houses with differing levels of lead, ranging from none to levels just below the existing legal limit in Baltimore, Maryland, and then measured the extent of lead in the children's blood at periodic intervals. (The overwhelming majority of families were composed of single African American mothers and their children.) By matching the expense of varying levels of partial lead

paint abatement—a \$1650 investment for the first group of homes, \$3500 for the second, and \$7000 for the third—with changing levels of lead found in the blood, the researchers hoped to find the most cost-effective means of reducing childhood exposure to the toxin. Completely removing lead paint from

populations in the 20th century. The KKI Repair and Maintenance Project, the court argued, differed from but presented

similar problems as those in the Tuskegee Syphilis Study, . . . the intentional exposure of soldiers to radiation in the 1940s and 50s, the test involving the exposure of Navajo miners to radia-



the homes, the researchers recognized, would be ideal for children's health, but they believed, with some justification, that to do so would be considered far too costly in such politically conservative times and likely to result in landlord abandonment of housing in the city's more poverty-stricken districts.

The court of appeals found that Johns Hopkins had engaged in highly suspect research that had direct parallels with some of the most infamous incidents of research abuse of vulnerable

tion . . . and the secret administration of LSD to soldiers by the CIA and the army in the 1950s and 60s.

The research defied many aspects of the Nuremberg Code, the court said.⁴ For the court it was deeply troubling that a major university would conduct research that might eventuate in permanent damage to children.

Many in the public health community later argued that this was just a "rogue court," an out-of-control panel of judges, but the Maryland Court of Appeals was

not known for its liberalism. In fact, the judge who wrote the opinion, Dale R. Cathell, was considered one of the more conservative judges on the bench.⁵ The researchers were not uncaring researchers or unfeeling persons either. In fact, one, J. Julian Chisolm, had dedicated his professional life to uncovering the extent and limiting the damage of lead poisoning in Baltimore, and the other, Mark Farfel, was a young committed public health advocate who had formed close alliances with many in the poor community surrounding Johns Hopkins.

This was a complex and troubling story, not just about the KKI research but also about the public health profession, the nation's dedication to the health of its citizens in the new millennium, and the conundrum that we as a society face as we confront revelations about many new environmental threats in the midst of a very conservative political culture and the continuing legacy of poverty and racism. In its ubiquity and harm, lead is an exemplary instance of these threats. Yet there are many others we encounter in everyday life that entail similar issues, from mercury in the fish we eat that comes from power plants to flame retardants used on our children's clothes and bisphenol A, which is in many plastics, cans, and glues that we commonly use.⁶

For much of its history the public health field has provided the vision and the technical expertise for remedying the conditions—both biological and social—that created environments conducive to harm and in which disease could spread. And throughout much of its history, public health leaders have joined with social activists to find ways

in the existing political and economic structures to prevent diseases.

Although the medical profession has often been given the credit for the vast improvements in the health and life span of Americans over the past century, it was the crusading spirit of public health reformers in the 19th and early 20th centuries who pushed for housing reforms, mass vaccination campaigns, clean water and sewage systems, and pure food laws that played the major role in improving children's health, lowering infant mortality, and limiting the impact of viral and bacterial diseases such as cholera, typhoid, diphtheria, smallpox, tuberculosis, measles, and whooping cough that had plagued the nation for decade after decade. These broad public health campaigns to control infectious diseases yielded great victories from the 1890s through the 1930s. With the first decades of the 20th century, however, a different view of the profession slowly began to gain ascendancy, redefining the mission of public health in ways that belied its role as an agent of social reform. In this view, the idea was to put the fast-growing science of biological medicine in the service, not of eradicating the conditions that facilitated disease and its spread but of concentrating on treating the disease itself person by person and reducing risk rather than eliminating it.⁷

PUBLIC HEALTH TRIUMPH OR PERSONAL TRAGEDIES

The story of campaigns to halt childhood lead poisoning mirrors this history, even though this is not the story often told. The reduction of children's blood lead levels is often seen, instead, as

one of the great public health victories, like the efforts to eliminate diphtheria, polio, and other major threats to America's children. After all, with the removal of lead from gasoline in the 1970s and 1980s, blood lead levels of American children aged one to five years declined precipitously, from 15.0 in 1976 to 1980 to 2.7 micrograms per deciliter by 1991 to 1994,⁸ and have continued to decrease. Today, the median blood lead level among children aged one to five years is 1.4 micrograms per deciliter, and 95% of these children have levels below 4.1 micrograms per deciliter.⁹

Viewed from a broader perspective, however, the story is more complicated and disturbing, and may constitute what Bruce Lanphear, a leading lead researcher, calls "a pyrrhic victory."¹⁰ If 95% of American children are below what is today considered the danger level for lead, then five percent, or a half million, still have dangerous amounts of lead in their bodies. A century of knowledge about the harmful effects of lead in the environment and the success of efforts to eliminate some of its sources has not stanchied the flood of this toxic material that is still polluting our children, our local environments, and our planet.

The KKI had been in the forefront of treating lead-poisoned children for more than 50 years when researchers there embarked in 1991 on what became its controversial study.¹¹ Baltimore's Johns Hopkins University had been at the center of work on childhood lead poisoning even longer, for almost a century.¹² Over this period, the city had made some of the more innovative attempts to address what has proven to be one of the

nation's most intractable environmental problems. The irony of this history is unmistakable. Here was the premier center for the study of lead poisoning, located in the virtual heart of the country's lead poisoning epidemic, at the eye of a storm over whether children were being used—as the Maryland Appeals Court ultimately opined—as “canaries in the mines” and “human guinea pigs.”¹³

LONG HISTORY OF JOHNS HOPKINS AND LEAD POISONING

To understand the tragedy that this case represents, we need to look back at the long history of Johns Hopkins's experience with lead poisoning in Baltimore's working-class neighborhoods. Fairly typical of the thousands of children that Johns Hopkins had sought to help before the 1960s, when children living in poorly maintained slum housing typically suffered from convulsions after ingesting lead paint, was J.L., aged nine months, who was brought by his distraught parents to the Harriet Lane Home of the Johns Hopkins Hospital in February 1940. J.L. was a well-nourished, playful, and cooperative child with no history of developmental problems, according to the admitting nurse. J.L.'s father was well educated, having spent three years at a theological seminary.¹⁴

J.L. was admitted to the hospital because he had developed an ear infection, but that was easily treated; his appetite was good and he slept well. The record reported a happy, healthy infant from a good home. In the ensuing months, J.L. returned periodically to the clinic for treatment of his chronic

earaches, but by the time he was two years old he had developed symptoms that were not at all routine. In May 1941, his parents rushed him to the hospital. A few hours earlier, he had “bent over to the left and couldn't straighten up,” they told the admitting nurse, and since that time he had “been acting ‘crazy-like.’” J.L. had been “eating plaster,” they said, and the previous day he had eaten “some paint.” At the hospital he “fell to the left side when he tried to walk, and he reeled around to the left. He didn't respond to his name or questions.”¹⁵ The hospital raised the possibility that J.L. suffered from lead poisoning, encephalitis, and secondary anemia. The blood work showed 390 micrograms of lead per deciliter of blood—almost 40 times the level now considered lead poisoning¹⁶ and clearly a cause of acute poisoning. The social worker in charge of the case noted that “because the landlord refused to make any repairs in this home, the family pooled their money and bought some paint which they have used all over the home.” The mother promised that in the future “she would make every effort to keep the child away from the paint.” She had “a large play pen and from now on the child [would] be kept there. It gives him adequate room to move about and have a good time,” the social worker wrote, “and will make it impossible to get to the window sill and eat more paint.”¹⁷ The social worker contacted the health department, which promised to investigate the home conditions, but we know neither the results nor what befell J.L. in subsequent years.¹⁸

What did and did not occur in response to the plight of J.L.'s family is telling. At the time,

Johns Hopkins was the lone institution and Baltimore the lone city in the country that was systematically trying to identify and treat large numbers of children affected by the increasing tonnage of lead polluting the nation's housing. Baltimore and Johns Hopkins had been the epicenter of this issue ever since the area's rapid growth at the turn of the century had created a huge housing boom and, with it, the use of lead-based paint throughout the central city. The first American case of poisoning

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because of lead paint ingestion was also documented here in 1914 by Henry Thomas and Kenneth Blackfan at the Harriet Lane Home of Johns Hopkins, where J.L. was treated. And Baltimore's Department of Health was the first local health agency to mount a campaign to protect a city's children from the effects of lead. In fact, in the 1930s it used the new media of radio to broadcast public service announcements warning its residents about lead's dangers.¹⁹

The response of Johns Hopkins to the epidemic was, however, fraught with practical and institutional problems that were emblematic of a larger crisis over lead poisoning and other ubiquitous toxic pollutants that continue to plague us. Lead poisoning was both a medical and a social problem of inordinate proportions.

The root of J.L.'s disease lay in the physical conditions in which he and his family lived—poor housing whose walls were covered with a poison. But, in the absence of widespread public understanding of the depths of the problem and with no popular movements demanding change, the only response was from the public health and medical professions, and they could only provide medical care to the individual child. That was important, of course, but the broad social problems that affected huge numbers of children living in similar conditions were left undressed, virtually guaranteeing that there would be many more J.L.s in urgent need of help in the future. J.L. was suffering from more than an environmental exposure to a known neurotoxin caused by ignominious landlords and peeling paint. Lead had been identified as industrial poison for centuries and as a specific cause of convulsions, comas, and deaths among children since 1904.²⁰ He suffered because of the failures of a social and economic system that condemned his family to poverty and racial discrimination, as well as the urban decay that put him in harm's way.

Public health administrators, advocates, and policy-oriented academics, though, faced a classic dilemma: How does one prevent disease and premature or unnecessary death when the means of effecting such prevention are controlled by a political and economic system that one has limited influence over and that profits from the existing social relationships that produce disease? In no small measure this dilemma was addressed through the development of the social movements against poverty, economic and

social disparities, and racism that marked the 1960s. During the War on Poverty, lead poisoning became a focal point for numerous community groups and activists, who saw in it a telling symbol of the physical harm that poor housing and health conditions in urban slums caused African American and Hispanic children. The alliance between community groups, social movements, and public health professionals produced the elimination of lead in gasoline and paint in the 1970s and beyond.

The decline of the various social movements by the 1980s had a striking effect on the public health profession because it was deprived of the power and energy of political and social allies that could influence legislators and bureaucrats in local, state, and federal agencies. Following the election of Ronald Reagan in 1980, even federal agencies whose mission coincided with public health activists were under attack and stymied in their attempts to regulate the environment, identify and remedy unhealthy working conditions, and provide services to the poor. New public housing construction virtually ceased in these years. At the behest of conservative critics of the Great Society programs of the 1960s, public health activism waned.²¹

Faced with this broad conservative onslaught, public health advocates have been divided about how best to protect children from lead in their homes. In 1991, the Centers for Disease Control and Prevention, under the auspices of the US Department of Health and Human Services, responded to the overwhelming evidence in the scientific literature by publishing its "Strategic Plan for the

Elimination of Childhood Lead Poisoning,"²² which some prominent researchers called "a truly revolutionary policy statement."²³ This document, building on an extensive period of reevaluation among researchers of childhood lead poisoning, proposed "a society-wide effort [to] virtually eliminate this disease as a public health problem in 20 years,"²⁴ a goal we have obviously not met. The document's publication led to many studies seeking ways to eliminate or at least broadly curtail lead poisoning in America. Although some researchers developed protocols aimed at eliminating lead as a widespread urban pollutant through its complete removal, others sought more pragmatic solutions—that is, from the viewpoint of the politics of the times, not from that of families whose children were at risk for permanent brain damage—seeking to remove some if not all of the lead from the windowsills, walls, ceilings, and woodwork of older homes.

The rise of Reaganism after 1980, the growing power of corporations, the decline of the civil rights and labor movements, the end of the construction of low-income public housing, and the antigovernment rhetoric and attacks on what were considered liberal social reforms undermined support for more far-reaching solutions to the lead poisoning problem. As Herbert Needleman, a pioneer in the early studies of low-level lead neurotoxicity, put it in 2002,

Instead of asking, "how can we develop a plan to spend U.S. \$32 billion over the next 15 years and eliminate all the lead in dangerous houses?" the question became, "how little can we spend and still reduce the blood lead levels in the short term?"²⁵

Opposition from industry, landlords, and others was so strong and the countervailing voices so few, said Needleman, that “it was not long before the vision of the early 1990s, true primary prevention, eradication of the disease in 15 years, was replaced by an enfeebled pseudopragmatism,”²⁶ which came down to only partial abatement of polluted homes.

One researcher’s pseudopragmatism, however, is another advocate’s realistic attempt to help children at risk. And one person’s policy failure is another’s public health success story. Those who have labored to reduce, rather than eliminate, lead in the environment of children, believing that this is the only “practical” course to pursue, celebrate dramatic declines in both blood lead levels and symptomatic children as one of the great successes in public health history.

KENNEDY KRIEGER CASE AND QUANDARY OF LEAD RESEARCH

The lead researchers at the KKI planned their study in the midst of this history: children living in Baltimore were being poisoned because their homes had been covered with lead paint that, when it deteriorated, the children inhaled or ingested. Despite the Centers for Disease Control and Prevention’s grand vision of lead’s elimination from the home, the money necessary was highly unlikely to be appropriated for a dramatic federal detoxification program. It was in this general context that the Environmental Protection Agency (EPA) funded the KKI: the federal government and various lead researchers were

looking for relatively inexpensive, nonconfrontational, noncoercive methods of partial abatement so that landlords would reduce the lead hazard to children rather than either evade an abatement law or abandon their properties.²⁷ As one of the researchers wrote:

The purpose of the study is to characterize and compare the short- and long-term efficacy of comprehensive lead paint abatement and less costly and potentially more cost-effective Repair and Maintenance (R&M) interventions for reducing levels of lead in residential house dust which in turn should reduce lead in children’s blood.²⁸

As the grant put it,

R&M, may provide a practical means of reducing lead exposure for future generations of children who will continue to occupy older lead-painted housing which cannot be fully abated or rehabilitated without substantial subsidy.²⁹

The study was designed to test the efficacy of three different levels of lead reduction in older homes. The investigators then planned to contrast those results with that of two control groups: one of children living in homes that had previously undergone what was thought to have been full lead abatement and the second of children living in homes built after 1978 and presumed to be lead free. More than 100 parents with young children were recruited for the study to live in partially lead-abated houses. The premise of the research was that children would now be in a safer environment, a home that was an improvement over the lead-covered homes that were generally available to poor residents of Baltimore. However, the blood lead levels of children in at least two of the homes rose during the study.³⁰ The two sets of parents

of these children filed the lawsuits alleging that they were not properly informed of the risks their children faced while participating in the study.³¹

THE OPENING SKIRMISH

The lawsuits of two children, M.H. and E.G., were initially brought separately to court.³² On February 22, 2000 KKI’s attorney Susan Boyce asked that the charges against her client brought in the Circuit Court of Baltimore be dismissed, on the grounds that “there is no contract or special relationship between KKI and [M.H.’s mother]” and that KKI was under no “duty to protect the plaintiff from harm.” In its initial written defense, then, KKI denied any responsibility for the lead poisoning that any children may have suffered. KKI argued that its role was simply to conduct research and that it had no role in inducing the family “to occupy the participant property.” Furthermore, Boyce argued, KKI had not leased the apartment and had only “limited contacts” with M.H.’s mother “after she moved into” the apartment and “voluntarily consented to participate in the study.” Boyce predicted dire consequences for science if the court were to hold KKI responsible in this case, suggesting that it “would have a chilling effect on all research projects that are being conducted every day in hospitals and institutions all over the country . . . that are designed to try to *eliminate* hazards in the most efficacious way.” To hold KKI responsible “would be a terrible tragedy for all citizens. And particularly for the children of Baltimore City who are being exposed to lead based paint in older homes every day.”³³

“For a century, lead poisoning had been a plague on the homes of Baltimore’s children, and almost no one had “taken up the banner of children exposed to this hazard.”³⁴

Poor African American children in Baltimore had been at risk for lead poisoning before any had volunteered to be part of the study; the housing the children lived in already had a lead hazard and, therefore, Boyce said, “It was not the study that presented any risk of harm” to the children. For a century, lead poisoning had been a plague on the homes of Baltimore’s children, and almost no one had “taken up the banner of children exposed to this hazard.”³⁴

In their argument, the lawyers for Johns Hopkins were returning to one of the fundamental rationales for the study’s design in the early 1990s: it was utopian to “require that all lead paint will be removed from all houses.”³⁵ In oral arguments before Allen L. Schwait, the judge in the circuit court, in early April 2000, Boyce argued that KKI was merely “an observer” that “collect[ed] information about an existing and evolving condition which KKI neither created nor controlled.” Second, KKI was carrying out a study that, to meet the requirements of epidemiological rigor, compared systematically the effects on children of differing levels of lead exposure in the home. If anything, Boyce argued, the plaintiffs in the case and all the study participants had benefited from being part of KKI’s research study because “all flaking, chipping and peeling paint was removed and some degree of additional remediation was provided.”³⁶

Because the study was merely observational, KKI argued, they did not need to inform or warn parents or the children themselves about the potential danger that lurked in the dust that was in their homes. KKI’s lawyers argued that the researchers were not involved in an experiment at all but were passively collecting data, rather than “actively doing something to the participants such as providing medical treatment or subjecting them to dangerous conditions such as a deep sea dive.” Because “the law requires informed consent before an actor does something to a person,” the legal team went on, KKI’s “only duty to Appellants was to inform them of any risks in collecting the data.” KKI did this by telling the study participants of the very minimal “risks attendant to the collection of blood,” and, therefore, KKI had met—even exceeded—the requirements of the law.³⁷ In fact, the consent form approved by Johns Hopkins’s Joint Committee on Clinical Investigation, its institutional review board, hardly mentioned any potential danger to the children living in the partially abated homes. As the Johns Hopkins’s attorney explained, the only risks that were explicitly mentioned were those associated with drawing blood.³⁸

Johns Hopkins’s lawyers were drawing a sharp distinction between active and passive research, medicine versus public health, a distinction that was rarely as clear in practice. But the argument that KKI presented initially to the Baltimore City Court did capture many of the rationales behind observational public health research in the 1990s and why it differed from medical research. Medical research introduced new procedures, medicines,

or technologies that were unavailable to the layperson. Public health research, by contrast, collected data useful in evaluating differing exposures and circumstances of persons in their everyday lives. Whatever the possible risks for individuals who lived in dangerous circumstances or engaged in unhealthful personal behaviors, the public health investigator was not actively subjecting the study participant to these dangerous circumstances or behaviors. Furthermore, testing a proprietary drug or device by providing it to some individuals and not to others was fundamentally different from surveillance of individuals in their everyday habitat. The argument KKI developed was that public health research could result in broad societal changes that could benefit entire populations and prevent illness, not simply treat it.³⁹

The lawyers for KKI gave a passionate defense of the institution and its public health mission. The only thing “foreseeable,” as they saw it, was that the selected children from Baltimore’s poor communities would have a lowered exposure to lead because KKI had been fixing up their houses and moving families into homes with lower lead dust levels. “If it hadn’t been for this study, this house would not have been touched; this child would have been exposed to more lead.”⁴⁰

KKI also had warned study participants through its informed consent form, Boyce said,

that lead poisoning in Baltimore City is a severe problem. That KKI was doing this study to determine whether they can find a cost-effective way to reduce a child’s exposure to lead, that repairs and maintenance were done to this property and they wanted to do periodic dust

sampling to find out whether the repairs and maintenance worked.

Boyce concluded, “I mean, I don’t know what more they could have told this woman.”⁴¹

The Circuit Court of Baltimore accepted KKI’s argument and dismissed the case the same day, April 5, 2000, writing that “KKI was sort of an institutional volunteer in the community.” KKI had come into the community with the best of intentions, the judge declared, and “the next thing you know they get sued.”⁴²

THE LAWSUIT APPEALED

There the matter stood legally for eight months, until January 2001, when the young attorney Suzanne Shapiro at Kerpelman and Associates filed an appeal of the circuit court’s decision to the Court of Appeals of Maryland, the state’s highest court. The appeal was specifically derived from what Shapiro saw as a misinterpretation and misrepresentation of the KKI study. Far from merely being a surveillance of existing conditions, she said, the study was a research experiment with no therapeutic value to the children who were put at risk. These children were part of a vulnerable population because of their socioeconomic status, race, and age. As such, KKI had a special obligation to make it absolutely clear that the families were not benefiting from the research and that their homes were still dangerous environments for young children. Furthermore, KKI could not claim that they were passive volunteers helping a community in need when they themselves were actively manipulating the conditions of the homes and the placement of families in these homes.

In sum, the appeal was an indictment of the KKI lawyers’ public health rationale for the study as its defense. KKI, working with poor children and young mothers, had a responsibility not only to document dangerous circumstances, Shapiro said, but also to inform the parents of all the potential dangers and to protect the children from harm. After all, “Kennedy could reasonably foresee the danger to which the minor plaintiff was exposed,”⁴³ Shapiro argued.

She pointed out that “Kennedy was well aware of the fact that the home contained unacceptable levels of lead in house dust” and that the children “could potentially ingest this leaded dust through normal hand to mouth activity, and that this ingestion could lead to permanent irreversible brain damage and neurobehavioral deficits.”⁴⁴ Although KKI may not have done the actual repairs or even paid for them, Shapiro argued, it was hardly a passive participant collecting data. It had designed the experiment, it had required that leaded homes be part of the study, it had contracted for limited repairs knowing that lead dust ingestion by children in residence was still a probability, it had received federal grants to carry out the research and the partial repairs on the houses, and, perhaps most damningly, KKI had “encouraged the landlord to lease the property to a family with a young child, and then waited for the minor plaintiff to move into the home to solicit the child’s participation in the experiment.”⁴⁵

“Kennedy’s intentions may have been benevolent,” she conceded, as “it sought to advance scientific knowledge.” But public health research had a greater

obligation than to the limited goals of finding cost-effective means of reducing lead poisoning or even to science. “[It] may have hoped that no child would be lead poisoned,” but, she argued, there was every “expectation . . . that some children would develop lead poisoning.” In essence, KKI was “sacrificing the health of the Study children” and was “utilizing them as guinea pigs to determine cost-effective environmental treatment of lead-based paint.”⁴⁶

At the heart of the legal and ethical issues of the case, Shapiro suggested, was the disparity of knowledge and power between the researchers and the participants of the study. “At a minimum, Kennedy owed a duty to warn of the specific hazards known to Kennedy and unknown to the participants.” Whatever the minimal, technical requirements of the institutional review board’s consent form, “every person has a right to freely choose what happens to his or her body and whether to participate in a research study that entails physical risks to his or her body.” The rights of vulnerable children and young parents, and the obligation of institutional review boards, she argued, went beyond a specific legal form or a narrow definition of responsibility. Simply put, KKI understood that the lead and dust tests performed in the house indicated that some areas “still contained high levels of lead in dust above the clearance criteria in Maryland for abated homes”⁴⁷ but did not inform M.H.’s mother that her child was at risk for weeks if not months later. By this time, the child’s blood lead levels had already risen.

KKI’s attorneys replied that lead poisoning as a result of the study’s interventions was not

foreseeable and, in fact, “the lives of each and every one of these children was improved.” They cited the researchers’ report to the EPA in 1998 after completion of the project’s second year. Those findings showed, they argued, that over time most children had reductions in blood lead levels, therefore proving the benefits of the research. KKI lawyers also rejected Suzanne Shapiro’s comparisons with not only Nazi medical experimentation but also the infamous Tuskegee study in which the US Public Health Service watched as more than 100 African American men slowly succumbed to the effects of syphilis over 40 years without offering them treatment of their disease.⁴⁸ Johns Hopkins said the accusations were absurd. “KKI concentrated its efforts in poor African American communities because that is where the need is greatest.” Far from exploiting a vulnerable population, KKI had acted in their best interest: “One can hardly imagine a more noble cause than KKI’s efforts to help the children of Baltimore fight against the scourge of lead paint poisoning.”⁴⁹

Shapiro argued that to have begun to fulfill its responsibility to fully inform the families of the potential dangers the children faced, Johns Hopkins would have used an adequate consent form that explicitly stated the dangers of exposure to lead. Referring to the very first sentence of the informed consent form, she noted that it stated, “Lead paint is a known problem in Baltimore City and other communities around the country,” but the document “never defines what that problem is.”⁵⁰

Shapiro then zeroed in on what she identified as a fatal flaw in the experiment. The study was

“not just examining the world as it already existed. Kennedy actually wanted to control the environments of these homes.”⁵¹ In other words, this was not an observational surveillance study of children and parents living in their preexisting home environments. Furthermore, the KKI researchers already knew the answers to the questions the study was meant to address, Shapiro charged.

Kennedy is not trying to find the safest way to prevent children from getting lead poisoning. Kennedy already knows that the safest way . . . is to fully and completely abate homes or put children in homes that were built after 1980 that don’t have any lead paint in them.⁵²

The real “purpose of the study,” Shapiro argued, “was to see if there was anything cheaper that could be done [because] landlords say it is too expensive to fully abate these homes.” KKI, she pointed out, “could have done a different experiment” that would have been observational. “They could have gone to the homes [of children identified by the health department as lead poisoned] and . . . measured the dust in those homes.” If they had done that, Johns Hopkins would have had a legitimate argument that “they were just passively observing the collected data.”⁵³

Shapiro insisted that federal regulations to protect human research participants were meant to address situations like this. History had taught, she pointed out, that “the researcher’s interest in advancing science conflicts sometimes with the duty to protect the research participant.” In this specific case, the mothers were never told directly, “We believe inherent in the study a child living in

that home may be poisoned. And that means permanent, irreversible brain damage to your child.”⁵⁴ The parents and children were volunteers and they were benefiting Kennedy, she said, yet they were “not getting any benefit from this at all.”⁵⁵

Michael Joseph of Godard, West, and Adelman, attorney for KKI, objected. He thought it was “disingenuous” to argue that “to be able to live in a home that had these repairs done to it” did not count as a benefit.⁵⁶ Whatever lead hazard existed in the house amounted to an improvement over what had existed before, Joseph asserted. “These homes were in disrepair. Kennedy went in there and improved the homes,” reducing the dust to “permissible lead levels. And in this case, the home was repaired so that it was below”⁵⁷ Maryland’s legal standard.

In the end, an 80-page court decision condemned the study and KKI for conducting it, comparing it to Tuskegee and Nazi-like human experimentation, a parallel that the researchers found particularly offensive, noting, “Society was already doing a Tuskegee experiment” because we were already allowing millions of children to be lead poisoned. “Very little if anything was happening to remove lead while children were being poisoned.”⁵⁸

Gary Goldstein, KKI’s chief executive, maintained that understanding the context in which the research was conducted was all-important. The children were at high risk for lead poisoning in any case: “If you come into East Baltimore,” Goldstein said, “it’s not like one child in 100 is exposed. It’s everyone, and we’re trying to fix it.” He argued that “if a child is lead-poisoned in one of those houses, is that our fault

and are we doing something wrong by studying those children?”⁵⁹ Goldstein denounced the court for suggesting that KKI and its doctors would purposely put children in harm’s way. Rather, the intentions were noble and benevolent, he said. Baltimore’s poor were stuck in neighborhoods “where 95 percent of the houses contain lead” and where “35 percent of the kids have lead poisoning.” The research was aimed at finding a way to provide housing residents could move into “and not get lead-poisoned.” In fact, that’s exactly what happened “for the majority of kids in the study, lead levels did go down.”⁶⁰ This position was echoed in many other public pronouncements by those connected to the KKI research effort and by others.⁶¹

The decision, particularly the court’s allusions to Nazi science and Tuskegee, rocked pediatric and public health researchers around the country, according to two prominent lead researchers not at Johns Hopkins, Kim Dietrich at the University of Cincinnati and David Bellinger at Harvard,⁶² who wondered whether they faced a similar predicament in their own studies. Like the KKI researchers, some of them were observing children in less than fully abated homes and recognizing that these children were at some risk. Unlike KKI, however, they had not actively intervened in the creation of the children’s environments. They were also faced with the challenge of reconciling traditional public health commitments to protection and prevention against disease with the desire to make at least some positive difference amid practical realities of governing institutions unwilling to spend the money to protect

the lives of primarily poor African American and Hispanic children.

Others worried about the legal implications of the court’s decision.⁶³ Michael Weissman, the director of the American Academy of Pediatrics, Center for Child Health Research, called this “a profoundly important, ironic and sad case.” He worried that the court’s decision could make it more difficult to conduct similar types of research in the future:

You never, ever want to hurt a child or put a child in harm’s way. But for very large numbers of America’s children, the only way that we can protect them from lead, at this particular point in history, is to do this type of research.⁶⁴

Other researchers agreed that there was an important rationale and need for such studies. Bruce Lanphear, then at the University of Cincinnati, was an important lead researcher and avid advocate for protecting children from lead who had recently published an article suggesting that there may not be any level of lead exposure that is safe for children; he captured the unhappiness of much of the research community with the court’s denunciation of the study. Lanphear argued that good, rigorous science demanded well-controlled studies such as KKI’s was intended to be. There was simply no other means of scientifically evaluating the effectiveness of specific lead control efforts in stemming the epidemic other than “testing blood lead levels in children.”⁶⁵

Paul Mushak, the toxicologist whose own work had been central to the discovery of airborne lead dust as a serious threat, argued that the logic and conclusions of the court decision were sounder than its hyperbolic

rhetoric. “The matter of some intemperate judicial hyperbole aside, the court’s concerns reasonably align with accepted (albeit often somnolent) guidelines in the health science communities.” The issues that arose at KKI emerged from a set of common realities that framed all research on any “pervasive toxic contaminant such as environmental lead.” The realities, Mushak posited, were that the toxin was ubiquitous throughout the environment and will cause “toxic harm . . . in the absence of effective remedial interventions becoming fundamental public health and regulatory policies.” “Primary prevention of toxic exposures” is the “ideal societal and health science option,” but it is not always politically possible. The “design and implementation of interim, i.e., not total or permanent, remedial interventions in the case of childhood lead exposures result in” real contradictions because “partial interventions require that children be studied in the absence of any empirical certitude as to total participant safety.” In such research the safety of the children “requires an added set of safeguarding methodologies that avert development of toxic risk to children” as a “toxicological artifact of the research from the research itself.”⁶⁶

The court of appeals decision sent the case back to the lower court for trial. However, that public airing of the research and ethical issues raised by the court of appeals never occurred because the parties in the suit, Johns Hopkins University and the parents of the lead-poisoned children, settled the matter out of court. But the story did not end in 2001. In September 2011, 10 years after the court of

appeals issued its rebuke of Johns Hopkins, lawyers in Baltimore filed a class action law suit against KKI for, in the words of the *New York Times*, “knowingly exposing Black children as young as a year old to lead poisoning in the 1990s as part of a study exploring the hazards of lead paint.”⁶⁷

THE LARGER MEANING OF THE JOHNS HOPKINS EXPERIENCE

The Baltimore study was organized in the wake of a dramatic rethinking of the use of human participants in scientific experiments. During the preceding 20 years, researchers had become acutely aware of the ethical dilemmas presented by human participant research, especially those involving vulnerable populations. The legacy of Nuremberg, the revelations about the Tuskegee experiments, and publication in the late 1970s of the “Belmont Report”—the landmark federal report that expanded and codified the principles of ethical research with human participants—combined to cast doubt on the morality and ethical basis of the KKI research.⁶⁸

The history of the KKI research could be seen as a fight between two defensible conceptions of the public good rather than a fight between the forces of good and the forces of evil. Of course, this raises a different question: are two defensible conceptions of the public good both ethically justifiable with respect to putting others knowingly in harm’s way? Could not valuable research be—and have been—done on levels of abatement without putting children in harm’s way with a differently designed study?

Above all, the KKI research effort exposed a fault line that divided poor people from the rest of Americans and extended far beyond the ethics of an occasional research project. No one would suggest that a middle-class family allow their children to be exposed to a toxin that could be removed from their immediate environment. But for decades, as a society we have accepted that poor children could be treated differently. We have watched for more than a century as children have, in effect, been treated as research participants in a grand experiment without purpose. How much lead is too much lead? What are the limits of our responsibility as a culture to protect those without the resources to protect themselves?

The history of lead poisoning and lead research is a paradigmatic tale of the developing controversies on a range of toxins and other health-related issues debated in the popular press, in the courts, and among environmental activists and consumer organizations, as well as in the public health profession itself. Public health officials struggle mightily with declining budgets, a conservative political climate, and many challenging and new health-related problems. Today, the public health community continues to have the responsibility to prevent disease. But it does not have the resources, the political mandate, or the authority to accomplish this task, certainly not by itself. It is an open question whether it has the vision to help lead the effort or to inspire the efforts needed.

Whatever the limitations of the bacteriological and laboratory-based model that public health developed in the early part of the 20th century in

response to the crises of infectious disease, there is no arguing that it provided a coherent and unifying rationale for the profession. But, as we witness the emergence of chronic illnesses linked to low levels of toxic exposures, no powerful unifying paradigm has replaced bacteriology. Some suggest that the “precautionary principle” can serve as an overall guide, arguing that it is the responsibility of companies to show that their products are safe before introducing them into the marketplace or the environment, that we as a society should err on the side of safety rather than await possible harm.⁶⁹ By adopting this approach, public health will reestablish prevention as its primary creed. Others insist that a renewed focus on corporate power, economic inequality, low-income housing options, racism, and other social forces that shape health outcomes is most needed to counter the antiregulatory regime of early 21st-century America. These ideas, or a more unified alternative, however, have yet to galvanize the field or the broader public, at least in the United States. This is a conundrum that affects us all, for we console ourselves with partial victories, often framed as progress in the form of harm reduction rather than prevention. We have become willing to settle for halfway measures. In this sense, we are all in that “experiment” in which we allow certain classes of people to be subjected to possible harm in the expectation of avoiding it ourselves.

In his own contribution to the discussion, Herbert Needleman, perhaps the most well-known lead researcher in the country, asked how good people ended up asking questions that were compromised from the beginning:

“Why did it become necessary or desirable to conduct studies looking for the least expensive means of removing lead from houses?” Needleman traced the ways that human participant research had evolved in the past few decades as statistical and epidemiological methodologies created abstractions of their clients and participants. He acknowledged the problems of early medical practice when physicians regularly “practiced” on patients, applying nostrums and experimental procedures “of uncertain efficacy and unknown risk.” As practitioners and researchers had become more aware of patients’ rights and their professional obligations to inform patients of the risks and benefits of various medical procedures, some positive changes had occurred.

Institutional review boards were certainly a part of this reform effort. But, Needleman pointed out, such efforts to oversee the activities of well-meaning practitioners and researchers were resented both by the medical and the public health communities, who saw them as an intrusion into the relationship “between us and the participants of our inquiry, or of digressions between us and the answers we seek.” Despite the good intentions and noble ambitions of investigators, such institutional oversight was necessary, Needleman said, “not because investigators are callous or evil, but because clinical studies by their nature do not grant participants full status as persons.” He specifically noted epidemiological studies, which, he argued, search “for normative content in *samples*, and deal with the differences in *people* by the use of summary variables such as standard deviations or confidence

limits.” Distancing was inherent in such epidemiological studies, he said:

There is simply no room in spreadsheets for the “I-Thou” relationship that Martin Buber described. It is in the spreadsheets, not in the people, that the principal investigator finds the information he seeks, and in them, the “Thou” of an individual is replaced by “It.”⁷⁰

Every aspect of a research project reinforces this disembodiment of the individuals in the study.

Needleman reminded his readers:

As a study is designed, the proposal written, the administrative structure to conduct it shaped and recruiting done, the patient as individual becomes more distant. As deadlines approach, problems appear and are dealt with, and participants’ singular identities fade. It requires a strenuous effort to keep their personhood in mind and a vigilant external force to assure it.

This was not the problem of researchers at Johns Hopkins only but, rather, “this distancing happens to everyone who has undertaken a clinical study.”⁷¹

Needleman criticized the court for comparing what happened at KKI with Tuskegee and Nazi science. Whatever happened at KKI, the conduct of the research did not rise to the level of a crime such as that which took place at Tuskegee. The problem at KKI was nevertheless profound and went to the heart of American medical and public health science. For a brief moment in the early 1990s, at the very moment that the KKI study was being formulated and implemented, Needleman argued, the federal government was on the verge of making a commitment “for the elimination

of childhood lead poisoning” following his meeting with government officials in 1991 when he was told that it was a goal to finally delead the nation. But then strong opposition “from a number of quarters” undermined this possibility.⁷²

It was “in this climate,” Needleman continued, that research limited its vision and constricted its goals: “The question became, ‘how little can we

“It was “in this climate,” Needleman continued, that research limited its vision and constricted its goals: ‘The question became, ‘how little can we spend and still reduce blood lead levels in the short term?’”⁷³

spend and still reduce blood lead levels in the short term?”⁷³

Needleman’s frustration at the time can perhaps be traced to his recognition that by the 1990s the vast majority of public health officials and researchers already knew that lead had to be removed from the child’s environment if they were to be protected from the low levels identified as a hazard. If researchers had been looking for ways to completely and safely abate the lead hazard, the rationale for the study may have been acceptable to Needleman and, later, the court and the public at large. But there was not the political will of the larger community to confront either the racial and class prejudices of the culture or the power of real estate interests by insisting that the children of poor, often minority populations be freed of the scourge of lead poisoning. Society as a whole had retreated from its responsibility to protect the most vulnerable. Public health practitioners and researchers alike

in this circumstance could only get funding to work at the margins and by and large would not confront the deeper social inequalities that were destroying children's lives. What was public health's response to this social abandonment? Do another study.

SOME CONCLUDING THOUGHTS

Acute lead poisoning, the kind of poisoning children suffered before the 1980s, was perhaps the oldest and best understood environmental disease. For the most part it has been successfully contained in the United States through a series of judicial, legislative, and regulatory decisions and a set of scientific discoveries and medical interventions over the past 50 years. Removing some of the most obvious sources of lead from the world of children and adults—including gasoline, paint, canned foods, and other widely available consumer products—was an outstanding public health achievement, one in aggregate that lowered the average exposure to lead by orders of magnitude. Through coalitions with social reformers, public health authorities were able to press national, state, or local authorities to enact legislation and authorize agencies to achieve reforms. Because of reduced exposure consequent to those reforms, US children today rarely go into convulsions or suffer massive brain damage from lead poisoning, although this is still a major problem in many areas of the developing world.⁷⁴

But, concern over acute lead poisoning has now given way to increasing recognition of subtler but often still devastating prob-

lems lead ingestion can induce that were only vaguely considered a generation or two ago. Indeed, lead researchers over the past few decades have changed our understanding of the effects that low levels of lead have on the developing child's brain. This has led to new research that has uncovered the low-dose dangers of other toxins such as mercury, chromium, and other heavy metals. The level of arsenic in some of our water supply is with good reason a cause of concern to the EPA and state health officials. Also, the widespread development by the chemical industry of chlorinated hydrocarbons such as the insecticide DDT (dichlorodiphenyltrichloroethane), PCBs (polychlorinated biphenyl), vinyl chloride, and numerous other persistent pollutants in the post-World War II era as well as a variety of endocrine disruptors, such as bisphenyl A and phthalates, pose many new threats to humans and the environment. As we confront new information about the environmental impact of many new chemicals that are introduced every year into the air, water, and soil, whose reach extends beyond the poor, the KKI story—and that of the modern history of the lead wars more generally—raises issues that by our responses will define us all.⁷⁵ ■

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We have testified on behalf of plaintiffs in lawsuits involving lead-poisoned children but have never had a role in the lawsuits discussed in this article.

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