TESTIMONY FROM INTERIM CHIEF EXECUTIVE OFFICER LISA BOVA-HIATT
WATER TESTING AT JACOB RIIS HOUSES
COMMITTEE ON PUBLIC HOUSING WITH THE COMMITTEE ON OVERSIGHT AND INVESTIGATIONS AND COMMITTEE ON ENVIRONMENTAL PROTECTION
FRIDAY, SEPTEMBER 23, 2022 – 1:00 PM
16th FLOOR COMMITTEE ROOM, 250 BROADWAY, NEW YORK, NY

Chairs Alexa Avilés, Gale Brewer, and James Gennaro; members of the Committees on Public Housing, Oversight and Investigations, and Environmental Protection; other distinguished members of the City Council; NYCHA residents; and members of the public: good afternoon. I am Lisa Bova-Hiatt, NYCHA's Interim Chief Executive Officer (CEO). I am pleased to be joined by Eva Trimble, Chief Operating Officer; Daniel Greene, Senior Vice President for Healthy Homes; and other members of NYCHA's team. Our partners Vincent Sapienza, Chief Operating Officer of the New York City Department of Environmental Protection (DEP), and Corinne Schiff, Deputy Commissioner of Environmental Health at the New York City Department of Health and Mental Hygiene (DOHMH), are also with us today.

I was recently appointed Interim CEO of NYCHA, as part of our Transformation and Implementation Plan efforts to separate the roles of CEO and Chair of the Board of Directors and strengthen our organization. I have dedicated my entire career to public service, and I come to this role after serving as NYCHA's General Counsel for more than two years.

We understand that the recent events at Riis Houses have been very disruptive and upsetting to residents, and I want to begin by telling them publicly that we are 100 percent committed to restoring their confidence in the drinking water, a vital necessity. We are also committed to providing a transparent and honest accounting of NYCHA's and its contractor's actions during this incident. As an organization, we have taken significant steps forward over the past three and a half years, and part of that progress involves admitting when mistakes were made and providing a plan for correcting them. That is what we would like to do today, in addition to answering your questions about this occurrence.

Transforming NYCHA

Before addressing Riis, I think it is important to describe some of the work that NYCHA has been doing over the past three and a half years. Since 2019, NYCHA has been working to fundamentally transform its business model as well as its compliance, operations, and management infrastructure – in tandem with the critical work to improve residents' quality of

life through various preservation and capital programs that bring comprehensive renovations to their homes.

The foundation of this work, which we are carrying out in partnership with the federal Monitor, is our Transformation Plan and the HUD Agreement; they guide our efforts to improve customer service and responsiveness to conditions at our developments, ensure that large projects are completed in a timely manner, promote accountability, manage our properties better, and use our limited funding more effectively, all while addressing critical areas that most impact residents.

For instance, we instituted a Neighborhood Model to create smaller property management portfolios and localize decision-making. We are rolling out the Work Order Reform initiative to streamline repairs. We revised our janitorial scheduling to best address the unique maintenance needs of each site. We launched an online capital projects tracker to enhance transparency. We are reorganizing and strengthening our leadership structure.

To date, we have generated more than $3.4 billion in capital funding for top-to-bottom building renovations for nearly 15,500 households through the PACT program. Our Comprehensive Modernization program will bring total renovations to additional sites. Through the newly established, historic NYC Public Housing Preservation Trust, we have the opportunity to fully repair and upgrade 25,000 apartments. To improve residents' quality of life, we are spending hundreds of millions of dollars on HUD Agreement pillar areas (an average of $75 million a month on capital projects alone); more than a billion dollars of construction work is currently underway across NYCHA developments to replace elevators, boilers, roofs, facades, and more. Our efforts have reduced the time it takes to resolve elevator and heat outages and are expediting lead-based paint abatement in homes where children under 6 live or regularly visit.

We are improving our procurement practices and we established an Environmental Health & Safety Department, a Quality Assurance Unit, and a Compliance Department. A key focus of the Compliance Department is to investigate actions taken by NYCHA staff that do not comply with rules, regulations, or internal procedures and to then integrate a set of procedural recommendations and changes into NYCHA's daily work at the properties.

We are making communication with residents and other stakeholders a priority. In 2021 alone, we published over 460 articles on our websites, drafted dozens of resident-wide emails and letters, released 45 videos, translated over 2,700 documents, fulfilled over 400 interpretation requests, posted over 3,600 items on social media, and regularly distributed robocalls to nearly

320,000 phone numbers. That same year, our Customer Contact Center (CCC) handled nearly 2 million calls. Every time there is a relevant service outage, we post flyers at developments and disseminate robocalls to residents. Our monthly rent inserts provide information by mail to 105,000 households and to over 58,000 households online. Our direct mailings reach more than 162,000 households. Oftentimes, we conduct direct outreach to residents on important topics through door-knocking. We also engage and communicate with residents extensively through our Resident Services, Partnerships, and Initiatives department, which ensures that residents' voices are heard through a variety of programs, services, and initiatives, including our work around resident elections. We meet with and speak with resident leaders on a very regular basis, and offer opportunities for residents to get involved through platforms like the Resident Roundtable.

Our goal at NYCHA in the last few years has been to focus on the basics. First, we must put residents' health and safety front and center in our efforts. Second, we must work to better maintain our aging building systems. Third, we must secure funds from all available sources to re-invest in our buildings, which are a critical source of deeply affordable housing for hundreds of thousands of New Yorkers. And fourth, which is what I want to focus on today, we must be willing to acknowledge when we make mistakes, assess those mistakes, and then work to improve.

Resident Safety Is Our Top Priority

Thank you for this opportunity to discuss the water testing efforts at Riis Houses. First, we would like to apologize to the residents of Riis Houses for the stress caused by the investigation into the drinking water at their development. Residents' health and safety is our top priority. Throughout the process, NYCHA endeavored to ensure residents' wellbeing while we assessed the situation, as quickly and transparently as possible and with regular communication to residents that included in-person meetings, robocalls, flyers, and emails in the covered languages of English, Spanish, Traditional Chinese, Simplified Chinese, and Russian. At each point, we took the most conservative and precautionary measures possible to ensure residents' health and safety.

We would also like to thank our partners across the community and in City government, including Mayor Eric Adams, Chief Housing Officer Jessica Katz, and members of the Council, for coming together during a challenging moment, helping us distribute more than 380,000

bottles and cans of clean water while we tested approximately 140 sites of the water system at Riis Houses.

The water at Riis Houses is safe. Unsafe levels of arsenic are not, and were never, present in the water supply at Jacob Riis Houses. To be as transparent as possible, NYCHA, DEP, and DOHMH published final test results in two places on NYCHA's website: one area enables Riis Houses residents and the public at large to review all test results related to arsenic; another area provides all test results related to bacteria. Both webpages link to the test results collected by two NYCHA vendors and DEP. Summaries of NYCHA, DEP, and DOHMH findings are also on our website. Copies of the test results will also be available in the property management office at Riis Houses.

We encourage everyone to review the results on our website and see how much work was put into ensuring the water was safe to drink before the drinking water advisory was lifted. Specifically, one can see the results of samples taken by a qualified NYCHA vendor, LiRo Environmental, at 140 locations throughout Riis Houses to test for arsenic as well as additional samples to test for bacteria. The public can also see the results of DEP's testing from mid-August to early September, as well as the results that were since retracted by the laboratory retained by NYCHA's original vendor. Taken together, they show that the water is safe to drink at Riis Houses.

Timeline of Events

I would also like to take this opportunity to clarify some of the public reports related to the timeline of events surrounding when NYCHA first learned about a possible exceedance of arsenic levels in the drinking water at Riis Houses and what NYCHA did about it. Please note that this reflects the facts that we have at the current moment, and that this is an ongoing investigation.

- From May 1 through September 3, 2022, NYCHA received 93 complaints about cloudy water from Riis Houses residents. The bulk of these complaints started the week of July 3 and subsided by August 27, and most of them came from buildings serviced by the water system flowing from Building 11.

- In those months, we undertook a number of strategies to address these issues, including cleaning and having our vendor re-test the water tank, eventually repairing one of the house pumps serving the Building 11 roof tank, and asking DEP to test the water mains.

In addition, in responding to such complaints, a maintenance worker will remove the apartment faucet's aerator, cleaning it of any debris, and run the water. If this doesn't resolve the matter, a plumber will examine the building's equipment (house pumps, etc.) to determine the source of the issue. If necessary, a roof tank cleaning or re-cleaning is conducted.

- On August 13, LiquiTech, a vendor previously retained by NYCHA, collected samples at the point of entry to Building 11 at Riis Houses in response to concerns raised by residents and elected officials about water quality at the development. This was not required by any law or regulation. This was something NYCHA decided to do voluntarily to gather information for our residents about water quality. We worked with LiquiTech to develop a plan to sample for a wide range of analytes, including arsenic, and to conduct bacteriological testing. LiquiTech took additional samples in other locations at Riis Houses on August 16 and August 17.

- LiquiTech then sent the samples from the Building 11 point of entry to the Environmental Monitoring and Technologies, Inc. (EMT) laboratory for broad-spectrum testing (i.e., testing for a range of contaminants). EMT is not a New York State Environmental Laboratory Accreditation Program (ELAP)-certified laboratory. I understand that EMT does have certifications and credentials from Illinois NELAP; DOD ELAP; Wisconsin DNR; Alaska ADEC; State of Texas; State of Washington; Field Services NEFAP; and ISO/IEC 17025:2017.

- LiquiTech sent other samples to Special Pathogens Laboratory/PACE (SPL), which conducted the bacterial testing. SPL is an ELAP-certified laboratory.

- On August 25, NYCHA followed up with LiquiTech for the test results, suggesting that partial results could be sent ahead of full results. LiquiTech had informed NYCHA that they hoped to begin providing results within two weeks. As you can see on our website, other tests by DEP were ongoing at a hydrant adjacent to the property during this time and results had been received by NYCHA.

- On Friday, August 26, EMT finalized its report (which is why the report is dated August 26). However, NYCHA did not receive the report from LiquiTech until the morning of Monday, August 29, after NYCHA had again followed up via email with LiquiTech that morning.

- The analysis, by EMT, reported an estimated value of arsenic at 12.2 parts per billion (PPB), which is above the U.S. Environmental Protection Agency's (EPA) standard, established in 2001, of 10 PPB. However, the report also showed that the laboratory had a reporting limit of 12.5 PPB, which means the smallest concentration the laboratory would need to find to report with precision was 12.5 PPB. To put a finer point on it, this reporting limit was slightly above the actual reported result and the lab could not confirm the result with full confidence.

- As you can see online, this value of 12.2 parts per billion was also defined by EMT as a qualified "J" (or estimated) value.

- Because this was an estimated value and there were uncertainties regarding the accuracy of the result, NYCHA's staff made the prudent decision based on this report to try to get a confirmed result with additional tests. NYCHA staff instructed LiquiTech to collect additional samples at Riis Houses the following morning, on August 30. NYCHA staff also reported this plan to NYCHA's executive leadership on the afternoon of August 29.

- On August 30, LiquiTech collected two samples at the point of entry for Building 11, one sample at the point of entry at Building 8, two apartment samples in Building 11, and one apartment in Building 8. EMT received these samples on August 31.

- On September 1 in the afternoon, LiquiTech informed NYCHA that five of the six samples were above the contaminant limit for arsenic, and LiquiTech produced a report from EMT showing levels of arsenic among these samples between 13.6 and 14.1 PPB.

- Within a few hours, NYCHA leadership notified DEP as well as DOHMH. DEP immediately coordinated with NYCHA to take samples for arsenic the next morning at the point of entry.

- On September 2, DEP sampled water at the hydrant it previously tested twice for other parameters in mid-August, and DEP also took samples from the Building 11 point of entry, testing for arsenic in addition to other standard parameters.

- Also on September 2, DOHMH advised NYCHA that, out of an abundance of caution, it should issue a drinking water advisory and tell residents to not drink or cook with the water. DOHMH also advised that NYCHA should flush the buildings before retesting the water. NYCHA convened its executive leadership team to discuss next steps and an

action plan for immediately implementing DOHMH's recommendations. City Hall was notified of the results, and NYCHA and City Hall began notifying elected officials and community partners.

- NYCHA notified residents (via flyers, emails, and robocalls) and the public about the elevated levels. The robocall to residents was in all the covered languages; the email and flyer were distributed in English while the translations were being completed. We notified Riis Houses' resident association president, as well as other members of the Riis resident association and the Chair of the Citywide Council of Presidents, before the robocalls went out. A script was provided to CCC call takers with information for residents.

- NYCHA also began distributing potable water: water was distributed 24 hours a day, every day from September 2 through September 11. In total, 46,000 gallons of water were distributed, thanks to the assistance of NYC Emergency Management, New York State, the New York State Division of Homeland Security and Emergency Services, the NYC Department of Citywide Administrative Services, and community partners. In addition, DEP set up two water stations that provided access to water 24 hours a day. Approximately 1,200 households picked up water each day from the distribution site, while NYCHA delivered water to approximately 150 households each day.

- LiquiTech later also shared with NYCHA the preliminary results from LiquiTech's bacterial testing conducted in mid-August. NYCHA shared this information with DEP, DOHMH, and City Hall. LiquiTech advised that the results were preliminary and should not be relied upon to determine whether water quality standards were exceeded. DEP reviewed the results and informed NYCHA that the species preliminarily identified are common to the NYC water system and that bacterial growth can be common in certain taps (especially if they have not been disinfected) and as a result of flushing. DOHMH also reviewed and stated that prior cleaning or removal of the aerators, flushing the tap, and disinfection are recommended to get representative results, which LiquiTech confirmed had not happened.

- Some of the samples also showed the presence of *Legionella* bacteria, and so NYCHA immediately consulted with DOHMH to determine next steps with respect to this finding. According to DOHMH, Riis Houses did not meet the criteria to initiate remediation protocols for *Legionella*, which follows CDC guidance.

- NYCHA also then had LiRo collect 22 additional samples to analyze for the standard bacteria tests for drinking water – including total coliform and E. coli – and 35 additional samples that included total coliform, E. coli, and heterotrophic plate count (a method used to measure the variety of bacteria that are common in water). The results did not indicate any area of concern within the Riis campus and also met EPA safety standards for drinking water.

This timeline from August 29 to September 2 demonstrates that NYCHA informed its expert agency partners and the public promptly upon receiving confirmed reports that there were elevated levels of arsenic at Riis (reports that turned out to be false positives). NYCHA acted quickly to try to confirm a result that was based on an estimated value below the laboratory's reporting limit by collecting additional samples. In addition, as soon as a confirmed result was received by NYCHA on September 1, the Authority informed experts at DEP and DOHMH. NYCHA then began to work with our agency partners to implement next steps that would help protect the health and safety of residents at Riis Houses.

From that point forward, NYCHA worked to implement a plan that would help ensure the water was safe to drink before the advisory could be lifted. This included following DOHMH's guidance regarding flushing the water systems, procuring a new vendor to take samples from approximately 140 locations throughout Riis Houses, coordinating access so that DEP could take their own samples, and working to provide potable water on a regular basis while communicating with residents. Of course, as we all know now, EMT would subsequently retract their results on September 9, 2022.

Assistance to Residents

In addition to ongoing water testing to demonstrate its safety, we've committed to holding additional periodic meetings with Riis Houses residents, in collaboration with the Riis resident association, and we're issuing a reimbursement to Riis residents. This had been discussed at a post-action plan meeting that we held recently with resident association members and elected officials.

I'd like to give a special acknowledgement to our Resident Services, Partnerships, and Initiatives staff, as well as our Operations and Emergency Management and Services teams, for delivering water to about 150 seniors and homebound residents daily, knocking on every door at Riis Houses to flush the water system and provide information, and providing other assistance when

needed. In collaboration with the resident association, we worked with our non-profit partners to provide meals to residents – for instance, ICNA Relief provided initially over 500, then about 4,000, meals each day as well as fresh fruit; Vision Urbana provided pantry items. Also, our Office of Public/Private Partnerships worked with a non-profit organization, Good Neighbor Collective, to provide backpacks and school supplies to Riis residents.

Operations staff were on-site around the clock to assist with water distribution and other matters, and Emergency Management and Services staff were on-site on a nearly 24/7 basis.

We assigned a strong contingent of staff on the ground so that we could visit every single apartment at least three times over the course of 11 days, addressing repairs or services requested by residents. In addition, staff were available at the tent we set up to follow up on concerns or issues raised by residents and answer questions. NYCHA leadership was also on the ground every day, from about 7:30 a.m. to as late as midnight, connecting with resident association members throughout the day in person or by phone to keep them abreast of every new development in real time. We also communicated regularly with elected officials via in-person meetings, Zoom and phone calls, and texts. NYC Emergency Management, DOHMH, DEP, and the NYPD were also on-site daily for several days – the latter two agencies on a 24/7 basis for a portion of the time period.

Spanish, Mandarin, and Cantonese interpreters were also on-site to assist during the flush of the water system on September 3 and during a public meeting held with residents on September 9. In addition, Spanish and Mandarin interpreters were on-site daily to assist from September 8 through 11.

Throughout the investigation, we sent an initial email to residents, disseminated nine robocalls, and posted six different flyers (all in the covered languages of English, Spanish, Traditional Chinese, Simplified Chinese, and Russian). We also updated the script for CCC call takers periodically.

Resident outreach as part of our Sandy recovery work has been particularly robust at Riis Houses. Residents have access to a dedicated construction liaison, email and phone hotline, and interpreters; receive bi-weekly construction progress emails; and can participate in community meetings. There are also weekly check-ins with resident leaders, depending on their availability. Since the Sandy recovery work started, there have been nearly 250 meetings, 42,000 phone calls (including robocalls), and 12,000 flyers posted about the construction work.

How We Improve From Here

I don't want to leave the Council with the impression that I think NYCHA did everything right. We did not. Since NYCHA signed our Agreement with HUD in January 2019, we have not been shy about calling out our mistakes and being transparent about what needs to change. To that end, we are committed to evaluating each step NYCHA took, or did not take, at Riis Houses related to water quality. This evaluation is critical to ensure we improve our performance as a property manager.

Our Compliance Department and Environmental Health & Safety Department are actively working with the federal Monitor, the NYC Department of Investigation's Inspector General for NYCHA, and others to evaluate what went wrong at Riis Houses and what we need to do to improve. Although the investigation is ongoing, we have already identified four key matters we need to improve here at NYCHA.

First, we need to do a better job sourcing and managing vendors. Clearly, the performance of the vendor chosen to collect the first round of samples, and the laboratory chosen by that vendor, did not perform up to the standard we expect. But we also know that it is the responsibility of NYCHA staff to properly manage any vendor, including by establishing a clear scope of work and by insisting that all the samples be sent to a laboratory certified for the evaluation and analysis we are seeking.

Second, we need to do a better job communicating with our residents. We should be informing resident leadership every step of the way when we are dealing with something as essential as drinking water.

Third, we need to do a better job assessing the performance and function of critical mechanical systems. In this case, early indications suggest that the failure of one of the two house pumps in Building 11 that pumps water up to one of the Riis Houses roof tanks may have been the root cause of the cloudy water complaints. Complaints were generally concentrated in a specific timeframe where we believe the system was not functioning fully, and virtually all of the complaints came from the buildings that are serviced by the Building 11 roof tank. It is true that many of NYCHA's mechanical systems are old, beyond their useful life, and difficult to maintain. However, it is also true that NYCHA must do better when it comes to identifying mechanical system failures – and then NYCHA must act quickly to remedy the problem. In this case, we already know that efforts to solve the problem took too long.

And finally, NYCHA needs to set up a standard protocol for what to do when there are complaints of cloudy water. This means we must define what constitutes an emergency situation, and work to set up clear benchmarks for when our agency partners and the public must be notified about a situation at a NYCHA development, among other items.

This work is critical, and we look forward to hearing the Council's recommendations on how NYCHA can continue improve.

Conclusion

We know this was a very disturbing and upsetting experience for our residents, and we are truly sorry that this happened. We are glad that the water is safe – the lab issued a full retraction and acknowledged its error – and that we were able to get to the truth of the matter quickly. Everything we do, and every decision that we make, is driven by our concern for our residents' health and safety. Thank you for your partnership as we strive to foster safe and healthy communities for NYCHA residents while transforming our organization. We will continue to keep you updated, and we are happy to answer any questions you may have.

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September 23rd, 2022

Chairperson Alexa Avilés and Chairperson Gale Brewer
Committee on Public Housing and the Committee on Oversight and Investigations
City Hall,
New York, NY 10007

Dear Chairperson's,

As the Council Member for the 49th district I have witnessed firsthand the egregious conditions that many residents of NYCHA housing are often forced to endure, whether it be a lack of cooking gas, falling ceilings, major leaks, heating issues, mold, elevator outages and a nearly endless list of problems. While today's hearing centers on the recent water conditions of the Jacob Riis Housing Complex, this issue is indicative of much larger and pervasive problems facing the residents of NYCHA housing.

Within my first year in office, we received notification that residents of both Stapleton and Mariner's Harbor NYCHA housing complexes had to endure weeks without cooking gas, with the former having this issue for over 11 months. Simultaneously, senior citizens who were residents of Cassidy-Lafayette Senior Housing Complex were subjected to several weeks without heating in the middle of the winter. This is not to mention the hundreds of constituent calls my office has received regarding other issues within their homes, including mold, leaks, cracked ceilings, exposed wires, and more.

When taken together, the issues facing both the residents of my district and those across the city, as evidenced by the incidents at the Jacob Riis Housing Complex, are indicative of pervasive shortcomings within NYCHA housing that must be addressed expeditiously. As the local representatives for the residents within our districts, it is incumbent upon all Council Members to have direct access and oversight over these complexes to better serve our constituents.

In sum, I would like to thank the committee chairs for overseeing this important hearing, and I want to urge the appropriate agencies to continue developing comprehensive approaches to resolving the unacceptable conditions of the NYCHA housing complexes within our City. All citizens are entitled to healthy and equitable living conditions and we must strive for nothing less.

Sincerely,

Kamillah M. Hanks
Council Member, 49th District

Legal Services NYC
DEMAND JUSTICE

TESTIMONY OF ROBERT SANDERMAN ON BEHALF OF LEGAL SERVICES NYC REGARDING THE DUTY OF PUBLIC HOUSING TO ENSURE SAFE AND HABITABLE LIVING CONDITIONS FOR RESIDENTS

September 23, 2022

I am a senior staff attorney in the community economic development and housing rights units at Queens Legal Services (QLS)—a borough office of Legal Services NYC (LSNYC).

LSNYC is a non-profit organization that fights poverty and seeks racial, social, and economic justice for low-income New Yorkers. LSNYC is the largest civil legal services provider in the country, with deep roots in all of the communities we serve. Our staff members assist more than 110,000 low-income New Yorkers each year and, along with other legal services providers in the city, LSNYC is at the forefront of the fight to prevent evictions, preserve affordable housing, and ensure that our clients' apartments are safe and habitable, and our clients are not subject to harassment. A significant part of our work is in tenant rights and eviction defense—in addition to a range of other legal matters

Specifically, LSNYC represents New York City Housing Authority (NYCHA) residents throughout the city in housing court, NYS supreme courts, administrative proceedings and federal courts. In our work, we witness the constant neglect and disrespect

that our clients living in NYCHA housing experience, including but not limited to deplorable housing conditions, rent overcharges and NYCHA's failure to provide essential services, such heat and hot water for extended periods of time. Yet, despite these conditions, the low incomes of our clients and the chronic shortage of affordable housing in New York means that it would be virtually impossible for many of them to live anywhere else in the City. Therefore, many NYCHA residents are forced to suffer neglect, harassment and subpar living conditions—while continuing to pay their rent.

Recently, NYCHA residents such as Shaquane Mitchell, who resides at Jacob Riis Houses, experienced another added stress. As reported in *The City*, a local newspaper, Jacob Riis residents informed NYCHA of cloudy water dripping from their kitchen faucets for several weeks or possibly months with no improvement and no tests conducted by the City.[1] On August 16, 2022, NYCHA obtained test results from the Department of Environmental Protection declaring the water at Jacob Riis to be drinkable. What followed has been a month of chaos and confusion for Jacob Riis residents. Sometime after that, NYCHA requested tests for other substances, including arsenic. Between August 29th and August 31st, NYCHA results that detected the presence of arsenic, and at some point, Legionella, in the water supply, which DEP had not tested for in the original tests.[2] Then, on or about September 2, 2022—apparently three days after the first positive tests for arsenic, residents, for the first time, learned of the issue and were instructed to refrain from drinking or using the water to

[1] Greg B. Smith and Katie Honan, "Mayor Adams Promises 'Thorough' Look at How His Team Handled Riis Arsenic Discovery," https://www.thecity.nyc/2022/9/6/23340177/nycha-arsenic-drinking-water-tenants-uninformed-city-investigates-cause.

[2] https://www.thecity.nyc/2022/9/8/23343829/arsenic-testing-nycha-taps-flushed

cook indefinitely. A few days later, NYCHA flushed the taps at Jacob Riis for hours and conducted more tests, which allegedly came back negative.

At a townhall held on September 9, 2022, the Mayor's Office and NYCHA announced that there was never arsenic in the water supply. The company that performed the tests issued a statement claiming that their results were inaccurate and that they were the ones who added arsenic to the water samples.[3] These conflicting accounts regarding the timeline of events and testing results have exacerbated confusion among the tenants and further inflamed longstanding distrust of the elected officials and city agencies involved. Tenants have been alarmed and concerned for their health since they were aware of the cloudy water, if not before due to conditions such as mold and infestation throughout their apartments. Their lives have been greatly disrupted by being restricted from utilizing the water supply in their apartments for more than a week. They deserve direct answers as to the various tests conducted and the status and quality of their water at all times over the past month.

The Water Contamination Poses a Significant Health Threat and Increased Risk of Death for NYCHA Residents

It is well documented that low-income communities of color disproportionately suffer from environmental racism and the lack of access to quality healthcare.[4] The residents of Jacob Riis Houses and NYC public housing residents at-large are

[3] Deanna Garcia et al., "Arsenic test results 'incorrect' at Jacob Riis Houses, water safe to drink: Adams administration," Sept. 9, 2022, https://www.ny1.com/nyc/manhattan/news/2022/09/09/arsenic-test-results--incorrect--at-jacob-riis-houses--adams-administration.
[4] https://www.nytimes.com/2021/04/28/climate/air-pollution-minorities.html

predominately low-income people of color, so the finding of arsenic in their water continues this trend. Levels of arsenic above 10 parts per billion can cause vomiting, nausea, diarrhea, paralysis and blindness, and prolonged exposure can lead to several types of cancers.[5] This is extremely worrisome because it may take years to discover the lasting deleterious health effects of unsafe arsenic levels in the water supply. Additionally, in at least one of the water quality tests, legionella was also detected. Legionella can cause pneumonia-like illnesses commonly known as Legionnaires disease.[6]

After being notified by the City of the presence of arsenic in their water, tenants such as Ms. Mitchell, out of great concern for her health, immediately visited her doctor's office and the emergency room to be tested since they had been exposed to the cloudy water for weeks.[7] Weeks after the initial reports of arsenic in the water, tenants are still without clear, credible, and conclusive answers and are concerned for themselves, their children and vulnerable neighbors such as senior citizens. Many are still scared to drink the water or bathe in their apartments and are spending money on bottled water and traveling to family residences outside of the Jacob Riis complex in order to shower.[8] Without clear and conclusive explanations for the water quality they endured for weeks, the residents at Jacob Riis will continue to be unsettled and in need for answers.

NYCHA Residents are Entitled to Clean and Safe Water

[5] https://gothamist.com/news/city-warns-east-village-public-housing-residents-not-to-drink-water-after-unsafe-arsenic-levels-found

[6] https://www.thecity.nyc/2022/9/8/23343829/arsenic-testing-nycha-taps-flushed

[7] https://pix11.com/news/local-news/manhattan/nycha-resident-says-he-has-suspected-arsenic-poisoning/

[8] David Brand, "Arsenic Alarm Still A Drain on Riis Residents' Routines and Resources," Sept. 16, 2022, https://citylimits.org/2022/09/16/nycha-riis-houses-arsenic-drain-on-wallets/

Tenants at Jacob Riis Houses have been dealing with cloudy water coming from their taps for more than a month. NYCHA and DEP's original tests of the water didn't even test for arsenic, and later tests have offered conflicting results—including a finding that there were unsafe levels of arsenic in the water. Such a finding cannot be taken lightly, and a sudden reversal of that finding cannot be accepted without further inquiry.

The NYC warranty of habitability guarantees to NYC residents safe and habitable housing conditions.[9] Landlords are required to maintain apartments so they are fit for human occupancy, that all things work as expected, and that no condition in the apartments exist that may harm or even kill the tenants.[10] High levels of arsenic in tenants' water supply is a clear violation of NYCHA's legal obligations. Because of the positive tests for arsenic, tenants were unable to cook and drink the water in their apartments for more than a week, and in some cases a month, which means they incurred unexpected out-of-pocket costs for restaurants and delivery services—despite being low-income and relying on paying thirty-percent of their income on rent so they may afford other living expenses.

To close, Jacob Riis Houses residents will greatly benefit from receiving direct answers as to the timeline of events, the test results from various agencies from August 16, 2022 to date, and other relevant information surrounding the alarming incident. They deserve answers and safe drinking water. This may address the lingering concerns tenants have around their health and safety. Their pleas for answers from NYCHA, local agencies and the mayor's office should not go ignored.

Thank you.

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[9] See Real Property Law § 235-B
[10] Id.

September 23, 2022

Testimony of Lonnie J. Portis, Environmental Policy and Advocacy Coordinator at WE ACT for Environmental Justice

To the New York City Council Committee on Public Housing

Regarding Water Testing at Jacob Riis Houses

To Chair Alexa Avilés and the Committee on Public Housing:

WE ACT for Environmental Justice, an organization based in Harlem, has been fighting environmental racism at the city, state, and federal levels for more than 30 years. WE ACT convenes a group of members living in New York City Housing Authority developments to discuss and organize around the various environmental health hazards that currently exist in their homes and communities.

Established in 1934, the New York City Housing Authority (NYCHA) was the first and is currently the largest public housing authority in the United States. It provides affordable housing to nearly 600,000 New Yorkers in 326 developments across the five boroughs of New York City.

NYCHA, however, faces a myriad of problems – most of which are tied to the fact that it has been chronically underfunded for years. As a result, the New Yorkers who rent apartments in NYCHA developments often have to endure environmental challenges such as mold, lead, and pests along with substandard service in terms of repairs and other basic issues.

After keeping residents in the dark for two weeks about potentially high levels of arsenic in the drinking water at Jacob Riis Houses in the East Village, New York City officials released an announcement that there was never any arsenic in Jacob Riis Houses to begin with.

In spite of this announcement, there is an enormous gap in the City's response to this potential water contamination event – not a single individual was tested for arsenic exposure. Anyone familiar with recent history will recognize a striking resemblance to the beginnings of the Flint

Water Crisis, where officials maintained that the water was safe until pediatrician Mona Hanna-Attisha raised alarms about the elevated blood-lead levels in children citywide.

Despite all of this press coverage and testing of more than 100 water samples, there was no mention of any exposure assessment to determine if the residents of Jacob Riis had increased levels of arsenic in their bodies. This begs the question – why did City officials not begin testing residents immediately after initial water samples showed elevated levels of arsenic?

The City is responsible for those individuals who may have been exposed to unsafe levels of arsenic due to the negligent response to this potential contamination. In addition to immediate testing for arsenic in the water and emergency solutions like distributing bottled water, residents must also be tested to assess their potential exposure to arsenic. This means the Department of Health and Mental Hygiene (DOHMH) should conduct an exposure assessment for residents immediately following any water testing in their building that shows unsafe levels of arsenic or any other heavy metals.

For any individuals who are shown to have elevated levels of heavy metals in their body, which for arsenic is anything above 50 micrograms per liter (µg/L), an in-depth risk assessment screening should be conducted at no cost to the individual, along with any necessary follow-up procedures as recommended from the screening. While the window of opportunity for testing may have closed for the 3,700 residents living in Jacob Riis Houses, these testing procedures must be implemented moving forward to safeguard the health of NYCHA residents.

NYCHA should focus on strengthening infrastructure that prevents environmental hazards from occurring in the future. Investments in more resilient infrastructure and procedures are vital to protecting people's health and well-being. There should be more emphasis in funding preventative actions and measures that protect the NYCHA community. Future responses to addressing and remediating environmental health hazards should be met with better planning and consideration.
The work order reform program in Queens and Staten Island shortens scheduling times and allows residents to address all of their infrastructure

and maintenance complaints at the same time – this should be afforded to all residents of NYCHA.

Sincerely,

Lonnie J. Portis

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September 23, 2022

Oral Testimony of Elizabeth Reyes, Cecil Corbin-Mark Fellow at WE ACT for Environmental Justice

To the New York City Council Committee on Public Housing

Regarding Water Testing at Jacob Riis Houses

Good Afternoon Chair Alexa Avilés and the Committee on Public Housing:

I'm Elizabeth Reyes, a Cecil Corbin-Mark Fellow at WE ACT for Environmental Justice. In my role, I work around topics of toxic chemicals and lead. I'm also involved in our community organizing work and with our various working groups including our Healthy Homes working group and our NYCHA working group. The NYCHA working group consists of members living in New York City Housing Authority developments to discuss and organize around the various environmental health hazards that currently exist in their homes and communities.

NYCHA faces a myriad of problems – most of which are tied to the fact that it has been chronically underfunded for years. As a result, the New Yorkers who rent apartments in NYCHA developments often have to endure environmental challenges such as mold, lead, and pests along with substandard service in terms of repairs and other basic issues.

After keeping residents in the dark for two weeks about potentially high levels of arsenic in the drinking water at Jacob Riis Houses in the East Village, New York City officials released an announcement last week that there was never any arsenic in Jacob Riis Houses to begin with.

In spite of this announcement, there is an enormous gap in the City's response to this potential water contamination event - not a single individual was tested for arsenic exposure. This begs the question – why did City officials not begin testing residents immediately after initial water samples showed elevated levels of arsenic?

The City is responsible for individuals who may have been exposed to unsafe levels of arsenic because of negligent responses to this potential contamination. In addition to immediate testing for arsenic in the water, residents must also be tested to assess their potential exposure to arsenic. The window of opportunity for testing may have closed for the residents living in Jacob Riis Houses, still these testing procedures must be implemented moving forward to safeguard the health of NYCHA residents.

NYCHA should focus on strengthening infrastructure that prevents environmental hazards from occurring in the future. Investments in more resilient infrastructure and procedures are vital to protecting people's health and well-being. There should be more emphasis in funding preventative actions and measures that protect the NYCHA community. Future responses to addressing and remediating environmental health hazards should be met with better planning and consideration.
The work order reform program in Queens and Staten Island shortens scheduling times and allows residents to address all of their infrastructure and maintenance complaints at the same time – this should be afforded to all residents of NYCHA.

Thank you for the opportunity to testify. WE ACT will be submitting a full written testimony as well.

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Written Testimony Regarding Jacob Riis Houses Water

My name is Eric Diaz, I am a lifelong resident of the Lower East Side and Executive Director of Vision Urbana Inc, a nonprofit organization in the neighborhood since 1996 providing services for seniors, youth, migrant and Immigrant families on health and wellness, workforce development, a Neighborhood NORC, senior center services and a food security initiative impacting thousands of residents weekly. We have been actively involved in the supply of bottled water and grocery and cooked meal donations to the Tenant Association to help provide stability and comfort for the residents at Jacob Riis. We understand there is great need for trusted and ongoing arsenic testing for residents even after the mayor's visit in drinking the water at Jacob Riis. As early as September 20th, this week, Vision Urbana visited the Tenant Association to inquire on how residents are responding to the arsenic levels test conclusions which came with feedback that there still exists anxiety and distrust among residents in drinking the water and even cooking with it as per NYCHA's guidelines in August. Vision Urbana remains committed in working with the city and the residents to facilitate resources to ensure water remains at healthy levels and education/townhalls are provided to the residents to mitigate misinformation. Vision Urbana has over 300 grocery bags each week delivered within Jacob Riis and Lillian Wald developments in addition to hundreds of pounds of fresh fruits and vegetables distributed to Jacob Riis residents each week with the Jacob Riis Tenant Association. We stand committed to providing outreach and engaging residents as needed with resources and information.

Eric Diaz
Executive Director
Vision Urbana, Inc.

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CITY COUNCIL SUBMISSION

TESTIMONY FOR JOINT COMMITTEES Oversight and Public Housing September 23,2022
Arsenic and Jacob Riis Houses

I am Joel R Kupferman. Executive Director and Senior Attorney at the Environmental Justice Initiative- and counsel to the Jacob RIIS and Alfred E Smith Resident Associations, respectively.

It is error to claim that there is no actionable exposure to arsenic by RIIS residents.

It is not only in the water. It is in the soil. The City and NYCHA are in error to put the attention on one and ignore the other. People are being poisoned by the dust in the air from the dirt piles -from the soil itself. The soil and residents must be tested. The soil must be contained. Currently, it is not controlled. We know the City applied massive amounts of arsenic to all surface and sub-surface soil, to kill the rats. But they have failed to remove the arsenic, which is cancerous, and noxious, thus continue to poison the tenants- who they were supposedly trying to protect.
Testing at NYCHA Smith Houses indicated 240 parts per million in the soil– which is 15 times the New York State Soil Cleanup Objectives of 16 parts per million—a huge elevation of allowable limit. We do not know the exact amount at Riis Houses – but NYCHA and NYC DOH and DEP have failed to measure or to mitigate the ongoing chronic exposure. The Smith Resident Association has urged Dan Greene, then NYCHA Compliance officer; DEP Commissioner Sepenzia; and STV (the same company in charge of construction and water infrastructure matters at RIIS), that all soil, thus toxic, must be covered, then controlled/removed. The pleas went on deaf ears.
Studies at Flint, Detroit, New Orleans show that resuspended soil leads to heightened Pb levels in children's blood. Harvard studies show that a slight increase in long term exposure to Particulate Matter 2.5, found in soil, leads to a major increase in Covid death.[1]
This is compounded by the indoor exposure of lead paint, asbestos, and mold as well as the close proximity to the particulate matter emitting East 14thSt. Con Ed power plant.
Despite the fact that RIIS residents are vulnerable and have suffered chronic exposure, neither NYCHA , NYC DEP and DOH nor its contractor, STV, have seen fit to adopt any preventative, protective, or mitigating practices to address the environmental and health hazards confronting the residents.[2] Instead, NYCHA has merely waived aside evidence indicating the presence of

serious hazards as well as the multiple vectors of exposure, and stands on the pronouncement withdrawal that the arsenic actionable levels in the water do not exist- states, *without support*, that RIIS residents face no real risks. NYCHA's pronouncement is deeply troubling not only because it articulates the shocking principle that toxic exposures should be accepted by affected populations merely because they happen all the time, but also because it completely elides the significant health effects from exposures to environmental toxicological agents. Such callousness by NYCHA is astounding, who is mandated to care for residents living in City housing;[3] as is the fact that NYCHA's deference puts at great risk the City's most vulnerable residents: young children, people with chronic respiratory illnesses, and the elderly. This evasion makes the situation even more distressing.

Figure 1 176 Ave D 9-9 -22 pic by J.Kupferman

In this regard, EJI calls attention to the fact that despite NYCHA's recent admissions regarding its failure to protect housing residents from serious lead and mold exposures,[4] NYCHA has additionally *refused* to adopt even the most basic and inexpensive measures at the RIIS Houses site—measures such as the placement of geo-textile matting, the planting of ground cover, and the layering of fresh soil on top of *in situ* soils—to prevent the dangerous re-suspension of contaminated soils and dust -all surfaces where children play, and their migration into RIIS Houses apartments, nearby local public schools, and the adjacent playgrounds. And finally, adding yet another layer of concern is the City's acceptance of NYCHA and its contractors' failure to adopt any effective protective measures. NYCHA, as the largest public housing authority in North America and as home to 1 in 14 New Yorkers,[5] presents a horrific example to state and local governments around the country- of how the nation's poorest residents and they are particularly people of color, are treated.

The Housing Authority cannot in good faith rely upon on a risk assessment report (or lack of one) that lacks both scientific integrity and legal support - a deficient risk assessment that stems from its failure to examine the full spectrum of harms faced by RIIS Houses residents and workers. First, NYCHA employed a deficient methodology- when it failed to undertake a comprehensive soil sampling plan including all sites that could contribute to residents' and workers' exposure to the lead, arsenic, VOCS, SVOCs, barium, and cadmium most likely contained in the soil. There has been failure to examine all following: the suspension, re-suspension, and dispersal of soil contaminants; the penetration of these contaminants into tenants' apartments, school building hallways and other residential common areas; the ingestion of contaminated soil by young children playing on the grounds. There are multiple avenues of exposure for individuals involved in one or more of the following activities, in addition to living with the re-suspended and transported, contaminated soil dust in their apartments: passing by the active sites; sitting outside near the apartment buildings; attending one of the public schools on the block; and playing in the area.

Assumption of Arsenic at RIIS:

The high levels of arsenic found at Smith Houses is a strong indicator of the probability of similar levels present at RIIS. Both these NYCHA Developments received the large arsenic doses placed by the NYC Department of Health's Rat Poison Control Program in prior years. NYCHA is recklessly discounting exceedance findings. Waldon was the environmental engineering firm employed by the contractor Navillus, which trenched and placed pipes at Smith as part of the Post-Sandy Rebuild. Waldon's tests show an arsenic concentration level in the topmost 12 inches of soil of 42.8 milligram per kilogram (mg/kg), 18.7 mg/kg, 18.6 mg/kg, 19.8 mg/kg, and 43.2 mg/kg—concentrations far exceeding—in fact, *2.7 times*—the Residential and Restricted Residential SCO of 16 ppm.[7] The arsenic concentrations of 85 ppm found in a prior test by EJI/NYELJP, and 240 ppm found in tests undertaken by the Urban Soils Institute, denote an extreme health concern given that the contaminated soil is located within the area surrounding a daycare facility where

very young children play outdoors for hours and near residential units without appropriate window protections. *(See* NYELJP's November 2018 letter, Attachment G.)

Toxic levels of arsenic exposure can occur through inhalation, absorption through the skin, and ingestion;[8] because it is tasteless and odorless, it is quite difficult for a person to know at the outset when they are exposed at levels falling below the acute poisoning range of 100 to 300 mg.[9] In fact, the onset of chronic arsenic poisoning is particularly insidious given that a person exposed to concentrations above 20 mg/kg may exhibit any of several non-specific symptoms, including abdominal pain, diarrhea, or sore throat,[10] all of which are associated with numerous and more benign illnesses. Long-term arsenic exposure from soil and water, leads to multi-system disease —including the cardiovascular, neurological, genitourinary, and respiratory systems—as exemplified by malignancy of the skin, lungs, liver, kidneys, and bladder.[11]

We should also be concerned about the assumed high levels of lead found in the soil and the lack of any lead soil testing or publication of results at RIIS. Lead was found at Smith to be 505 ppm, 592 ppm, and 802 ppm by EJI/NYELJP and 551 & 552 ppm by Waldon. The lead concentration of these sets of samples all exceed the SCO limit of 400 ppm, the level deemed by DEC to require remedial action.[12] The Housing Authority's failure to act in such circumstances defies comprehension. The US Environmental Protection Agency "has recognized that lead poisoning is the number one environmental health threat in the United States for children ages 6 and younger".[13] According to the Centers for Disease Control, in this country there are approximately half a million children, aged 1 through 5 years,[14] with blood lead levels above 5 micrograms per deciliter (μg/dL), the reference level at which the CDC recommends that public health actions be initiated. However, the CDC has made clear that this action level should not be taken as a demarcation of a zone of harmless exposure because "no safe blood lead level in children has been identified".[15] Indeed, even very low levels of lead in blood have been shown to result in neurologic impairments such as behavioral and learning issues, slowed growth and, in rare cases, seizures and death. Even when lead exposure is caught before the direst consequences, its effect on children is never inconsequential because the *effects of lead exposure cannot be corrected*.[16] It is for all these reasons that the public health goal is to prevent children's exposure to lead *before* they are harmed. And pursuing this objective is the most critical for populations like the residents of RIIS Houses because children living at or below the poverty line who live in older housing are at greatest risk.

NYCHA's soil inaction appears to be based on the fundamental misconception that the risks from exposure to contaminated soil dust posed by renovation, construction, and demolition activities[17] are short-term and geographically limited. In other words, NYCHA's myopic position is that these risks may be assessed in complete isolation from people's health status, past exposures, cumulative impact and experience of current exposures to other toxic agents. However, neither the law nor environmental health science permits the use of such a stunted assessment. Beyond any concern over short-term exposures to airborne toxic particulate matter("PM") arising from construction/maintenance activities, consideration must also be taken for long-term

exposures to particulate matter from contaminated soil dust that settles across the Housing complex for inhalation, ingestion, or dermal exposure after re-suspension.[18] In addition to the plethora of studies establishing the prevalence of this risk in urban settings, New York City's own Division of Environmental Health confirmed the existence of this risk when it investigated the Smith Project site on August 14, 2018, and issued an Inspection Report and Notice of Violation to both to Navillus and NYCHA.[19] The Notice of Violation states that both entities must "contain dust areas, use dust suppression methods while working," and "isolate work from the public."[20] The City issued the Notice of Violation after undertaking a site investigation and determined that Navillus' practices are deficient to such a degree that the public is at risk of exposure to contaminated soil dust. Given this determination, it is difficult to understand why neither NYCHA nor Navillus have seen fit to alter practices at the SMITH site to comply with the City's order. The same concern is ever more present at RIIS.

NYC Health Department most certainly must be aware of this egregious soil situation there, at RIIS. NYC DOH Deputy Commissioner Corinne Schiff and NYC DEP Operating Officer Sapienza were at RIIS for many hours according to administration testimony at Friday's hearing. I, myself, Joel Kupferman/EJI, contacted DOH-Environmental Division about the arsenic soil endangerment-only to be told that the Health Department can only deal with one issue at a time.

At the time, Chief Operating Officer-Vincent Sapienza, then DEP Commissioner Sapienza, was apprised of the similar SMITH situation in a eleven-page, well-documented, April 3, 2018 letter. Daniel Green, then NYCHA's Chief Compliance Officer, now NYCHA's Vice President for Healthy Homes, was apprised of the toxic soil exposure problem at Smith via letters, direct communication by phone, weekly-meeting discussions, and staged walkthrough. He was apparently aware of the evident soil problem by his several ongoing inspections.

In addition to the health risks created by short- and long-term exposures, STV and NYCHA fail to take into account the health status of RIIS Houses residents. Given that NYCHA Housing residents now remain in their apartments on average for 22 years,[21] there is a high probability that many, if not all, of the residents living in RIIS Houses are exposed to the extremely toxic plume of particulate matter and aerosolized compounds resulting from the operation of the particulate matter emitting East 14th St Con Ed powerplant .[22] Moreover, added to this combination of exposures, RIIS Houses residents have been subjected to environmental assaults stemming from the contaminated indoor dust and particulate matter generated by adjacent highways and waterways packed with toxin-emitting sources.[23] Studies have shown that PM2.5 and PM10 concentrations are increased by local fugitive sources of particulate matter from vehicle exhaust,[24] road construction activities, and air and sea transportation sources (which produce particles across the range from PM2.5 to PM10).[25] The RIIS Houses apartment complex falls within the atmospheric dispersal zone of a number of these cumulative, aggravating toxic sources; it is located by the FDR Drive on the East River, which serves as a main waterway for tug boats, water taxis, and garbage barges; it is bounded by both ground and raised highways; and it is within the flight jet path taking off and landing at the City's two major airports. The destruction of East River Park has been a major source of particulate matter. In addition to these permanent and incessant progenitors of toxins, there are other occasional polluting sources, such as the re-surfacing of adjacent highways[26] and the salting of roadways to address icy conditions.[27] The

effects of these polluting sources is revealed in the data: the Lower East Side ("LES") neighborhood in which the Smith Houses complex sits has higher percentages than City averages of black carbon, particulate matter, nitric oxide, nitric dioxide, and sulfur dioxide.[28] And adding yet another burden to this toxic environment are the years of people's exposures to pesticides and rodenticides, (including arsenic),[29] black mold,[30] and dust from the unremediated lead paint inside apartments and in the hallways of buildings.[31] Given the widespread knowledge that people in NYCHA housing complexes suffer disproportionately from respiratory illnesses[32] -for example, the LES has a crude rate of verified tuberculosis of 15.1 as compared to the city-wide rate of 7.2 (representing a 210% increase) and a preventable asthma hospitalization rate of 384.6 as compared to the city-wide rate of 232.9 (representing a 165% increase)[33]—this reliance of NYCHA on a deeply flawed report is incomprehensible. *See, e.g., Baez, Maribel et al. v New York City Housing Authority*, 13-cv-08916 (SDNY).

In this regard, EJI/NYELJP notes further that schoolchildren, a particularly vulnerable segment of the population, are being subject to multiple vectors of exposure resulting from the presence of a public school PS/MS 34 located directly across the street from the RIIS immediate area, two within the complex and one adjacent to it near the school across the street. Those children living in the Smith Homes complex and attending one of the public schools are exposed to lead, arsenic, pesticides (recently including Roundup) and other toxic agents through at least four different vectors, including: (1) airborne particulate matter resulting from construction and demolition activities disturbing contaminated soil; (2) indoor apartment building dust and household dust resulting from the transport of contaminated soil and airborne particulates and the continual resuspension and deposition of these particulates; (3) indoor school building dust resulting from the same processes; and (4) airborne particulate matter resulting from activities on the playground during and after school. There is little doubt that children who live in the apartment complex but do not attend school there visit the playgrounds near them and thereby are subjected to three of the four noted vectors for exposure. With regard to the health statuses of these children, the latest data shows an asthma hospitalization rate of 40.8 per 100,000 children ages 5-14 years in the neighborhood as compared to the city-wide rate of 37.1.[34] The health of elderly residents of the RIIS Houses, many of whom are likely to suffer from respiratory disease, should be of equal concern to NYCHA given that they are subject to airborne particulate matter from Project activities, re-suspended contaminated soil dust during times they are outside, contaminated indoor dust and contaminated water According to the City's own data, 42% of all families living in Manhattan's public housing complexes are headed by an adult over the age of 62, and according to data for New York County, 7.8% of adults have asthma and 4.9% have Chronic obstructive pulmonary disease (COPD.)[35]

Finally, the NYELJP would be remiss if it did not reiterate its deep concern over the lack of trees, vegetation and ground cover at RIIS Houses caused by reckless renovation activities, poor planning and lack of commitment to maintaining a proper landscape at RIIS . Trees serve as resiliency hydrological anchors in a flood prone area '' And to reiterate the mismanagement and malfeasance of protecting the water supply infrastructure - an area well covered by City Council members and testifiers. ST V, as construction manager must be held accountable. Arsenic, in the water and in the soil pose a serious endangerment to health and the environment.

Recommendations for actions are found in notes. Please feel free to reach out to me and THE Environmental Justice Initiative for clarification or more information.

Joel R Kupferman,Esq.
9-29-22

FOOTNOTES on Separate page

Pertinent cited and additional Files available at
https://www.dropbox.com/sh/oxmax8mfj76bs8c/AADgaTdhtBdcd2UwVOrQw0B8a?dl=0

WORKING NOTES

1. INTRO
    a. EJI www.nyenvirolaw.org
    b. COUNSEL to Alfred E Smith and Jaco Riis Residents Association
    c. Worked with Flint lawyers
    d. 9/11 – forced reconsideration that the "AIR was SAFE" in lower Manhattan, litigated, sampled
2. WATER CONCERNS
    a. Myriad of problems at Riis
    b. Problems with Pump
    c. STV – construction manager – exercised project management malfeasance at Smith Houses
    d. Cumulative and long-term impact of arsenic exposure discounted or ignored
    e. Water tank – possible arsenic treated wood.
    f. Legionnaires– de minimis investigation Arcane risk assessment that should be examind/revised.
        i. Unsubstantiated denial of problem – arcane NYC DOH assessment/classification . Failure to determine source and risk assessment.
3. SOIL EXPOUSRE
    a. Major route of exposure
        i. Cite David Carpenter's letter
    b. ATSDR: The primary routes of arsenic entry into the body are via ingestion and inhalation. Dermal exposure can occur, but is not considered a primary route of exposure. Exposure dose is the cumulative exposure by all routes.
    c. Arsenic from Water and Soil …Elevated levels of arsenic in soil (due to either natural or man-made contamination) may be an ingestion risk, especially for children with pica and mouthing behaviors during play [Rossman 2007]. However, the bioavailability of arsenic in soil is variable, and dependent on the chemical form of arsenic. https://www.atsdr.cdc.gov/csem/arsenic/what_routes.html
    d. High levels of arsenic in soil – NYC Rat poison Control Program
        i. Findings at Smith: 85 parts per million 240 parts per million

ii. NYC Health Dept violation cite (non-cover

e. Loose uncovered soil at Riis – including six foot mounds

[MISSING IMAGE: ,]

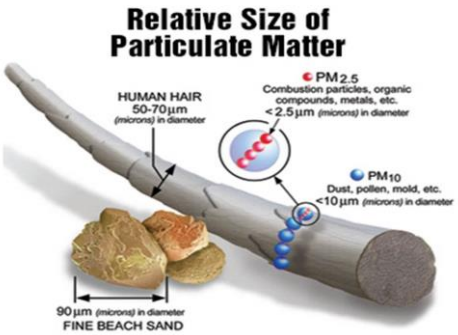
i.

[MISSING IMAGE: ,]

[MISSING IMAGE: ,]

[MISSING IMAGE: ,]

a. Lead in soil
b. Resuspension of soil – vector for lead blood levels
    i. Flint report
    ii. Mielke report – arsenic in soil – flooding
    iii. Children playing in soil – dermal and ingestion
    iv. Trekking into apartments
    v. Penetration through windows
c. Pesticide application – warning markers – but no listing of pesticide used
d. Failure to cover – lack of ground cover
e. Storm Water Management violations –
    i. Run-off into sewer system
    ii. CONSTRUCTION – PLACEMENT OF NEW PIPES causes further soil disturbance



a. PM 2.5 (picture - Wu q)
b. Respiratory problems exacerbated – NEJM article https://www.nejm.org/doi/full/10.1056/NEJMoa1702747 Conclusions: In the entire Medicare population, there was significant evidence of adverse effects related to exposure to PM2.5 and ozone at concentrations below current national standards. This effect was most pronounced among self-identified racial minorities and people with low income. (Supported by the Health Effects Institute and others.)
c. Cumulative impact – chronic exposure
d. LACK OF BIOMARKER TESTING – Urine and Hair
e. Failure of gov't agencies to act
    i. DEP Deputy Commissioner at site
    ii. Deputy NYC DOH Commissioner at site
    iii. I was told by Assistant Commissioner that NYC DOH can only work on one problem at time

f. False reassurance THAT THERE IS NO PROBLEM to residents
g. Dan Green – knowledge about Smith arsenic problem – and failure to contain resuspension
h. STV – apprised of situation at Smith Houses
    i. IN CHARGE of water infrastructure construction management –
    ii. Should be fully audited and investigated - lack of accountability & oversight of faulty contractors
i. High probability of flooding - no resiliency plan , misoending of FEMA rebuild funds
j. Federal Court Case
k. NYS Green Amendment

4. DEMANDS – SOLUTION
    a. Immediate removal of large piles
    b. Geo textile cover
    c. Fast growing ground cover
    d. Soil Testing - Full RCRA 8
    e. Planting of flora - ground cover, shrubs, and trees
        i. Multitude of benefits including hydrological retention
        ii. Shade, mitigate strong rain fall, Air quality
        iii. Removal of toxic soils – Follow NYS DEC # Soil Cleanup
        iv. Much resiliency money available Fed and State CLIMATE funds
    f. Provide HEPA vacuums for residents on lower levels
        i. Share program – based on Syracuse EPA HEPA Vacuum Project
    g. Request for risk assessment BY NYS DOH ASTDR
    h. Provide resources for Tenant Association to hire independent environmental assessors and investigators
        i. Difficult for Tenant Association to procure funds & experts
5. Increase Whistleblower protection
6. Create an Ombudsperson position at DEP,DOH and NYCHA
        i.
        ii.

5. Vulnerable population --- disabled ,elderly, people of color, children – utilize full EJ regs and con
6. CITY Health Clinic – state Network Bellevue Clinic provide evaluation at site , request

7. Problem area - 14th Street Con Ed plant

STATE REGS

FOOTNOTES

1. 6 NYCRR Part 375 NYS Environmental Remediation Programs
   https://www.dec.ny.gov/docs/remediation_hudson_pdf/part375.pdf

2. DER-10 provides an overview of the site investigation and remediation process for DEC's remedial programs administered by the Division of Environmental Remediation (DER). These include the Inactive Hazardous Waste Disposal Site Remedial Program, known as the State Superfund Program (SSF); Brownfield Cleanup Program (BCP); Environmental Restoration Program (ERP); and Voluntary Cleanup Program (VCP); and certain petroleum releases. https://www.dec.ny.gov/regulations/67386.html
3. --- **Generic Remedial Action Objectives (RAOs)**
   https://www.dec.ny.gov/regulations/67560.html
   a. **Soil**
      i. **RAOs for Public Health Protection**
         1. Prevent ingestion/direct contact with contaminated soil.
         2. Prevent inhalation exposure to contaminants volatilizing from soil
      ii. **RAOs for Environmental Protection**
         1. Prevent migration of contaminants that would result in (include all appropriate media: groundwater, surface water, or sediment) contamination.
         2. Prevent impacts to biota from ingestion/direct contact with soil causing toxicity or impacts from bioaccumulation through the terrestrial food chain
   b. **Soil Vapor**
      i. RAOs for Public Health Protection
         1. Mitigate impacts to public health resulting from existing, or the potential for, soil vapor intrusion into buildings at a sit
4. ENVIRONMENTAL JUSTICE – heightened analysis and protection
   a. NYC NYS and federal

RESOURCES
https://medicine.tulane.edu/departments/pharmacology/faculty/howard-w-mielke-phd
HOWARD R. MIELKE
Illegally subjects people who breathe or ingest PM2.5, lead and arsenic to serious harm.
Similar health risks for workers… presumed safe levels

Particulate Matter and Soils Articles

Resuspension of urban soils as a persistent source of lead poisoning in children: A review and new directions Mark A.S.Laidlaw Gabriel M.Filippelli Mark A.S.LaidlawGabriel M.Filippelli

https://www.sciencedirect.com/science/article/abs/pii/S0883292708001832

Abstract

Urban soils act as the repository for a number of environmental burdens, including Pb. Significant attention has been devoted to reducing Pb burdens to children with outstanding success, but the fact that

blood Pb levels above 10 μg/dL are disproportionately found in children living in many USA cities (15–20% in some cities compared to a national average of less than 2%) indicates that not all of the sources have been eliminated. Although the health risk of fine particulates has begun to raise concerns in cities, little attention has been paid to Pb associated with these particulates and the potential role of this pathway for continued Pb burdens of urban youth. This review summarizes recent work on particulate resuspension and the role of resuspension of Pb-enriched urban soils as a continued source of bio-available Pb both outside and inside homes, then presents recent efforts to model Pb burdens to children based on the atmospheric parameters that drive particulate resuspension. A strong seasonal relationship is found between atmospheric particulate loading and blood Pb levels in children, and new particulate loading models are presented for a range of US cities involved in the Interagency Monitoring of Protected Visual Environments (IMPROVE) program. These seasonal particulate loading models have implications for a number of respiratory health impacts, but can also be used to calculate seasonal patterns in bio-available Pb redistribution onto contact surfaces (the primary pathway for ingestion-related uptake in toddlers) and assist clinicians in interpreting time-specific blood Pb tests

Arsenic from Water and Soil …Elevated levels of arsenic in soil (due to either natural or man-made contamination) may be an ingestion risk, especially for children with pica and mouthing behaviors during play [Rossman 2007]. However, the bioavailability of arsenic in soil is variable, and dependent on the chemical form of arsenic. **https://www.atsdr.cdc.gov/csem/arsenic/what_routes.html** **ATSDR**

Dermal contact when handling preserved wood products containing arsenic could result in arsenic exposure. However, very little is known regarding the chemical form, conditions for absorption, kinetics, or other information needed to make a statement regarding skin absorption in specific populations [NAS 1977]. Toxic effects have been reported in the occupational literature from splashes of arsenic trichloride or arsenic acid on worker's skin [Garb and Hine 1977].

a.

Footnotes

[1] Xiao Wu, Rachel C. Nethery, Benjamin M. Sabath, Danielle Braun, Francesca Dominici (2020) "Exposure to air pollution and COVID-19 mortality in the United States." medRxiv 2020.04.05.20054502; doi: 10.1101/2020.04.05.20054502

[2] In this regard, NYELJP draws attention to the contract between NYCHA and Navillus which states that the re-use of site soils is permitted only if "they meet the project environmental

requirements and specifications," and that "excavated materials unsuitable for filling or backfilling" must be "legally disposed of off-site." *See* Division 31 – Earthwork, Contract between NYCHA and Navillus included in prior submissions. These provisions make clear that soil testing should have been done prior to any other Project activities in order to determine contamination levels and appropriate procedures for handling contaminated soils.

[3] *See, e.g.*, 24 CFR §1.4(b)(2)(i) ("A recipient, in determining the types of housing, accommodations, facilities, services, financial aid, or other benefits which will be provided under any such program or activity, or the class of persons to whom, or the situations in which, such housing, accommodations, facilities, services, financial aid, or other benefits will be provided under any such program or activity, or the class of persons to be afforded an opportunity to participate in any such program or activity, *may not, directly or through contractual or other arrangements, utilize criteria or methods of administration which have the effect of subjecting persons to discrimination because of their race, color, or national origin, or have the effect of defeating or substantially impairing accomplishment of the objectives of the program or activity as respect to persons of a particular race, color, or national origin*") (emphasis supplied).

[4] *See* NYCHA Admissions, Consent Decree in *USA v. NYCHA*, 18 Civ. 5213, at 1-3 (June 11, 2018), available at https://www.epa.gov/sites/production/files/2018-06/documents/nycha-cd.pdf (last visited on March 1, 2019).

[5] New York City Housing Authority, "NYCHA 2018 Fact Sheet," (2018), available at https://www1.nyc.gov/assets/nycha/downloads//pdf/NYCHA-Fact-Sheet_2018_Final.pdf (last visited on March 1, 2019).

[6] Of course, NYELJP does not agree that the levels noted by Waldon represent a correct analysis of soil contaminants. Accordingly, this statement should not be taken as any such confirmation of either Waldon's methodology or its findings.

[7] 6 NYCRR § 375-6.8, Table 375-6.8(b) (2006).

[8] R.N. Ratnaike, "Acute and Chronic Arsenic Toxicity," *Postgrad Med J.*, 2003, v. 79, at 391-96.

[9] *Id.*; W.L. Schoolmeester, D.R. White, "Arsenic Poisoning," *South Med J.*, 1980, v. 73, at 198-208. The acute lethal dose of ingested arsenic "has been estimated to be about 0.6 mg/kg/day." R.N. Ratnaike, "Acute and Chronic Arsenic Toxicity," *Postgrad Med J.*, 2003, v. 79, at 392.

[10] *See, e.g.*, Affidavit of Stephen Lester, *Matter of Daisy Wright, et al. v. New York State Department of Health*, dated April 2015; R.N. Ratnaike, "Acute and Chronic Arsenic Toxicity," *Postgrad Med J.*, 2003, v. 79, at 393-94 (internal citations omitted).

[11] R.N. Ratnaike, "Acute and Chronic Arsenic Toxicity," *Postgrad Med J.*, 2003, v. 79, at 393-94 (internal citations omitted).

[12] 6 NYCRR § 375-6.8, Table 375-6.8(b) (2006).

[13] Department of Justice Press Release, "The United States and Indiana Reach Agreement With SunCoke Energy and Cokenergy to Resolve Clean Air Act Violations at Indiana Harbor Coke Plant," January 25, 2018, available at https://www.justice.gov/opa/pr/united-states-and-indiana-reach-agreement-suncoke-energy-and-cokenergy-resolve-clean-air-act (last visited on April 2, 2019).

[14] Children under the age of 6 years old are at risk because they are growing rapidly and because they tend to put their hands or other objects, which may be contaminated with lead dust, into their mouths.

[15] *See* CDC website information, available at https://www.cdc.gov/nceh/lead/https://www.cdc.gov/nceh/lead/ (last visited on April 2, 2019).
[16] *Id.*
[17] Studies have shown that construction and demolition activities result in high local concentrations of PM10, which contains a wide variety of toxic substances and adversely affect the respiratory health of nearby residents. *See* D. Hansen, B. Blahout, *et al., J. Hosp. Infect.*, 2008, v. 70, at 259-264; C.M. Beck, A. Geyh, *et al., J. Air Waste Manage. Assoc*., 2003, v. 53, at 1256-1264; J. Joseph, R.S. Patil and S.K.Gupta, *Environ. Monit. Assess*., 2009, v. 159, at 85-98.
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[19] *See* August 14, 2018 Inspection Report and Notice of Violations issued to NYCHA and Navillus by the New York City Department of Health and Mental Hygiene, Division of Environmental Health.
[20] *See* August 14, 2018 Inspection Report and Notice of Violations issued to NYCHA and Navillus by the New York City Department of Health and Mental Hygiene, Division of Environmental Health.
[21] The Times reports that the average period a NYCHA tenant stays put these days is 22 years, up from 19 years in 2005 and 17 years in 1995. Mireya Navarro, "As New York Rents Soar, Public Housing Becomes Lifelong Refuge," NY Times, Aug. 3, 2015, available at https://www.nytimes.com/2015/08/04/nyregion/as-new-york-rents-soar-public-housing-becomes-lifelong-refuge.html?partner=rss&emc=rss&_r=0.
[22] =
[23] P. Kumar, A. Robins, S. Vardoulakis and R. Britter, *Atmos. Environ*., 2010, v. 44, at 5035–5052; P. Kumar, A. Robins, S. Vardoulakis and P. Quincey, Particulogy, 2011, v. 9, at 566–571; M. Abu-Allaban, J. Gillies, A. Gertler, R. Clayton and D. Proffitt, *Environ. Monit. Assess*., 2007, v. 132, at 155–163; S. H. Cadle, P. A. Mulawa, E. C. Hunsanger, K. Nelson, R. A. Ragazzi, R. Barrett, G. L. Gallagher, D. R. Lawson, K. T. Knapp and R. Snow, *Environ. Sci. Technol*., 1999, v. 33, at 2328–2339; A. J. Kean, R. F. Sawyer and R. A. Harley, *J. Air Waste Manage. Assoc*., 2000, v. 50, at 1929–1939
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[26] This includes, among other highway projects, the re-surfacing of the F.D. Roosevelt Drive, which entailed the application of 35,000 tons of asphalt over a six-month period ending on

November 30, 2015. *See* CBS News, "$8.5 million FDR Drive Resurfacing Project Finished Ahead of Schedule," (November 30, 2015), available at https://newyork.cbslocal.com/2015/11/30/fdr-drive-resurfacing-project-complete/ (last visited March 10, 2019).

[27] Recent studies have shown that fine dry road salts migrate in excess of 300 meters after the snowpack melts, and more immediately if the salts are applied in the absence of precipitation. *See* J. Lazarcik, J.E. Dibb, "Evidence of Road Salt in New Hampshire's Snowpack Hundreds of Meters from Roadways," *Geosciences*, 2017, v. 7(3), 54. Rock salt causes burns when it comes into contact with the skin, and respiratory tract irritation when inhaled. Repeated exposures corrode major components of the respiratory tract.

[28] Public Tableau, Bizlitics, NYC Health Dashboard, Lower East Health Outcomes and Neighborhood Conditions, available at https://public.tableau.com/profile/bizlitics#!/vizhome/NYCHealthDashboards_v4demo_0/AllMaps, (last visited February 20, 2019).

[29] Division of Environmental Health, New York City Department of Health and Mental Hygiene, *Pesticide Use by New York City Agencies in 2017*, 1, 42-43 (November 2018) (found at: https://www1.nyc.gov/assets/doh/downloads/pdf/pesticide/pesticide-use-report2017.pdf)

[30] Institute of Medicine of the National Academies, "Report Brief: Damp Indoor Spaces and Health," May 2004, available at http://www.nationalacademies.org/hmd/~/media/Files/Report%20Files/2004/Damp-Indoor-Spaces-and-Health/dampindoor2pagerforPDF.pdf; Former State Senator Jeffrey Klein, et al., "Break the Mold: Cleaning Up NYCHA's Mess," March 8, 2018, available at https://www.nysenate.gov/sites/default/files/press-release/attachment/break_the_mold_full_report.pdf.

[31] *See* NYCHA Admissions, Consent Decree in *USA v. NYCHA*, 18 Civ. 5213, at 1-3 (June 11, 2018), available at https://www.epa.gov/sites/production/files/2018-06/documents/nycha-cd.pdf (last visited on March 1, 2019).

[32] Dan Goldberg, "The long-term health consequences of living at NYCHA," Politico, April 9, 2018, available at https://www.politico.com/states/new-york/albany/story/2018/04/06/the-long-term-health-consequences-of-living-at-nycha-352931.

[33] Public Tableau, Bizlitics, NYC Health Dashboard, Lower East Health Outcomes and Neighborhood Conditions, available at https://public.tableau.com/profile/bizlitics#!/vizhome/NYCHealthDashboards_v4demo_0/AllMaps, (last visited February 20, 2019).

[34] Public Tableau, Bizlitics, NYC Health Dashboard, Lower East Health Outcomes and Neighborhood Conditions, available at https://public.tableau.com/profile/bizlitics#!/vizhome/NYCHealthDashboards_v4demo_0/AllMaps, (last visited February 20, 2019).

[35] American Lung Association, "Estimated Prevalence and Incidence of Lung Disease," May 2014, available at https://www.lung.org/assets/documents/research/estimated-prevalence.pdf (last visited March 10, 2019).

Seasonality and Children's Blood Lead Levels: Developing a Predictive Model Using Climatic Variables and Blood Lead Data from Indianapolis, Indiana, Syracuse, New York, and New Orleans, Louisiana (USA)

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On a community basis, urban soil contains a potentially large reservoir of accumulated lead. This study was undertaken to explore the temporal relationship between pediatric blood lead (BPb), weather, soil moisture, and dust in Indianapolis, Indiana; Syracuse, New York; and New Orleans, Louisiana. The Indianapolis, Syracuse, and New Orleans pediatric BPb data were obtained from databases of 15,969, 14,467, and 2,295 screenings, respectively, collected between December 1999 and November 2002, January 1994 and March 1998, and January 1998 and May 2003, respectively. These average monthly child BPb levels were regressed against several independent variables: average monthly soil moisture, particulate matter < 10 μm in diameter (PM_{10}), wind speed, and temperature. Of temporal variation in urban children's BPb, 87% in Indianapolis (R^2 = 0.87, p = 0.0004), 61% in Syracuse (R^2 = 0.61, p = 0.0012), and 59% in New Orleans (R^2 = 0.59, p = 0.0000078) are explained by these variables. A conceptual model of urban Pb poisoning is suggested: When temperature is high and evapotranspiration maximized, soil moisture decreases and soil dust is deposited. Under these combined weather conditions, Pb-enriched PM_{10} dust disperses in the urban environment and causes elevated Pb dust loading. Thus, seasonal variation of children's Pb exposure is probably caused by inhalation and ingestion of Pb brought about by the effect of weather on soils and the resulting fluctuation in Pb loading. *Key words:* **climate, lead dust, lead exposure seasonality, modeling, PM_{10}, soil lead, soil moisture.** *Environ Health Perspect* **113:793–800 (2005). doi:10.1289/ehp.7759 available via** *http://dx.doi.org/* **[Online 24 February 2005]**

Lead poisoning causes permanent neurologic, developmental, and behavioral disorders, particularly in children. The identification and removal of new sources of human exposure to Pb over the past several decades have significantly reduced the percentage of Pb-poisoned children in the United States, although one remaining population that has not seen this improvement is urban children, particularly from minority groups (Macey et al. 2001) or families with low socioeconomic standing (Mielke et al. 1999). Although some of this continued Pb poisoning is due to remaining point sources (e.g., paint dust from poorly maintained homes), it appears that a significant additional source of Pb contamination is from soil (Filippelli et al. 2005; Mielke et al. 1983)—the legacy of 100 years of Pb use in cities linked to multiple sources (e.g., leaded gasoline, leaded paint, smelters). Recent work has suggested that seasonal increases in children's blood Pb (BPb) levels relate to exposure via activity, that is, summer days of outdoor play and open windows and doors leading to increased contact with Pb-contaminated soils (Haley and Talbot 2004; Mielke and Reagan 1998; Yiin et al. 2000). Here we suggest an additional possibility—that higher children's BPb levels may be related to a combination of weather, soil moisture, and wind that effectively remobilizes and makes more bioavailable the diffuse soil Pb. This process may exacerbate this usual summertime behavioral link, with added impacts on urban children's health.

Urban Pb. In the 1970s, the assumed source of soil Pb contamination was Pb-based house paint (Ter Haar and Aronow 1974). An early study of garden soils conducted in metropolitan Baltimore, Maryland, raised questions about that assumption. Soil around Baltimore's inner-city buildings, predominantly unpainted brick, exhibited the highest amounts of Pb, and soils outside of the inner city, where buildings were commonly constructed with Pb-based paint on wood siding, contained comparatively low amounts of Pb, suggesting that Pb-based house paint could not account for the observed pattern of soil Pb (Mielke et al. 1983). Similarly, the same pattern was also found in Ottawa, Canada (Ericson and Mishra 1990). The quantity and distribution of soil Pb have been studied in numerous places: cities in Minnesota (Mielke et al. 1984/85); New Orleans, Louisiana (Mielke 1994); Milwaukee County, Wisconsin (Brinkmann 1994); Washington, DC (Elhelu et al. 1995); Indianapolis, Indiana (Filippelli et al. 2005; Laidlaw 2001); Syracuse, New York (Johnson and Bretsch 2002); Oslo, Norway (Tijhuis et al. 2002); and Ibadan, Nigeria (Sridhar et al. 2000). All these cities exhibited the same distance decay characteristic of high soil Pb contamination in the inner city and decreasing contamination toward the outer parts of the city as initially identified in garden soils of Baltimore (Mielke et al. 1983). Further, similarities in this distance decay pattern of soil Pb supports the idea that Pb-based house paint was not the sole source contributing to these observed differences.

Sources of Pb. Except for storage batteries, paint and gasoline additives were the two major high-volume products containing Pb; about the same quantity of Pb, 5 to 6 million metric tons, was used to manufacture each (Mielke and Reagan 1998). Lead-based house paint sales were phased out in 1978 in response to the Lead Paint Poison Prevention Act (Tong 1990). The major processes that now release Pb-based house paint into the soil are deterioration and especially disturbance of old Pb-based paint by power sanding (Mielke et al. 2001).

In the United States, motor vehicles used gasoline containing tetramethyl and tetraethyl Pb additives from the 1920s to 1986. By the 1950s, Pb additives were contained in virtually all grades of gasoline. By 1986, when leaded gasoline was banned, 5 to 6 million metric tons of Pb had been used as a gasoline additive, and about 75% of this Pb was released into the atmosphere (Chaney and Mielke 1986; Mielke and Reagan 1998). Thus, an estimated 4 to 5 million tons of Pb has been deposited into the U.S. environment by way of gasoline-fueled motor vehicles (Mielke 1994). Accumulation of soil Pb created by leaded gasoline is proportional to highway traffic flow (Mielke et al. 1997).

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T. Griffin of the Louisiana Childhood Lead Poisoning Prevention Program, Office of Public Health, supplied the New Orleans blood lead data set; the Marion County Health Department made available the Marion County (Indianapolis) blood lead data; and the Onondaga County Health Department provided the child blood lead database for Syracuse. D. Bivin suggested the use of monthly dummy variables to increase modeling significance, and Y. Fan of the National Oceanic and Atmospheric Administration provided soil moisture data.

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Pb content and Pb loading of urban soils. A critical aspect of Pb accumulated in soils is the relationship between Pb content and Pb loading. Studies in Minnesota and Louisiana examined the issue of Pb loading of the soil (Mielke 1993; Mielke et al. 1992). In large cities of Minnesota and Louisiana, the median soil Pb for various site types measured from 6.0 to 32.25 g/m^2, and the top 0.025 mm contained 6,000–32,250 μg Pb/m^2 (557–2,996 μg Pb/ft^2) (Mielke 1993). When one compares this Pb loading rate with the U.S. Department of Housing and Urban Development's guideline of 40 μg Pb/ft^2 [U.S. Department of Housing and Urban Development 1999; U.S. Environmental Protection Agency (EPA) 2001] for interior floors, it becomes evident that soil is an enormous reservoir of Pb dust. Because of the low mobility of Pb in soil, all of the Pb that accumulates on the surface layer of the soil is retained within the top 20 cm (Laidlaw 2001; Mielke et al. 1983). The half-life of Pb in surface soils has been estimated to be approximately 700 years, so without corrective action, Pb dust will persist for many generations (Semlali et al. 2004). The persistence of the Pb burden that has accumulated in soil has significant long-term public health implications (Lejano and Ericson 2005).

Anthropogenic soil Pb speciation and bioavailability. Pb deposited by human activity onto and retained by surface soils has been added to the relatively small quantities of Pb naturally occurring in the soil. This anthropogenic Pb is generally speciated in the highly bioavailable carbonate, iron, and manganese hydroxide soil fractions, whereas the Pb in natural soils is speciated in the residual, or nonbioavailable fractions (Chlopecka et al. 1996; Lee 1997). Therefore, dust originating from urban soils contaminated by anthropogenic Pb is more toxic than naturally occurring Pb dust. Lead is associated with the smallest particles, the clay grain size fraction in urban soils (Dong et al. 1984); therefore, Pb in dust originating from urban soils is more potent and concentrated than would be expected from simple measurements of the Pb content of the soil (Young et al. 2002).

Bioavailability is indicated by an isotope study of BPb and soil Pb. Each source of Pb has an isotopic signature that is unique to a particular mine. When this characteristic of Pb was first described, most manufacturers began interchanging Pb mining sources, and the effect was to scramble the isotope signatures and render Pb isotopes essentially useless for source identification. The former Soviet Union, however, did not scramble Pb sources that were used in gasoline. Armenia eliminated the use of leaded gasoline before 1997 (Kurkjian and Flegal 2003). The half-life of BPb is about 30 days and is therefore cleared from the blood in a matter of months. If Pb exposure continues, then BPb remains elevated. A study conducted in Yerevan, Armenia, 2 years after the elimination of leaded gasoline indicated that the soil Pb from previous gasoline Pb emissions persisted as a route of exposure for adults (Kurkjian and Flegal 2003). The Pb isotopes of the BPb of adults and the Pb isotopes in contaminated soils were identical, and this provided strong evidence that prior leaded gasoline emissions persist and are highly bioavailable as a route of exposure (Kurkjian and Flegal 2003).

Seasonal changes in BPb concentration. Average monthly BPb of children from urban areas tends to increase significantly in summer months (Billick et al. 1979; Blatt and Weinberger 1993; Haley and Talbot 2004; Hayes et al. 1994; Hunter 1977; Hwang and Wang 1990; Johnson and Bretsch 2002; Johnson et al. 1996; Kimbrough et al. 1994; Marrero et al. 1983; Mielke and Reagan 1998; Rabinowitz and Needleman 1982; Rothenberg et al. 1996; Stark et al. 1980; U.S. EPA 1995, 1996; Yiin et al. 2000). Summertime increases of children's BPb were so prominent over many years in Syracuse, New York, that researchers concluded that the phenomenon was probably caused by the interaction between climate and soils (Johnson and Bretsch 2002; Johnson et al. 1996). The purpose of this study is to test the hypothesis that children's exposure as measured by BPb is associated with climate and soil factors affecting Pb dust flux in three cities: Indianapolis, Indiana; Syracuse, New York; and New Orleans, Louisiana. Figure 1 presents a map illustrating the locations of the three cities.

Materials and Methods

This study differs from previous studies because it uses environmental variables as predictors of children's BPb concentrations, which does not appear to have been attempted before using an ecologic study design. The U.S. EPA studies in Milwaukee (U.S. EPA 1996) and Boston (U.S. EPA 1995) attempted to model BPb using sinusoidal functions; however, it appears that multiple linear regression using climate and soil moisture variables may be more robust due the high percentage of variation explained in the model (up to 87%). The U.S. EPA models did not attempt to use environmental variables to predict BPb concentrations; however, both studies suggested that Pb from the environment might be causing the child BPb seasonality.

This study's design is described as an analytic time-trend ecologic study (Morgenstern 1998). In ecologic studies, the unit of analysis is the group rather than the individual. The ecologic unit of analysis in this study is the group of children within the city limits of each city who have had their BPb measured. An ecologic design was selected because it is neither practical nor ethical to draw blood from large groups of children on a monthly basis over a long period. One potential limitation of ecologic studies is known as the ecologic fallacy (Morgenstern 1998): the failure of expected ecologic effect estimates to reflect biologic effects at the individual level. However, the

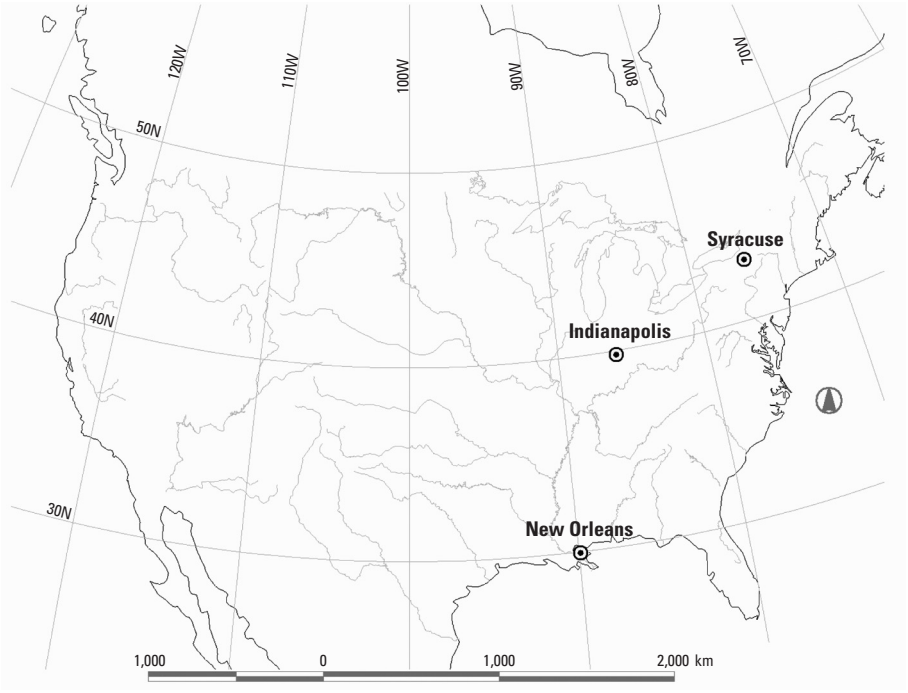

Figure 1. Map showing the locations of Indianapolis, Indiana; Syracuse, New York; and New Orleans, Louisiana.

biologic plausibility of the associations found at the ecologic level in this study have been found at the individual level in smaller studies (Aschengrau et al. 1994; Lanphear et al. 2003; Maisonet et al. 1997; Mielke and Reagan 1998; Sheldrake and Stifelman 2003). This supports the biologic plausibility of the suggested model. Another facet of this study is that it uses empiric data from three cities that differ in geographic location and climate. Syracuse (latitude 43° N and longitude 76° W) has a cold continental climate; Indianapolis (latitude 40° N and longitude 86° W) is located in the middle continent region; and, New Orleans (30° N latitude and 90° W longitude) has a southerly and warm Gulf Coast climate. The relationship between BPb, weather, and soil moisture is thus studied in geographically and hence climatically diverse locations.

Data Sources

The independent variables—average monthly soil moisture, particulate matter < 10 μm (PM_{10}), wind speed, and temperature—were obtained from state or federal government data sources. Blood Pb databases for each city were obtained from local or state governmental sources as follows.

Indianapolis. In Indianapolis, Indiana, BPb data for 15,944 children were obtained from the Marion County Health Department (personal communication). Nearly 15% of the children listed in the Indianapolis database were < 1 year (n = 2,320), 20% were 1–2 years (n = 3,202), 13% were 2–3 years (n = 2,078), 19% were 3–4 years (n = 3,050), 22% were 4–5 years (n = 3,476), and 11% were ≥ 5 years of age (n = 1,820). The BPb measurements were collected using the venous method. PM_{10} data were obtained from the Indiana Department of Environmental Management air monitoring station located at 3302 Englist Avenue (personal communication). Soil moisture data were obtained (personal communication) from actual field measurements of the top 6 inches of soil at Illinois Water Survey soil moisture monitoring site number 81 located near Champaign, Illinois, which is approximately 110 miles west of Indianapolis (Hollinger and Isard 1994). Wind speed and temperature data were obtained from the National Oceanic and Atmospheric Administration (NOAA) National Climatic Data Center (NCDC 2004).

Syracuse. In Syracuse, New York, child BPb data were obtained from the Onondaga County Health Department (personal communication). The child BPb screenings for the Syracuse BPb data set were collected from within the city limits of Syracuse. Approximately 90% of child BPb screenings were obtained from passive sources such as county clinics or physicians, and 10% of the screenings were collected from a mobile bus that screened children at locations including day care centers, prekindergarten centers, and Head Start centers. The bus schedule started in May and ended in September, operating full time in June, July, and August. The bus traveled to different locations each summer period. The bus sampling strategy typically targeted areas that had high percentages of BPb concentrations greater than 20 μg/dL. The child BPb screenings were conducted through a combination of capillary and venous methods. The BPb analysis was completed by laboratories certified by the New York State Department of Health. PM_{10} data were obtained from the New York State Department of Environmental Conservation's Solvay High School air monitoring site located on Gertrude Avenue (personal communication). Soil moisture data were obtained from NOAA (Fan Y, personal communication), and wind speed and temperature data were obtained from the NCDC (2004).

New Orleans. In New Orleans, Louisiana, the child BPb data were obtained from the Louisiana Childhood Lead Poisoning Prevention Program Office of Public Health (personal communication). The screenings for the New Orleans BPb data set were collected from within the city limits. No known geographic or temporal sampling bias was reported. Eighty-four percent of the screenings originated from private providers such as pediatric clinics, physicians, and family practice physicians. Approximately 70% of the children whose BPb was screened were eligible or enrolled in Medicaid. The BPb levels were analyzed primarily by the following laboratories: Labcorp (Burlington, NC), Tamarac (Centennial, CO), Medtox (St. Paul, MN), Quest Diagnostics (Metairie, LA), and ARUP Laboratories (Salt Lake City, UT). The screening procedures were not reported to have changed between January 1998 and May 2003. The data set used in this study was screened for children that had blood drawn using the venous method. The PM_{10} data were obtained from the Louisiana Department of Environmental Quality (personal communication). The soil moisture data were obtained from NOAA (Fan Y, personal communication), and the wind speed and temperature data were obtained from the NCDC (2004).

Statistical Analysis

We computed the average BPb concentration in each city using the child BPb measurements for each month. The outcome variable, children's average monthly city BPb concentration for each city, was regressed against the independent variables average monthly soil moisture, PM_{10}, wind speed, and temperature; interaction variables; and monthly dummy variables using backward elimination procedures. The independent variables temperature, PM_{10}, and soil moisture were computed as the arithmetic mean, whereas the wind speed was computed as the median. Each model's entry and criteria were 0.10 and 0.15, respectively. Backward variable elimination enters all of the variables in the block in a single step and then removes them one at a time based on removal criteria. Spearman's rank correlation coefficient was used to assess the association between variables. Statistical analysis was performed using SPSS (version 11.5; SPSS Inc., Chicago, IL).

The Durbin-Watson (DW) and Lagrange multiplier (LM) statistics were calculated to assess the presence of serial autocorrelation. The LM was calculated by regressing the residuals of a model versus the same residuals shifted backward one value relative to the other residuals. The LM statistic is computed by multiplying the R^2 value of this regression by the number of values in the regression. The DW statistic was calculated using SPSS.

Results

For each city, we calculated Spearman's rank correlation coefficient matrices for the variables soil moisture, wind speed, PM_{10}, and temperature; interaction variables; and monthly dummy variables (M1 to M11). In Indianapolis, Syracuse, and New Orleans, BPb concentration and soil moisture exhibited inverse correlations of –0.41, –0.75, –0.47, respectively. The correlations are presented in Tables 1–3.

Table 1. Indianapolis: Spearman's correlation matrix (December 1998 to November 2002).

	SM	W	PM_{10}	Temp
BPb all	–0.41	–0.36	0.16	0.20
SM		0.55	–0.13	–0.66
W			–0.18	–0.65
PM_{10}				0.19

Abbreviations: SM, soil moisture; Temp, temperature; W, wind speed.

Table 2. Syracuse: Spearman's correlation matrix (January 1994 to March 1998).

	SM	W	PM_{10}	Temp
BPb all	–0.75	–0.28	0.10	0.43
SM		0.61	–0.19	–0.57
W			–0.48	–0.66
PM_{10}				0.49

Abbreviations: SM, soil moisture; Temp, temperature; W, wind speed.

Table 3. New Orleans: Spearman's correlation matrix (January 1998 to May 2003).

	SM	W	PM_{10}	Temp
BPb all	–0.47	0.03	–0.05	–0.16
SM		0.18	–0.12	–0.13
W			–0.24	–0.48
PM_{10}				0.59

Abbreviations: SM, soil moisture; Temp, temperature; W, wind speed.

Regression results: Indianapolis. The time period of the regression consisted of 36 months between December 1999 and November 2002. The dependent variables for the first model consisted of the average monthly child BPb from a data set of 15,969 children. This model was run using backward elimination procedures.

This model indicates that the variables or interaction variables including soil moisture, wind speed, PM_{10}, temperature, and the monthly dummy variables for March, April, June, July, August, and September explain 87% of the variation in the response variable, monthly average child BPb concentration (R^2 = 0.87, p = 0.0004). The DW and LM statistics indicate that the model did not display serial autocorrelation (DW = 1.73, LM = 0.24). Figure 2 presents a chart of the average monthly child BPb concentration for the entire data set versus the predicted child BPb concentration.

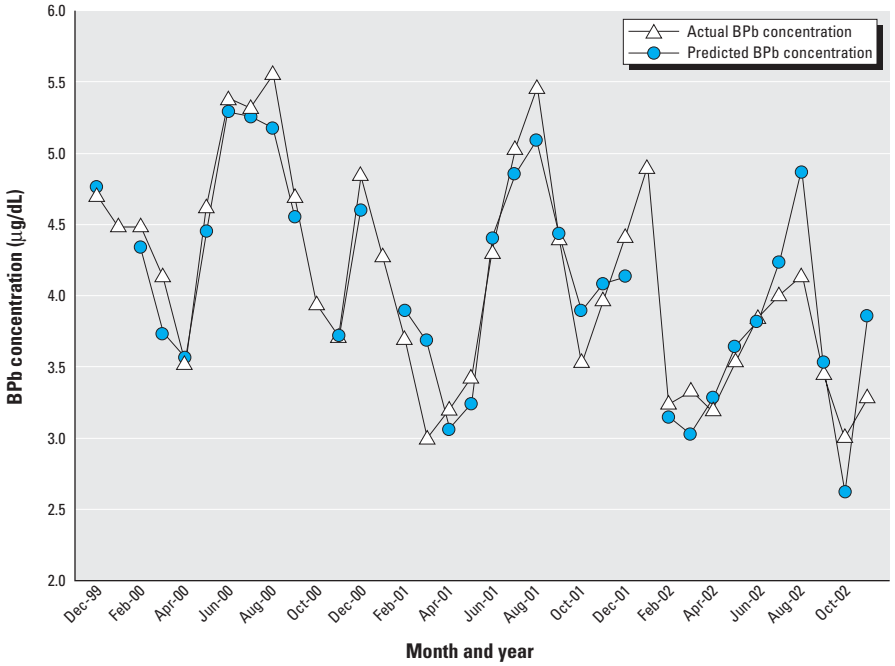

Figure 2. Actual monthly average BPb versus predicted monthly average BPb in Indianapolis, Indiana, for a 36-month period between December 1999 and November 2002 (n = 15,969, R^2 = 0.87, p = 0.0004, DW = 1.71, LM = 0.85).

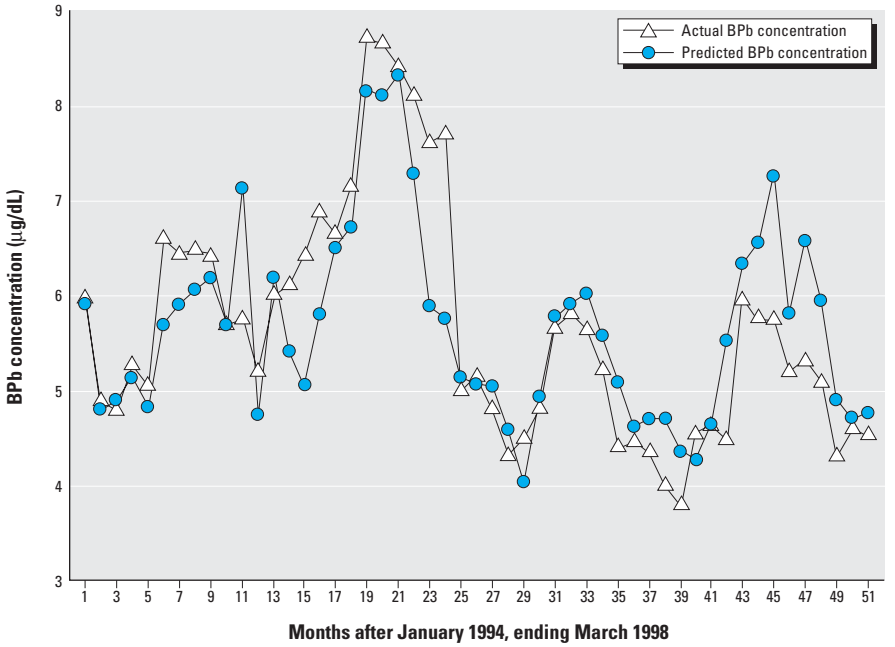

Figure 3. Actual monthly average BPb versus predicted monthly average BPb in Syracuse, New York, for a 51-month period between January 1994 and March 1998 (n = 14,467, R^2 = 0.61, p = 0.0012, DW = 2.05, LM = 0.049).

The model regression coefficients indicate that the seven predictors with p-values less than 0.05 are temperature (p = 0.00093), wind speed (p = 0.00093), the interaction between temperature and wind (p = 0.002), soil moisture (p = 0.006), the interaction between soil moisture and temperature (p = 0.0076), the interaction between wind and soil moisture (p = 0.011), and the interaction between wind and PM_{10} (p = 0.016).

Regression results: Syracuse. The time period of the regression consisted of 51 months from January 1994 through March 1998. The use of a mobile clinic to screen children in Syracuse in high-risk areas may have biased the high aggregate monthly average during the months of May through September. However, starting with the 1996 data, the universal screening requirement of the New York State Department of Health (2002) went into effect; subsequently, higher screening rates and more random sampling were apparent in the results. The dependent variables consisted of the average monthly child BPb concentration of a data set of 14,467 children from Syracuse. The model was run using backward elimination procedures. The time-series difference method was used to correct for serial autocorrelation.

This model indicates that the variables or interaction variables including soil moisture, wind speed, PM_{10}, temperature, and the monthly dummy variables for January, March, April, May explained 61% of the variation in the response variable, monthly average child BPb concentration (R^2 = 0.61, p = 0.0012). The DW and LM statistics indicate that the model did not display serial correlation (DW = 2.05, LM = 0.049). Figure 3 presents a chart of the average monthly child BPb concentration versus the predicted child BPb concentration.

The model regression coefficients indicate that the four predictors with p-values less than 0.05 are the interaction between temperature and PM_{10} (p = 0.0004), PM_{10} (p = 0.0047), wind speed (p = 0.029), and the interaction between soil moisture and temperature (p = 0.042).

Regression results: New Orleans. The time period of the regression consisted of 65 months from January 1998 through May 2003. The dependent variable is the average monthly blood level of a data set of 2,295 children. This model was run using backward elimination procedures.

The model indicates that the variables soil moisture, wind speed, PM_{10}, temperature, several interaction variables, and the monthly dummy variables for January, February, March, April, July, and October explained 59% of the variation in the response variable,

monthly average child BPb concentration (R^2 = 0.59, p = 0.0000078). The DW and LM statistics indicated that the model did not display serial autocorrelation (DW = 1.71, LM = 0.85). Figure 4 presents a chart of the average monthly child BPb concentration versus the predicted child BPb concentration.

The model regression coefficients indicate that the predictors with p-values < 0.05 are PM_{10} (p = 0.00003), the interaction between PM_{10} and wind (p = 0.00005), the interaction between PM_{10} and temperature (p = 0.0006), and soil moisture (p = 0.006). A summary of the statistics from the three cities is presented in Table 4.

Discussion

Soil moisture and soil suspension. Numerous studies have demonstrated that soil moisture concentration is a significant control of dust (PM_{10}) suspension and loading (Chen et al. 1996; Clausitzner and Singer 1996, 2000; Cornelis and Gabriels 2003; Nickovic et al. 2001). Soil moisture is a predictor of wind erosion because soil moisture contributes to bind particles together (McKenna-Neuman and Nickling 1989). Soil particles will become deflated when destabilizing forces such as drag, lift, and aerodynamic forces become greater than stabilizing forces such as particle weight and interparticle binding forces (Iverson et al. 1976).

The threshold shear velocity of a particle is the wind velocity required to deflate (suspend) a particle in the atmosphere (Cornelis and Gabriels 2003). Most models that predict wet threshold shear velocity (u_{tw}) of a particle take the form

$$u_{tw} = u_t f(\text{moisture}),$$

where u_t is the threshold shear velocity under dry conditions. The function f(moisture) is a function of the surface moisture expressed in terms of moisture content w (kilogram per kilogram) or capillary potential (Pascal) (Cornelis and Gabriels 2003).

Most models of the threshold shear velocity predict a rise in deflation threshold with increasing moisture content (Cornelis and Gabriels 2003).

With decreasing soil matrix potential from a dry soil, the u_{tw} will increase exponentially until a soil matrix potential of –1.5 MPa occurs, at which no soil deflation takes place. The matrix potential (ψ) has been found to be a function of temperature (T), air humidity (e/e_s), molar volume of water (V_w; 0.0224 m^3/mol), and the universal gas constant (R; 8.3145 J/mol K) (Edlefson and Anderson 1943):

$$\psi = [(RT)/V_w][\ln(e/e_s)].$$

These equations suggest that when temperature is high and soil moisture is low in the summertime, soils are susceptible to deflation. The modeling approach used in this study may have successfully explained the temporal variation in BPb because the matrix potential variables soil moisture (volumetric water content) and temperature were incorporated, which permits prediction of when soils are susceptible to dust emission. The variables PM_{10} and atmospheric Pb represent the end product of dust generation, and the variable wind speed may contribute to the explanation of the variance because of its effect on the PM_{10} (dust) deposition rate. Essentially, the high R^2 values suggest that these variables predict temporal dust generation and exposure of children to Pb from dust in the environment.

The regression models indicate that environmental variables from outside the home, adjusted for seasonality, such as soil moisture, PM_{10}, temperature, and wind speed, are significant predictors (p < 0.05) of children's seasonal BPb fluctuations. This suggests that the Pb controlling the seasonal fluctuations originates from the outdoor environment. In the three cities studied here, the urban soils are highly contaminated by Pb (Filippelli et al. 2005; Johnson and Bretsch 2002; Laidlaw 2001; Mielke 1994; Mielke et al. 1999). Thus, there is an abundant source of Pb in urban soils that could be suspended, resulting in elevated Pb dust loading rates during certain weather conditions.

The hypothesis that urban soils are being resuspended into the atmosphere is also supported by the literature that indicates a strong relationship between the suspension of surface soils and atmospheric particulates. In Bakersfield, California, 74% of PM_{10} from July through September 1988 was composed of geologically originated materials (Young et al. 2002). One study estimated that street dust was composed of approximately 76% soil materials (Hopke et al. 1980), and another study estimates that soil contributes between 57 and 90% of road dust (Hunt et al. 1993). Finally, 43% of Pb emissions in the South Coast Air Basin in California resulted from the resuspension of soil and road dust (Lankey et al. 1998).

Blood Pb seasonality. Blood Pb seasonality suggests that Pb exposure varies over time. Thus, those who postulate that Pb-based paint is the primary source of Pb exposure also theorize that dust generation from Pb paint is somehow related to accelerated flaking from painted surfaces during summer months. Some have suggested that the opening and closing of windows painted with Pb paint may

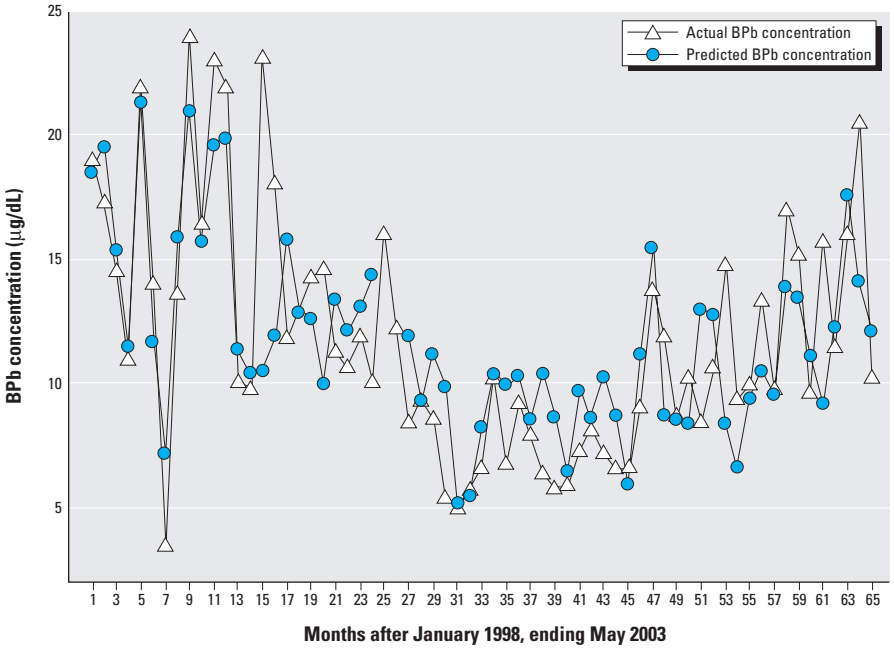

Figure 4. Actual monthly average BPb versus predicted monthly average BPb in New Orleans, Louisiana, for a 65-month period between January 1998 and May 2003 (n = 2,295, R^2 = 0.59, p = 0.0000078, DW = 1.71, LM = 0.85).

Table 4. Multiple linear regression modeling results: all three cities.

City	R^2	df	F-value	p-Value	SE	DW	LM	Month	No.	Time-series transform
Indianapolis	0.87	16	6.43	0.0004	0.39	1.73	0.24	36	15,969	No transform
Syracuse	0.61	15	3.52	0.0012	0.51	2.05	0.049	51	14,467	Difference
New Orleans	0.59	13	5.33	< 0.00001	3.58	1.71	0.85	65	2,295	No transform

produce seasonal exposure to Pb dust (Haley and Talbot 2004). However, this study indicates that soil moisture, PM_{10}, wind speed, and temperature fluctuations, adjusted for each other, are very strongly associated with children's BPb levels. If these variables were noncausally associated with BPb fluctuations, and Pb paint was the source of the seasonality, this would imply that the opening and shutting of doors was associated with soil moisture, PM_{10}, wind speed, and temperature. This appears to be counterintuitive because the opening and shutting of windows is likely temperature dependent and not dependent on soil moisture, PM_{10}, and median wind speed.

We propose that BPb seasonality results from three or four exposure routes: First, children are likely seasonally exposed to elevated dust Pb loading on interior and exterior surfaces via hand-to-mouth processes, and the elevated Pb loading likely results from seasonal high Pb loading rates due to suspension of urban soils. Second, children are also exposed to direct ingestion of urban Pb-contaminated soil during warmer months. Third, it is possible that children are being seasonally exposed to Pb particles derived from the seasonal opening and shutting of windows painted with Pb paint. Fourth, children are exposed through inhalation to elevated atmospheric dust Pb concentrations resulting from seasonal soil suspension.

In addition, on the basis of the relationship between BPb, high temperatures, low soil moisture, and PM_{10} found in this study, we infer that arid climates with major urban areas and a long-term historical use of Pb in petroleum will experience high sustained rates of Pb loading that originate from Pb dust in soils. We also expect a more prolonged exposure when compared with colder climate areas, resulting in a muting of seasonality trends. These regions may include areas such as Los Angeles, California (USA), Mexico City and Tijuana, Mexico; arid areas of China, Pakistan, and India; and Nigeria, Saudi Arabia, and Cairo, Egypt. Furthermore, the aridity may exacerbate Pb exposure and childhood poisoning, particularly in emerging economies, where leaded gasoline is still in use (Nriagu et al. 1996; Sridhar et al. 2000). Soil Pb may be an important exposure variable in these environments, possibly overwhelming exposure to other sources of Pb.

Soil Pb and exposure. A growing body of research supports the conclusion that urban soils contribute significantly to child BPb poisoning (Mielke and Reagan 1998). Several ecologic studies have found associations between urban soil Pb concentrations and children's BPb concentrations. A significant logarithmic relationship was reported between soil concentration (> 3,000 sampling points) and child BPb in New Orleans by census tract ($R^2 > 0.65$) (Mielke et al. 1997). An independent study found a similar relationship in Syracuse ($R^2 > 0.65$) (Johnson and Bretsch 2002). Both these studies show that, nontemporally, soil accounts for a significant amount of the variation in BPb on a spatial basis. A study of urban dusts and soils in Britain (Culbard et al. 1988) found that soil and outdoor and indoor dusts were the most significant predictor variables in the regression model used to explain children's BPb levels. The study also found that Pb in interior paint was not a strong independent variable in the final stepwise regression analysis used to explain children's blood levels (Culbard et al. 1988). A pooled study of 12 epidemiologic studies found that dust Pb loading and soil Pb concentration were the two most significant predictors of children's BPb levels (Lanphear et al. 1998). In Bunker Hill, Idaho, structural equation modeling indicated that 40–50% of the BPb is from house dust, whereas approximately 30% was from community-wide soils and 30% from the yard at the home and the immediate neighborhood (von Lindern et al. 2003). In Tijuana, Mexico, several studies have found associations between soil Pb and children's BPb levels (Ericson and Gonzalez 2003; Gonzalez et al. 2002).

The epidemiology literature has also indicated that the removal of Pb-contaminated soil results in significant reductions in child BPb concentration and supports the causal spatial relationship between soil Pb and BPb that has been found in the ecologic studies (Johnson and Bretsch 2002; Mielke et al. 1997, 1999). Soil Pb abatement resulted in a 2.25–2.70 μg/dL reduction in BPb levels when a randomized trial of soil abatement was conducted (Malcoe et al. 2002). Logistic regression indicated that soil Pb > 165 mg/kg was independently associated with BPb concentrations > 10 μg/dL [odds ratio (OR) = 4.1; 95% confidence interval (CI), 1.3–12.4]. Yard soil removal resulted in a 3-fold reduction in the child BPb concentrations of children in the Silver Valley of Idaho, located near the Bunker Hill Superfund site, and reduced the dust Pb levels inside the homes (Sheldrake and Stifelman 2003). Removal of soil from children's yards reduced the children's BPb when compared with controls (OR = 0.28; 95% CI, 0.08–0.92) (Maisonet et al. 1997). A study conducted on the effect of soil removal on child BPb concentrations at homes where the soil Pb concentration was greater than 500 mg/kg showed a statistically significant difference between BPb concentrations in homes in which soil was removed versus those where contaminated soil was not removed ($p < 0.05$) (Lanphear et al. 2003).

Integrated Exposure Uptake Biokinetic Model for Lead in Children. The degree to which the proposed exposure hypotheses result in reasonable predictions for BPb levels can be examined with the U.S. EPA's Integrated Exposure Uptake Biokinetic Model for Lead in Children (IEUBK) (U.S. EPA 1994). To develop an exposure regime for the IEUBK model input, we note that indoor residential dusts generally show Pb concentrations about two times higher, on average, than the corresponding outdoor soils, although these results may have been influenced by fine particulate automotive Pb emissions (Clark et al. 1988; Rabinowitz et al. 1985; Thornton et al. 1990). More recent data are available as summaries from 299 residential locations in eight different Idaho communities for the Human Health Risk Assessment for the Coeur d'Alene Basin showed an average enrichment factor of 1.6 for Pb concentration in carpet dusts compared with outdoor soils (TerraGraphics and URS Greiner 2001; von Lindern et al. 2003). Studies also indicate that dust Pb loading was 1.2 times higher in spring and fall than in winter and that in summer the loading was 1.6 times higher than in winter (Yiin et al. 2000). Model predictions were obtained by specifying seasonal dust concentration differences that would result in the observed dust Pb loading differences. Using the IEUBK default values for Pb in air, water, food, and soil, soil and dust ingestion rates, and with soil representing 45% of the combined soil and dust ingestion, dust Pb concentration was specified as 333 ppm or 550 ppm. For children 1–2 years of age, this increased BPb values from 5.5 μg/dL (winter) to 7.0 μg/dL (summer). When the soil ingestion was specified as 25% of the combined soil/dust intake, the predictions ranged from 5.8 μg/dL (winter) to 7.8 μg/dL (summer).

A more realistic exposure regime for Syracuse might specify a soil Pb concentration of 150 mg/kg, with a winter–summer range of 200–320 mg/kg for the indoor dusts. If the ingested soils are limited to 10% of the total ingestion for combined soils and dusts, the predicted BPb values range from 4.5 to 5.9 μg/dL. This corroborates the range of observations for the 1997–1998 monitoring (Figure 3). Mean observed BPb values for recent Indianapolis data are lower than the 1994–1998 results in Syracuse, so IEUBK model input values would have to be lower to replicate the observations. If one assumes soil Pb is 100 mg/kg and ingestion of soil represents 10% of the total soil/dust ingestion, and the dust concentration varies from 100 to 180 mg/kg and is associated with a bioavailability of 40% instead of the 30% default value, predicted BPb values range from 3.6 to 4.9 μg/dL. This shows reasonable agreement with the observations (Figure 2).

These exploratory uses of the IEUBK are meant only to indicate the types of concentration values and changes in physiochemical parameters that might provide a mechanistic

explanation for the correlations observed in this work. A temporal structure in BPb levels can be modeled by the multicompartmental biokinetic IEUBK model using a wide variety of ingestion rates, soil and dust concentration values, and bioavailability parameters. Because we posit the seasonal variations in PM_{10}, it is not unreasonable to consider changes in model default parameters for bioavailability. Small particle size is known to increase Pb uptake from particles (Rieuwerts and Farago 1995; Steele et al. 1990; Wixson and Davies 1994). The potential influence of soil resuspension processes in modulating BPb levels needs careful examination, and future studies should incorporate detailed monitoring for temporal resolution of suspended Pb per volume of air, seasonal influences on residential dust Pb loading and concentration, and measures of Pb bioavailability. Further discussion about the many influences that the natural environment has on public health may be found in Selinus et al. (2005).

Conclusion

A conceptual model of child BPb seasonal Pb poisoning is suggested. Lead from multiple sources has accumulated in soils of urban environments. The seasonal resuspension of Pb-contaminated soil in urban atmospheres appears to be controlled by soil moisture and climate fluctuations. This study indicates that higher urban atmospheric Pb loading rates are experienced during periods of low soil moisture and within areas of Pb-contaminated surface soils. Children and adults living in urban areas where surface soils are contaminated with Pb may become exposed through indoor and outdoor inhalation of Pb dust and ingestion of Pb deposited within homes and outdoor surfaces. Because resuspension of Pb from contaminated soil appears to be driving seasonal child BPb fluctuations, concomitantly, we suggest that Pb-contaminated soil in and of itself may be the primary driving mechanism of child BPb poisoning in the urban environment.

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To: COMMITTEE ON OVERSIGHT AND INVESTIGATIONS
Meeting of September 23, 2022

Written Testimony of Taras M. Czebiniak
Submitted Online

RE: A Demand To End Human Rights Violations in New York City, Perpetuated by Mayor Eric Adams and the City Council, with Covid-19 Private and Public Worker Injection Mandates

The purpose of this written testimony with supporting exhibits is to make it easy for future historians of New York City to confirm that you, the City Council, together with Mayor Eric Adams commit and perpetuate human rights violations here with your full personal knowledge and consent. There remains a legal mandate in New York City that all City workers, and all private workers, have received a Covid injection in order to earn a living (the "**Mandate**"). (*See* EXHIBIT 1: Emergency Executive Order No. 317, December 15, 2021.) The Mandate is inconsistent, hypocritical, dangerous, it goes against the global consensus against mRNA injection mandates, and it violates the Nuremberg Code established after examination of the Nazi atrocities of World War II.

You can no longer claim ignorance of, or deny your full complicity with, Human Rights Violations in New York City in 2022.

The City Council has the power to stop the human rights violations, but up until today, the Council has refused to stand against the Mayor, and the Council therefore stands against human rights.

1. The Mandate violates the fundamental human right of every New Yorker to choose his or her medical interventions, a right enunciated in the Nuremberg Code of August 1947. EXHIBIT 2 provides the relevant text of the Nuremberg Code. The threat of being fired from one's job, losing one's pension or retirement benefits, and any and all other methods of coercion and duress to force the Covid injection violate the Nuremberg Code -- period. The Nuremberg Code is clear, it is written in plain English, and it is accessible and understandable by every human citizen on each. One need not be an 'expert' of any kind to understand and demand the rights confirmed by the Nuremberg Code.

2. Private employers continue to block non-injected workers from working, and they threaten existing workers with an ultimatum to take the injection and return to the office, or else be fired. The Mayor has stated that he is not personally enforcing the private employer mandate. But New Yorkers remain unable to work or are forced into taking the injection, because the Mayor has merely deputized private employers who conduct the enforcement on his behalf. My personal friend was given an ultimatum to either permit Mayor Adams to violate her bodily autonomy and take a Covid injection, or else be fired. (*See* NEW YORK CITY COUNCIL, Testimony of Taras M. Czebiniak, online video of the proceedings of the September 9, 2022 meeting of the Committee on Civil Service and Labor, time index: 3 hours 44 minutes.) Large private employers will not violate standing law, regardless of a politician's promise not to enforce, therefore the Mandate remains pernicious to private workers and violates them. As another example, Goldman Sachs has dropped all of its Covid injection mandates – except in New York City and Lima, Peru. (*See* BLOOMBERG, August 30, 2022, *Goldman Lifts Most Vaccination Rules for Staff in Office*.) This is because only those cities still require Covid injection from employees where Goldman Sachs maintains offices. (Regarding the worker mandates in Lima, Peru, *see* ACTUALIDAD CIVIL, March 28, 2022, *A partir del 1 de abril, trabajadores deberán tener las tres dosis de la vacuna contra el covid-19*.)

3. The Mandate forces a medically dangerous intervention, that both government and pharmaceutical companies have provably lied about, for nearly 2 years. A recent study published in VACCINE confirms that the Covid mRNA injections, those most prevalent in the United States, carry a 1 in 800 rate of serious adverse events, defined by the Code of Federal Regulations (21 C.F.R. section 312.32(a)) as death, life-threatening illness, hospitalization or prolongation of hospitalization, permanent disability, congenital anomaly, or birth defect. Neither the federal or city government, nor the pharmaceutical companies themselves, have disclosed these numbers. Consent to any medical procedure is not informed, as required by medical ethics, when material information is withheld, obfuscated, censored, and outright lied about by those in power. (EXHIBIT 3: VACCINE 40:40, 22 September 2022, pages 5798-5805, *Serious adverse events of special interest following mRNA COVID-19 vaccination in randomized trials in adults*.) Further, the authors of the VACCINE study confirm that both the federal FDA and Pfizer-BioNTech have the underlying data, but they refuse to release it to unbiased third parties to determine safety and efficacy. Finally, the German Health Ministry has confirmed that 1 in 5,000 Germans have experienced "serious side effects" from Covid injections.

4. Most other countries have long since ended their Covid injection mandates. Denmark has gone even further: Denmark no longer recommends Covid injections to anyone under 50 years without other health risks. The Danish Health Authority now recognizes that the Covid injections no longer have a benefit for individuals under 50. Not only are the injections not mandated, but they are not even recommended. (*See* EXHIBIT 4: Danish Health Authority, updated September 13, 2022, *Vaccination against covid-19*.) Mayor Adams is not a physician nor a public health official, and yet he claims to magically know more about Covid than virtually every other country on earth that has eliminated mandates and even recommendations to continue injecting.

5. The Mandate exempts celebrities and athletes and treats them differently from everyday New Yorkers. This policy which has absolutely no scientific or medical basis. The Mandate must end for all. On March 4, 2022, Mayor Adams exempted performing artists and their staff, as well as professional athletes and their staff, from the private sector Covid injection mandate. (EXHIBIT 5: Emergency Executive Order 62.) There is no study demonstrating any scientific or medical reason for exempting rich, elite artists and athletes from the mandate. The entire mandate itself constitutes a human rights violation, and the Mayor must immediately rescind the Mandate for all New Yorkers -- not just his rich buddies that he wants to rub elbows and have himself photographed with.

CONCLUSIONS

It is a **crime against humanity** to coerce under duress harmful medical interventions to individuals without their free, voluntary, and informed consent to the intervention.

Mayor Adams has directly and indirectly **violated the bodies of tens of thousands of New Yorkers** by maintaining his Covid injection requirement to earn a living in New York City, which is a human right.

The New York **City Council is complicit in crimes against humanity** through its inaction to rein in this dictatorial Mayor and return and restore proper representation to the citizens of New York City.

Historians will look upon the 2022 New York City Council and the Mayor with absolute horror. You are fully aware of your perpetuation of crimes against humanity, yet, you have done nothing to stop this. Today is the day for the Council to draft and pass legislation to END the Mayor's Covid injection mandate.

Best regards,
Taras M. Czebiniak
TarasMC@gmail.com

EXHIBIT 1

Emergency Executive Order No. 317, December 15, 2021

See attached.

THE CITY OF NEW YORK
OFFICE OF THE MAYOR
NEW YORK, N.Y. 10007

EMERGENCY EXECUTIVE ORDER NO. 317
December 15, 2021

WHEREAS, the COVID-19 pandemic has severely impacted New York City and its economy, and is addressed effectively only by joint action of the City, State, and Federal governments; and

WHEREAS, the state of emergency to address the threat and impacts of COVID-19 in the City of New York first declared in Emergency Executive Order No. 98, and extended most recently by Emergency Executive Order No. 296, remains in effect; and

WHEREAS, on October 29, 2021, U.S. Food and Drug Administration authorized the emergency use of the Pfizer-BioNTech COVID-19 Vaccine for the prevention of COVID-19 to include children 5 through 11 years of age; and

WHEREAS, on November 26, 2021, New York State Governor Kathy Hochul issued Executive Order No. 11 to address new emerging threats across the State posed by COVID-19, finding that New York is experiencing COVID-19 transmission at rates the State has not seen since April 2020 and that the rate of new COVID-19 hospital admissions has been increasing over the past month to over 300 new admissions a day; and

WHEREAS, the recent appearance in the City of the highly transmissible Omicron variant of COVID-19 suggests an increased risk of reinfection; and

WHEREAS, 70% of City residents are fully vaccinated and mandating vaccinations at the types of establishments that residents frequent will incentivize vaccinations, increasing the City's vaccination rates and saving lives; and

WHEREAS, additional reasons for requiring the measures continued in this Order are set forth in Emergency Executive Order No. 316;

NOW, THEREFORE, pursuant to the powers vested in me by the laws of the State of New York and the City of New York, including but not limited to the New York Executive Law, the New York City Charter and the Administrative Code of the City of New York, and the common law authority to protect the public in the event of an emergency:

Section 1. I hereby direct that Emergency Executive Order No. 316, dated December 13, 2021, shall be superseded in its entirety by the provisions of section 2 of this Order.

§ 2. a. The program set forth in this section shall be known as the "Key to NYC" program.

b. I hereby order that, except as provided in subdivision c of this section, a covered entity shall not permit a patron, full- or part-time employee, intern, volunteer, or contractor to enter a covered premises without displaying proof of vaccination and identification bearing the same identifying information as the proof of vaccination. However, for a child under the age of 18 only proof of vaccination, and not additional idenfication, is required to be displayed.

c. I hereby order that the following individuals are exempted from this section, and therefore may enter a covered premises without displaying proof of vaccination, provided that such individuals wear a face mask at all times except when they are consuming food or beverages:

(1) Individuals entering for a quick and limited purpose (for example, using the restroom, placing or picking up an order or service, changing clothes in a locker room, or performing necessary repairs);

(2) A nonresident performing artist not regularly employed by the covered entity, or a nonresident individual accompanying such a performing artist, while the performing artist or individual is in a covered premises for the purposes of such artist's performance, except that a performing artist is not required to wear a face mask while performing;

(3) A nonresident professional or college athlete/sports team that is not based in New York City (i.e., not a New York City "home team"), or a nonresident individual accompanying such professional or college athlete/sports team, who enters a covered premises as part of their regular employment for purposes of the professional or college athlete/sports team competition, except that such athlete is not required to wear a face mask while playing in a competition;

(4) An individual 5 years of age or older who enters a covered premises to participate in a school or after-school program offered by any pre-kindergarten through grade twelve public or non-public school, the Department of Youth & Community Development (DYCD), or another City agency, except that Department of Education (DOE) and charter school students participating in high risk extracurricular activities must comply with the vaccination requirements for high risk extracurricular activities as described in the relevent Order of the Commissioner of Health and Mental Hygiene Order issued on December 10, 2021;

(5) An individual who enters for the purposes of voting or, pursuant to law, assisting or accompanying a voter or observing the election; and

(6) An individual who was younger than five years of age on December 13, 2021, until 45 days after such individual's fifth birthday.

d. I hereby direct each covered entity to develop and keep a written record describing the covered entity's protocol for implementing and enforcing the requirements of this section. Such written record shall be available for inspection upon a request of a City official as allowed by law.

e. I hereby direct each covered entity to:

(1) Maintain a copy of workers' proof of vaccination or, if applicable, a record of reasonable accommodation(s) as described in paragraph (2)(iv) of this subdivision; or

(2) Maintain a record of such proof of vaccination, provided that such record shall include:

(i) the worker's name; and

(ii) whether the person is fully vaccinated; and

(iii) for a worker who submits proof of the first dose of a two-dose vaccine, the date by which proof of the second dose must be provided, which must be no later than 45 days after the proof of first dose was submitted; and

(iv) for a worker who does not submit proof of COVID-19 vaccination because of a reasonable accommodation, the record must indicate that such accommodation was provided, and the covered entity must separately maintain records stating the basis for such accommodation and any supporting documentation provided by such worker; or

(3) Check the proof of vaccination before allowing a worker to enter the workplace and maintain a record of the verification.

For a non-employee worker, such as a contractor, a covered entity may request that the worker's employer confirm the proof of vaccination in lieu of maintaining the above records. A covered entity shall maintain a record of such request and confirmation.

Records created or maintained pursuant to this section shall be treated as confidential.

A covered entity shall, upon request by a City agency, make available for inspection records required to be maintained by this section, consistent with applicable law.

f. I hereby direct each covered entity to post a sign in a conspicuous place that is viewable by prospective patrons prior to entering the establishment. The sign must alert patrons to the vaccination requirement in this section and inform them that employees and patrons are required to be vaccinated. The Department for Health and Mental Hygiene ("DOHMH") shall determine the text of such sign and provide a template on its website that a covered entity may use. A covered entity may use the sign available online at

nyc.gov/keytoNYC, or use its own sign, provided its sign must be no smaller than 8.5 inches by 11 inches, with text provided by DOHMH in at least 14-point font.

g. For the purposes of this Order:

(1) "Contractor" means the owner or employee of any business that a covered entity has hired to perform work within a covered premise.

(2) "Covered entity" means any entity that operates one or more covered premises, except that it shall not include pre-kindergarten through grade twelve (12) public and non-public schools and programs, houses of worship, childcare programs, senior centers, community centers, or as otherwise indicated by this Order.

(3) "Covered premises" means any of the following locations, except as provided in subparagraph (iv) of this paragraph:

(i) **Indoor Entertainment and Recreational Settings, and Certain Event and Meeting Spaces** including indoor portions of the following locations, regardless of the activity at such locations: movie theaters, music or concert venues, adult entertainment, casinos, botanical gardens, commercial event and party venues, museums, aquariums, zoos, professional sports arenas and indoor stadiums, convention centers and exhibition halls, hotel meeting and event spaces, performing arts theaters, bowling alleys, arcades, indoor play areas, pool and billiard halls, and other recreational game centers;

(ii) **Indoor Food Services**, including indoor portions of food service establishments offering food and drink, including all indoor dining areas of food service establishments that receive letter grades as described in section 81.51 of the Health Code; businesses operating indoor seating areas of food courts; catering food service establishments that provide food indoors on its premises; and any indoor portions of an establishment that is regulated by the New York State Department of Agriculture and Markets offering food for on-premises indoor consumption. The requirements of this Order shall not apply to any establishment offering food or drink exclusively for off-premises or outdoor consumption, or to a food service establishment providing only charitable food services, such as soup kitchens; and

(iii) **Indoor Gyms and Fitness Settings**, including indoor portions of standalone and hotel gyms and fitness centers, gyms and fitness centers in higher education institutions, yoga/Pilates/barre/dance studios, boxing/kickboxing gyms, fitness boot camps, indoor pools, CrossFit or other plyometric boxes, and other facilities used for conducting group fitness classes.

(iv) "Covered premises" do not include houses of worship or locations in a residential or office building the use of which is limited to residents, owners, or tenants of that building.

(4) "Identification" means an official document bearing the name of the individual and a photo or date of birth. Examples of acceptable identification include but are not limited to: driver's license, non-driver government ID card, IDNYC, passport, and school ID card.

(5) "Indoor portion" means any part of a covered premises with a roof or overhang that is enclosed by at least three walls, except that the following will not be considered an indoor portion: (1) a structure on the sidewalk or roadway if it is entirely open on the side facing the sidewalk; and (2) an outdoor dining structure for individual parties, such as a plastic dome, if it has adequate ventilation to allow for air circulation.

(6) "Nonresident" means any individual who is not a resident of New York City.

(7) "Patron" means any individual 5 years of age or older who patronizes, enters, attends an event, or purchases goods or services within a covered premise.

(8) "Proof of vaccination" means proof of receipt of a full regimen of a COVID-19 vaccine authorized for emergency use or licensed for use by the U.S. Food and Drug Administration or authorized for emergency use by the World Health Organization, not including any additional recommended booster doses, except that for children who are 5 years of age or older as of December 13, 2021, but younger than 12 years of age, "proof of vaccination" means proof of receipt of at least one dose of such a vaccine until January 28, 2022, after which time it shall mean proof of receipt of a full regimen of such vaccine. Such proof may be established by:

(i) A CDC COVID-19 Vaccination Record Card or an official immunization record from the jurisdiction, state, or country where the vaccine was administered or a digital or physical photo of such a card or record, reflecting the person's name, vaccine brand, and date administered; or

(ii) A New York City COVID Safe App (available to download on Apple and Android smartphone devices);

(iii) A New York State Excelsior Pass;

(iv) CLEAR's digital vaccine card; or

(v) any other method specified by the Commissioner of Health and Mental Hygiene as sufficient to demonstrate proof of vaccination.

(9) "Worker" means an individual who works in-person in New York City at a workplace in New York City. Worker includes a full- or part-time staff member, employer, employee, intern, volunteer or contractor of a covered entity, as well as a self-employed individual or a sole practitioner.

Worker does not include an individual who works from their own home and whose employment does not involve interacting in-person with co-workers or members of the public. Worker also does not include an individual who enters the workplace for a quick and limited purpose.

(10) "Workplace" means any location, including a vehicle, where work is performed in the presence of another worker or member of the public.

h. I hereby direct that each instance that a covered entity fails to check an individual's vaccination status shall constitute a separate violation of this section.

i. I hereby direct the City's Commission on Human Rights to publish guidance to assist covered entities in complying with this section in an equitable manner consistent with applicable provisions of the New York City Human Rights Law.

j. I hereby direct, in accordance with section 25 of the Executive Law, that staff from any agency designated by the Commissioner of Health and Mental Hygiene shall enforce the directives set forth in this section.

k. (1) I hereby direct that any person or entity who is determined to have violated the requirements of the Key to NYC program shall be subject to a fine, penalty and forfeiture of not less than $1,000. If the person or entity is determined to have committed a subsequent violation of this section within twelve months of the initial violation for which a penalty was assessed, such person or entity shall be subject to a fine, penalty and forfeiture of not less than $2,000. For every violation thereafter, such person or entity shall be subject to a fine, penalty and forfeiture of not less than $5,000 if the person or entity committed the violation within twelve months of the violation for which the second penalty was assessed. This section may be enforced pursuant to sections 3.05, 3.07, or 3.11 of the Health Code and sections 558 and 562 of the Charter.

(2) I hereby suspend: (i) Appendix 7-A of Chapter 7 of Title 24 of the Rules of the City of New York to the extent it would limit a violation of this section to be punished with a standard penalty of $1,000 or a default penalty of $2,000; and (ii) section 7-08 of such Chapter 7 and section 3.11 of the Health Code, to the extent such provisions would limit the default penalty amount that may be imposed for a violation of this section to $2,000.

(3) Notwithstanding the foregoing, this subdivision shall not apply until December 27, 2021 with respect to proof of receipt of a second dose of a two-dose vaccine.

l. Covered entities shall comply with further guidelines issued by DOHMH to further the intent of this section and increase the number of vaccinated individuals in the City.

m. I hereby order that section 20-1271 of the Administrative Code of the City of New York is modified by adding the following provision to the definition of "just cause:" Notwithstanding any provision of this chapter, a fast food employer shall be deemed to

have just cause when a fast food employee has failed to provide proof of vaccination required by an emergency executive order issued in response to the COVID-19 pandemic and shall not be required to follow progressive discipline procedures prior to terminating the employee, provided that the employee shall have 30 days from the date when the employer notified the employee of the requirement to submit such proof and the employee shall be placed on leave following such notification until such proof is provided. This provision shall not excuse the employer from the responsibility to provide a reasonable accommodation where required by law.

§ 3. This Emergency Executive Order shall take effect immediately.

Bill de Blasio,
MAYOR

EXHIBIT 2

Nuremberg Code, August 1947

1. The voluntary consent of the human subject is absolutely essential.

This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment.

The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity.

Source: https://www.ushmm.org/information/exhibitions/online-exhibitions/special-focus/doctors-trial/nuremberg-code

EXHIBIT 3

Scientific Journal VACCINE, volume 40, issue 40, September 22, 2022

Serious Adverse Events of Special Interest Following mRNA Covid-19 Vaccination in Randomized Trials in Adults

See attached.

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Serious adverse events of special interest following mRNA COVID-19 vaccination in randomized trials in adults

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Serious adverse events
Adverse events of special interest
Brighton Collaboration
Coalition for Epidemic Preparedness Innovations
Safety Platform for Emergency vACcines

ABSTRACT

Introduction: In 2020, prior to COVID-19 vaccine rollout, the Brighton Collaboration created a priority list, endorsed by the World Health Organization, of potential adverse events relevant to COVID-19 vaccines. We adapted the Brighton Collaboration list to evaluate serious adverse events of special interest observed in mRNA COVID-19 vaccine trials.

Methods: Secondary analysis of serious adverse events reported in the placebo-controlled, phase III randomized clinical trials of Pfizer and Moderna mRNA COVID-19 vaccines in adults (NCT04368728 and NCT04470427), focusing analysis on Brighton Collaboration adverse events of special interest.

Results: Pfizer and Moderna mRNA COVID-19 vaccines were associated with an excess risk of serious adverse events of special interest of 10.1 and 15.1 per 10,000 vaccinated over placebo baselines of 17.6 and 42.2 (95 % CI −0.4 to 20.6 and −3.6 to 33.8), respectively. Combined, the mRNA vaccines were associated with an excess risk of serious adverse events of special interest of 12.5 per 10,000 vaccinated (95 % CI 2.1 to 22.9); risk ratio 1.43 (95 % CI 1.07 to 1.92). The Pfizer trial exhibited a 36 % higher risk of serious adverse events in the vaccine group; risk difference 18.0 per 10,000 vaccinated (95 % CI 1.2 to 34.9); risk ratio 1.36 (95 % CI 1.02 to 1.83). The Moderna trial exhibited a 6 % higher risk of serious adverse events in the vaccine group: risk difference 7.1 per 10,000 (95 % CI –23.2 to 37.4); risk ratio 1.06 (95 % CI 0.84 to 1.33). Combined, there was a 16 % higher risk of serious adverse events in mRNA vaccine recipients: risk difference 13.2 (95 % CI −3.2 to 29.6); risk ratio 1.16 (95 % CI 0.97 to 1.39).

Discussion: The excess risk of serious adverse events found in our study points to the need for formal harm-benefit analyses, particularly those that are stratified according to risk of serious COVID-19 outcomes. These analyses will require public release of participant level datasets.

1. Introduction

In March 2020, the Brighton Collaboration and the Coalition for Epidemic Preparedness Innovations partnership, Safety Platform for Emergency vACcines (SPEAC), created and subsequently updated a "priority list of potential adverse events of special interest relevant to COVID-19 vaccine trials." [1] The list comprises adverse events of special interest (AESIs) based on the specific vaccine platform, adverse events associated with prior vaccines in general, theoretical associations based on animal models, and COVID-19 specific immunopathogenesis. [1] The Brighton Collaboration is a global authority on the topic of vaccine safety and in May 2020, the World Health Organization's Global Advisory Committee on Vaccine Safety endorsed and recommended the reporting of AESIs based on this priority list. To our knowledge, however, the list has not been applied to serious adverse events in randomized trial data.

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We sought to investigate the association between FDA-authorized mRNA COVID-19 vaccines and serious adverse events identified by the Brighton Collaboration, using data from the phase III randomized, placebo-controlled clinical trials on which authorization was based. We consider these trial data against findings from post-authorization observational safety data. Our study was not designed to evaluate the overall harm-benefit of vaccination programs so far. To put our safety results in context, we conducted a simple comparison of harms with benefits to illustrate the need for formal harm-benefit analyses of the vaccines that are stratified according to risk of serious COVID-19 outcomes. Our analysis is restricted to the randomized trial data, and does not consider data on post-authorization vaccination program impact. It does however show the need for public release of participant level trial datasets.

2. Methods

Pfizer and Moderna each submitted the results of one phase III randomized trial in support of the FDA's emergency use authorization of their vaccines in adults. Two reviewers (PD and RK) searched journal publications and trial data on the FDA's and Health Canada's websites to locate serious adverse event results tables for these trials. The Pfizer and Moderna trials are expected to follow participants for two years. Within weeks of the emergency authorization, however, the sponsors began a process of unblinding all participants who elected to be unblinded. In addition, those who received placebo were offered the vaccine. These self-selection processes may have introduced nonrandom differences between vaccinated and unvaccinated participants, thus rendering the post-authorization data less reliable. Therefore, to preserve randomization, we used the interim datasets that were the basis for emergency authorization in December 2020, approximately 4 months after trials commenced.

The definition of a serious adverse event (SAE) was provided in each trial's study protocol and included in the supplemental material of the trial's publication. [2–4] Pfizer and Moderna used nearly identical definitions, consistent with regulatory expectations. An SAE was defined as an adverse event that results in any of the following conditions: death; life-threatening at the time of the event; inpatient hospitalization or prolongation of existing hospitalization; persistent or significant disability/incapacity; a congenital anomaly/birth defect; medically important event, based on medical judgment.

In addition to journal publications, we searched the websites of the FDA (for advisory committee meeting materials) and Health Canada (for sections of the dossier submitted by sponsors to the regulator). [5] For the FDA website, we considered presentations by both the FDA and the sponsors. [6] Within each of these sources, we searched for SAE results tables that presented information by specific SAE type; we chose the most recent SAE table corresponding to the FDA's requirement for a safety median follow-up time of at least 2 months after dose 2.

For each trial, we prepared blinded SAE tables (containing SAE types without results data). Using these blinded SAE tables, two clinician reviewers (JF and JE) independently judged whether each SAE type was an AESI. SAE types that matched an AESI term verbatim, or were an alternative diagnostic name for an AESI term, were included as an AESI. For all other SAE types, the reviewers independently judged whether that SAE type was likely to have been caused by a vaccine-induced AESI, based on a judgment considering the disease course, causative mechanism, and likelihood of the AESI to cause the SAE type. Disagreements were resolved through consensus; if consensus could not be reached, a third clinician reviewer (PW) was used to create a majority opinion. For each included SAE, we recorded the corresponding Brighton Collaboration AESI category and organ system. When multiple AESIs could potentially cause the same SAE, the reviewers selected the AESI that they judged to be the most likely cause based on classical clinical presentation of the AESI.

We used an AESI list derived from the work of Brighton Collaboration's Safety Platform for Emergency vACcines (SPEAC) Project. This project created an AESI list which categorizes AESIs into three categories: those included because they are seen with COVID-19, those with a proven or theoretical association with vaccines in general, and those with proven or theoretical associations with specific vaccine platforms. The first version was produced in March 2020 based on experience from China. Following the second update (May 2020), the WHO Global Advisory Committee on Vaccine Safety (GACVS) adopted the list, and Brighton commenced a systematic review process "to ensure an ongoing understanding of the full spectrum of COVID-19 disease and modification of the AESI list accordingly." [7] This resulted in three additional AESIs being added to the list in December 2020. The subsequent (and most recent fourth) update did not result in any additional AESIs being added to the list. [1].

We matched SAEs recorded in the trial against an expanded list of AESIs created by combining Brighton's SPEAC COVID-19 AESI list with a list of 29 clinical diagnoses Brighton identified as "known to have been reported but not in sufficient numbers to merit inclusion on the AESI list." [7] Sensitivity analysis was used to determine whether use of the original versus expanded list altered our results.

Risk ratios and risk differences between vaccine and placebo groups were calculated for the incidence of AESIs and SAEs. We excluded SAEs that were known efficacy outcomes (i.e. COVID-19), consistent with the approach Pfizer (but not Moderna) used in recording SAE data. The Pfizer study trial protocol states that COVID-19 illnesses and their sequelae consistent with the clinical endpoint definition were not to be reported as adverse events, "even though the event may meet the definition of an SAE." [8] For unspecified reasons, Moderna included efficacy outcomes in their SAE tables, effectively reporting an all-cause SAE result. Because we did not have access to individual participant data, to account for the occasional multiple SAEs within single participants, we reduced the effective sample size by multiplying standard errors in the combined SAE analyses by the square root of the ratio of the number of SAEs to the number of patients with an SAE. This adjustment increased standard errors by 10 % (Pfizer) and 18 % (Moderna), thus expanding the interval estimates. We estimated combined risk ratios and risk differences for the two mRNA vaccines by averaging over the risks using logistic regression models which included indicators for trial and treatment group.

We used a simple harm-benefit framework to place our results in context, comparing risks of excess serious AESIs against reductions in COVID-19 hospitalization.

3. Results

Serious adverse event tables were located for each of the vaccine trials submitted for EUA in adults (age 16 + for Pfizer, 18 + for Moderna) in the United States: Pfizer-BioNTech COVID-19 vaccine BNT162b2 (NCT04368728) [2,9,10] and Moderna COVID-19 vaccine mRNA-1273 (NCT04470427). [3,11,12] (Table 1).

3.1. Reporting windows and serious adverse events

Moderna reported SAEs from dose 1 whereas Pfizer limited reporting from dose 1 to 1 month after dose 2. Both studies

Table 1
Data sources for phase III trials.

Trial	Data cutoff date	Journal articles	FDA sources	Health Canada sources
Pfizer trial in ages 16 and above (NCT04368728)	14 Nov 2020 (supported Dec 2020 EUA)	Aggregate data only	**Table 23 in sponsor briefing document**	**Table 55 in sponsor document C4591001 Final Analysis Interim Report Body**
Moderna trial in ages 18 and above (NCT04470427)	25 Nov 2020 (supported Dec 2020 EUA)	Table S11 in publication	Table 27 in sponsor briefing document	**Table 14.3.1.13.3 in sponsor document mRNA-1273-P301 Unblinded Safety Tables Batch 1 (DS2)**

Note: bolded font indicates dataset chosen for analysis; EUA = Emergency Use Authorization.

reported all data at the time of data cutoff (14 Nov 2020 for Pfizer, 25 Nov 2020 for Moderna). 17 SAEs that were efficacy endpoints were removed from the Moderna trial (16 "COVID-19" SAEs and 1 "COVID-19 pneumonia" SAE). One such efficacy endpoint meeting the definition of a SAE was removed from the Pfizer trial ("SARS-CoV-2 test positive" SAE).

The Pfizer trial exhibited a 36 % higher risk of serious adverse events in vaccinated participants in comparison to placebo recipients: 67.5 per 10,000 versus 49.5 per 10,000; risk difference 18.0 per 10,000 vaccinated participants (95 % compatibility[1] interval 1.2 to 34.9); risk ratio 1.36 (95 % CI 1.02 to 1.83). The Moderna trial exhibited a 6 % higher risk of SAEs in vaccinated individuals compared to those receiving placebo: 136 per 10,000 versus 129 per 10,000; risk difference 7.1 per 10,000 (95 % CI −23.2 to 37.4); risk ratio 1.06 (95 % CI 0.84 to 1.33). Combined, there was a 16 % higher risk of SAEs in mRNA vaccine recipients than placebo recipients: 98 per 10,000 versus 85 per 10,000; risk difference 13.2 (95 % CI −3.2 to 29.6); risk ratio 1.16 (95 % CI 0.97 to 1.39). **(**Table 2**)**.

3.2. Serious adverse events of special interest

Regarding whether each SAE type was included on the SPEAC derived AESI list, agreement between the two independent clinician reviewers was 86 % (281/325); 40 of the 44 disagreements were resolved through consensus, and only four disagreements necessitated a third clinician reviewer. **Supplemental** Table 1 includes a full list of included and excluded SAEs across both trials.

In the Pfizer trial, 52 serious AESI (27.7 per 10,000) were reported in the vaccine group and 33 (17.6 per 10,000) in the placebo group. This difference corresponds to a 57 % higher risk of serious AESI (RR 1.57 95 % CI 0.98 to 2.54) and a risk difference of 10.1 serious AESI per 10,000 vaccinated participants (95 % CI −0.4 to 20.6). In the Moderna trial, 87 serious AESI (57.3 per 10,000) were reported in the vaccine group and 64 (42.2 per 10,000) in the placebo group. This difference corresponds to a 36 % higher risk of serious AESI (RR 1.36 95 % CI 0.93 to 1.99) and a risk difference of 15.1 serious AESI per 10,000 vaccinated participants (95 % CI −3.6 to 33.8). Combining the trials, there was a 43 % higher risk of serious AESI (RR 1.43; 95 % CI 1.07 to 1.92) and a risk difference of 12.5 serious AESI per 10,000 vaccinated participants (95 % CI 2.1 to 22.9). **(**Table 2**)**.

Of the 236 serious AESIs occurring across the Pfizer and Moderna trials, 97 % (230/236) were adverse event types included as AESIs because they are seen with COVID-19. In both Pfizer and Moderna trials, the largest excess risk occurred amongst the Brighton category of coagulation disorders. Cardiac disorders have been of central concern for mRNA vaccines; in the Pfizer trial more cardiovascular AESIs occurred in the vaccine group than in the placebo group, but in the Moderna trial the groups differed by only 1 case. **(**Tables 3 and 4**)**.

[1] A compatibility interval is identical to a confidence interval, but relabeled to emphasize that it is not a Bayesian posterior interval (as is improperly suggested by the "confidence" label).[13,14].

3.3. Sensitivity analysis

As a sensitivity analysis, we restricted the serious AESI analysis to those AESIs listed in SPEAC's COVID-19 AESI list (i.e. separating out Brighton's list of 29 clinical diagnoses "known to have been reported but not in sufficient numbers to merit inclusion on the AESI list.") This reduced the total number of AESIs across the two trials by 48 (35 vaccine group, 13 placebo group). There was still a higher risk of serious AESI when limited to the SPEAC COVID-19 AESI list, but the magnitude of the excess (in both relative and absolute terms) was smaller than when using the larger AESI list. **(Supplemental** Table 2**)**.

3.4. Harm-benefit considerations

In the Moderna trial, the excess risk of serious AESIs (15.1 per 10,000 participants) was higher than the risk reduction for COVID-19 hospitalization relative to the placebo group (6.4 per 10,000 participants). [3] In the Pfizer trial, the excess risk of serious AESIs (10.1 per 10,000) was higher than the risk reduction for COVID-19 hospitalization relative to the placebo group (2.3 per 10,000 participants).

4. Comparison with FDA reviews

In their review of SAEs supporting the authorization of the Pfizer and Moderna vaccines, the FDA concluded that SAEs were, for Pfizer, "balanced between treatment groups," [15] and for Moderna, were "without meaningful imbalances between study arms." [16] In contrast to the FDA analysis, we found an excess risk of SAEs in the Pfizer trial. Our analysis of Moderna was compatible with FDA's analysis, finding no meaningful SAE imbalance between groups.

The difference in findings for the Pfizer trial, between our SAE analysis and the FDA's, may in part be explained by the fact that the FDA analyzed the total number of participants experiencing any SAE, whereas our analysis was based on the total number of SAE events. Given that approximately twice as many individuals in the vaccine group than in the placebo group experienced multiple SAEs (there were 24 more events than participants in the vaccine group, compared to 13 in the placebo group), FDA's analysis of only the incidence of participants experiencing any SAE would not reflect the observed excess of multiple SAEs in the vaccine group.

A more important factor, however, may be that FDA's review of non-fatal SAEs used a different analysis population with different follow-up windows. The FDA reported 126 of 21,621 (0.6 %) of vaccinated participants experienced at least one SAE at data cutoff compared to 111 of 21,631 (0.5 %) of placebo participants. In contrast, our analysis found 127 SAEs among 18,801 vaccine recipients versus 93 SAEs among 18,785 placebo recipients. [15] While summary results for the population we analyzed was provided in a table, FDA did not report an analysis of them. The substantially larger denominators in FDA's analysis (5,666 more participants) reflect the fact that their analysis included all individuals receiving at least one dose (minus 196 HIV-positive participants), irrespec-

Table 2
Serious adverse events.

Trial	Total events (events per 10,000 participants)[a] Vaccine	Placebo	Risk difference per 10,000 participants (95 % CI)[e]	Risk ratio (95 % CI)[e]
Serious adverse events				
Pfizer[b]	127 (67.5)	93 (49.5)	18.0 (1.2 to 34.9)	1.36 (1.02 to 1.83)
Moderna[c,d]	206 (135.7)	195 (128.6)	7.1 (−23.2 to 37.4)	1.06 (0.84 to 1.33)
Combined[f]	333 (98.0)	288 (84.8)	13.2 (-3.2 to 29.6)	1.16 (0.97 to 1.39)
Serious adverse events of special interest				
Pfizer	52 (27.7)	33 (17.6)	10.1 (-0.4 to 20.6)	1.57 (0.98 to 2.54)
Moderna	87 (57.3)	64 (42.2)	15.1 (-3.6 to 33.8)	1.36 (0.93 to 1.99)
Combined[f]	139 (40.9)	97 (28.6)	12.5 (2.1 to 22.9)	1.43 (1.07 to 1.92)

[a] Denominators for Pfizer were 18,801 in the vaccine group and 18,785 in the placebo group, and for Moderna were 15,185 in the vaccine group and 15,166 in the placebo group.
[b] Pfizer excluded efficacy outcomes from its SAE table (COVID-19 illnesses and their sequelae meeting the definition of an SAE). However, at least one SAE appears to have been inadvertently included, which we removed from our calculations (“SARS-CoV-2 test positive”: 0 vaccine group; 1 placebo group).
[c] Moderna included efficacy outcomes in its SAE table (COVID-19 illnesses and their sequelae meeting the definition of an SAE). We removed efficacy SAEs outcomes that could be identified: “COVID-19” and “COVID-19 pneumonia.” Lacking access to participant level data, SAEs that were sequelae of serious COVID-19 could not be identified and therefore remain included in this analysis.
[d] “All SAEs” for Moderna was calculated using the “Number of serious AEs” row in Moderna’s submission to FDA.[11].
[e] Standard errors used to estimate 95% CIs were inflated by the factor $\sqrt{}$[#SAE]/[#patients with SAE] to account for multiple SAE within patients.
[f] The combined risk differences and risk ratios were computed from the fitted logistic regression models and so may not exactly equal comparisons computed from the first two columns.

Table 3
Serious AESIs, Pfizer trial.

Brighton category	Vaccine	Placebo	Vaccine events per 10,000	Placebo events per 10,000	Difference in events per 10,000	Risk ratio
Association with immunization in general						
Anaphylaxis	1	1	0.5	0.5	0.0	1.00
Association with specific vaccine platform(s)						
Encephalitis/encephalomyelitis	0	2	0.0	1.1	−1.1	0.00
Seen with COVID-19						
Acute kidney injury	2	0	1.1	0.0	1.1	N/A
Acute liver injury	0	1	0.0	0.5	−0.5	0.00
Acute respiratory distress syndrome	2	1	1.1	0.5	0.5	2.00
Coagulation disorder	16	10	8.5	5.3	3.2	1.60
Myocarditis/pericarditis	2	1	1.1	0.5	0.5	2.00
Other forms of acute cardiac injury	16	12	8.5	6.4	2.1	1.33
Subtotal	39	28	20.7	14.9	5.8	1.39
Brighton list of 29 clinical diagnoses seen with COVID-19						
Abscess	4	1	2.1	0.5	1.6	4.00
Cholecystitis	4	2	2.1	1.1	1.1	2.00
Colitis/Enteritis	1	1	0.5	0.5	0.0	1.00
Diarrhea	1	0	0.5	0.0	0.5	N/A
Hyperglycemia	1	1	0.5	0.5	0.0	1.00
Pancreatitis	1	0	0.5	0.0	0.5	N/A
Psychosis	1	0	0.5	0.0	0.5	N/A
Subtotal	13	5	6.9	2.7	4.3	2.60
Total	**52**	**33**	**27.7**	**17.6**	**10.1**	**1.57**

tive of the duration of post-injection follow-up time. In contrast, our analysis was based on the study population with median follow-up $\geq$ 2 months after dose 2 (minus 120 HIV-positive participants), of which 98.1 % had received both doses. [2,17] The FDA’s analysis of SAEs thus included thousands of additional participants with very little follow-up, of which the large majority had only received 1 dose.

4.1. Comparison with post-authorization studies

Although the randomized trials offer high level evidence for evaluating causal effects, the sparsity of their data necessitates that harm-benefit analyses also consider observational studies. Since their emergency authorization in December 2020, hundreds of millions of doses of Pfizer and Moderna COVID-19 vaccines have been administered and post-authorization observational data offer a complementary opportunity to study AESIs. Post-authorization observational safety studies include cohort studies (which make use of medical claims or electronic health records) and disproportionality analyses (which use spontaneous adverse event reporting systems). In July 2021, the FDA reported detecting four potential adverse events of interest: pulmonary embolism, acute myocardial infarction, immune thrombocytopenia, and disseminated intravascular coagulation following Pfizer’s vaccine based on medical claims data in older Americans. [18] Three of these four serious adverse event types would be categorized as coagulation disorders, which is the Brighton AESI category that exhibited the largest excess risk in the vaccine group in both the Pfizer and Moderna trials. FDA stated it would further investigate the findings but at the time of our writing has not issued an update. Similarly, spontaneous-reporting systems have registered serious adverse reactions including anaphylaxis (all COVID-19 vaccines), thrombocytopenia syndrome among premenopausal females (Janssen vaccine), and myocarditis and pericarditis among younger males (Pfizer and Moderna vaccines). [19,20].

Using data from three postmarketing safety databases for vaccines (VAERS, EudraVigilance, and VigiBase), disproportionality studies have reported excess risks for many of the same SAE types as in

Table 4
Serious AESIs, Moderna trial.

Brighton category	Vaccine	Placebo	Vaccine events per 10,000	Placebo events per 10,000	Difference in events per 10,000	Risk ratio
Association with specific vaccine platform(s)						
Bell's Palsy	1	0	0.7	0.0	0.7	N/A
Encephalitis/encephalomyelitis	1	0	0.7	0.0	0.7	N/A
Seen with COVID-19						
Acute kidney injury	1	3	0.7	2.0	−1.3	0.33
Acute liver injury	1	0	0.7	0.0	0.7	N/A
Acute respiratory distress syndrome	7	4	4.6	2.6	2.0	1.75
Angioedema	0	2	0.0	1.3	−1.3	0.00
Coagulation disorder	20	13	13.2	8.6	4.6	1.54
Generalized Convulsions	2	0	1.3	0.0	1.3	N/A
Myelitis	0	1	0.0	0.7	−0.7	0.00
Myocarditis/pericarditis	4	5	2.6	3.3	−0.7	0.80
Other forms of acute cardiac injury	26	26	17.1	17.1	0.0	1.00
Other rash	1	1	0.7	0.7	0.0	1.00
Rhabdomyolysis	0	1	0.0	0.7	−0.7	0.00
Single Organ Cutaneous Vasculitis	1	0	0.7	0.0	0.7	N/A
Subtotal	65	56	42.8	36.9	5.9	1.16
Brighton list of 29 clinical diagnoses seen with COVID-19						
Abscess	1	0	0.7	0.0	0.7	N/A
Arthritis	3	1	2.0	0.7	1.3	3.00
Cholecystitis	4	0	2.6	0.0	2.6	N/A
Colitis/Enteritis	6	3	4.0	2.0	2.0	2.00
Diarrhea	2	1	1.3	0.7	0.7	2.00
Hyperglycemia	1	0	0.7	0.0	0.7	N/A
Hyponatremia	1	1	0.7	0.7	0.0	1.00
Pancreatitis	2	0	1.3	0.0	1.3	N/A
Pneumothorax	0	1	0.0	0.7	−0.7	0.00
Psychosis	1	1	0.7	0.7	0.0	1.00
Thyroiditis	1	0	0.7	0.0	0.7	N/A
Subtotal	22	8	14.5	5.3	9.2	2.75
Total	**87**	**64**	**57.3**	**42.2**	**15.1**	**1.36**

the present study. [21–23] For example, a study using VAERS and EudraVigilance comparing the disproportionality of adverse event reports between the influenza vaccine versus the mRNA COVID-19 vaccines reported excess risks for the following Brighton AESIs: cardiovascular events, coagulation events, hemorrhages, gastrointestinal events, and thromboses. [22] While CDC published a protocol[24] in early 2021 for using proportional reporting ratios for signal detection in the VAERS database, results from the study have not yet been reported. [25] Among self-controlled case series, one reported a rate ratio of 1.38 (95 % CI 1.12–1.71) for hemorrhagic stroke following Pfizer vaccine, [26] another reported 0.97 (95 % CI 0.81–1.15), [27] while a cohort study[28] reported 0.84 (95 % CI 0.54–1.27).

5. Discussion

Using a prespecified list of AESI identified by the Brighton Collaboration, higher risk of serious AESI was observed in the mRNA COVID-19 vaccine group relative to placebo in both the Pfizer and Moderna adult phase III trials, with 10.1 (Pfizer) and 15.1 (Moderna) additional events for every 10,000 individuals vaccinated. Combined, there was a risk difference of 12.5 serious AESIs per 10,000 individuals vaccinated (95 % CI 2.1 to 22.9). These results raise concerns that mRNA vaccines are associated with more harm than initially estimated at the time of emergency authorization. In addition, our analysis identified a 36 % higher risk of serious adverse events in vaccinated participants in the Pfizer trial: 18.0 additional SAEs per 10,000 vaccinated (95 % CI 1.2 to 34.9). Consistent with the FDA evaluation, our analysis found no clear difference in SAEs between groups in the Moderna trial.

Results between the Pfizer and Moderna trials were similar for the AESI analysis but exhibited substantial variation in the SAE analysis. Caution is needed in interpreting this variation as it may be substantially explained by differences in SAE recording practices in the trials rather than differences in actual vaccine harm profiles. For reasons that are not documented in the trial protocol, Moderna included efficacy outcomes in its SAE tabulations, while Pfizer excluded them. As a result, Moderna's SAE table did not present a traditional SAE analysis but rather an all-cause SAE analysis. The FDA analysis of the Moderna trial presented an all-cause SAE analysis, which estimates total vaccine effects on SAEs, including effects transmitted via effects on COVID-19. It did not however present a traditional SAE analysis with efficacy endpoints removed, which attempts to estimate only the direct effects on SAEs. While our analysis attempted to perform a traditional SAE analysis by excluding efficacy SAEs (serious COVID-19 and its sequelae), our effort was hindered because we did not have access to patient level data. Easily recognizable efficacy SAEs ("COVID-19", "COVID-19 pneumonia," and "SARS-CoV-2 test positive") could be removed, but many participants who experienced a COVID-19 SAE likely experienced multiple other SAEs (e.g. pneumonia, hypoxia, and thrombotic events) which could not be identified and therefore remain included in our analysis. Of 17 total efficacy SAEs (16 "COVID-19" and 1 "COVID-19 pneumonia") removed from our analysis of the Moderna trial, 16 were in the placebo arm. As a consequence, the background SAE risk (risk in absence of COVID-19) would be overestimated by the Moderna placebo group, resulting in underestimation of the actual risk of SAEs and AESIs attributable to the vaccine in the Moderna comparisons as well as in the combined analysis. Access to patient-level data would allow adjustments for this problem.

Rational policy formation should consider potential harms alongside potential benefits. [29] To illustrate this need in the present context, we conducted a simple harm-benefit comparison using the trial data comparing excess risk of serious AESI against reductions in COVID-19 hospitalization. We found excess risk of serious AESIs to exceed the reduction in COVID-19 hospitalizations in both Pfizer and Moderna trials.

This analysis has the limitations inherent in most harm-benefit comparisons. First, benefits and harms are rarely exact equivalents, and there can be great variability in the degree of severity within both benefit and harm endpoints. For example, intubation and short hospital stay are not equivalent but both are counted in "hospitalization"; similarly, serious diarrhea and serious stroke are not equivalent but both are counted in "SAE." Second, individuals value different endpoints differently. Third, without individual participant data, we could only compare the number of individuals hospitalized for COVID-19 against the number of serious AESI events, not the number of participants experiencing any serious AESI. Some individuals experienced multiple SAEs whereas hospitalized COVID-19 participants were likely only hospitalized once, biasing the analysis towards exhibiting net harm. To gauge the extent of this bias, we considered that there were 20 % (Pfizer) and 34 % (Moderna) more SAEs than participants experiencing any SAE. As a rough sensitivity calculation, if we divide the Pfizer excess serious AESI risk of 10.1 by 1.20 it becomes 8.4 compared to a COVID-19 hospitalization risk reduction of 2.3; if we divide the Moderna excess serious AESI risk of 15.1 by 1.34 it becomes 11.3 compared to a COVID-19 hospitalization risk reduction of 6.4.

Harm-benefit ratios will be different for populations at different risk for serious COVID-19 and observation periods that differ from those studied in the trials. Presumably, larger reductions in COVID-19 hospitalizations would have been recorded if trial follow-up were longer, more SARS-CoV-2 was circulating, or if participants had been at higher risk of serious COVID-19 outcomes, shifting harm-benefit ratios toward benefit. Conversely, harm-benefit ratios would presumably shift towards harm for those with lower risk of serious COVID-19 outcomes--such as those with natural immunity, younger age or no comorbidities. Similarly, waning vaccine effectiveness, decreased viral virulence, and increasing degree of immune escape from vaccines might further shift the harm-benefit ratio toward harm. Large, randomized trials in contemporary populations could robustly answer these questions. Absent definitive trials, however, synthesis of multiple lines of evidence will be essential. [30,48,49].

Adverse events detected in the post-marketing period have led to the withdrawal of several vaccines. An example is intussusception following one brand of rotavirus vaccine: around 1 million children were vaccinated before identification of intussusception, which occurred in around 1 per 10,000 vaccinees. [31] Despite the unprecedented scale of COVID-19 vaccine administration, the AESI types identified in our study may still be challenging to detect with observational methods. Most observational analyses are based on comparing the risks of adverse events "observed" against a background (or "expected") risk, which inevitably display great variation, by database, age group, and sex. [32] If the actual risk ratio for the effect was 1.4 (the risk ratio of the combined AESI analysis), it could be quite difficult to unambiguously replicate it with observational data given concerns about systematic as well as random errors. [33–35].

In addition, disproportionality analyses following COVID-19 vaccination also have limitations, particularly with respect to the type of adverse events seen in our study. The majority of SAEs that contributed to our results are relatively common events, such as ischemic stroke, acute coronary syndrome, and brain hemorrhage. This complicates signal detection because clinical suspicion of an adverse vaccine reaction following an event commonly seen in clinical practice will be lower than for SAEs like myocarditis.[50] For this reason, clinical suspicion leading to the filing of an individual case safety report--may be far less common in the post-authorization setting than in the trials. At the same time, heightened awareness about COVID-19 vaccine SAEs can result in under and overreporting. Public health messages assuring vaccine safety may lower clinical suspicion of potential causal relationships, whereas messages about potential harms can conversely stimulate reports that otherwise may not have been made. These factors can lead to bias both directions, further complicating interpretation. In contrast to these problems, in the randomized trials used in this analysis, all SAEs were to be recorded, irrespective of clinical judgment regarding potential causality.

Although our analysis is secondary, reanalyses of clinical trial data have led to the detection of adverse events well after the market entry of major drugs such as rofecoxib and rosiglitazone. [36,37] Our analysis has an advantage over postmarketing observational studies in that the data are from blinded, placebo-controlled randomized trials vetted by the FDA, which were matched against a list of adverse events created before the availability of the clinical-trial results and designed for use in COVID-19 vaccine trials.

Our study has several important limitations. First, Pfizer's trial did not report SAEs occurring past 1 month after dose 2. This reporting threshold may have led to an undercounting of serious AESIs in the Pfizer trial. Second, for both studies, the limited follow up time prevented an analysis of harm-benefit over a longer period. Third, all SAEs in our analysis met the regulatory definition of a serious adverse event, but many adverse event types which a patient may themselves judge as serious may not meet this regulatory threshold. Fourth, decisions about which SAEs to include or exclude as AESIs requires subjective, clinical judgements in the absence of detailed clinical information about the actual SAEs. We encourage third party replication of our study, with access to complete SAE case narratives, to determine the degree to which these decisions affected our findings. For additional sensitivity analyses, such replication studies could also make use of other AESI lists, such as those prepared by FDA, [38–41] CDC, [24], Pfizer, [42], or a *de novo* AESI list derived from a list of COVID-19 complications understood to be induced via SARS-CoV-2's spike protein. [43,44].

A fifth important limitation is our lack of access to individual participant data, which forced us to use a conservative adjustment to the standard errors. The 95 % CIs[13,14] calculated are therefore only approximate because we do not know which patients had multiple events. Finally, as described above, in the Moderna analysis, the SAEs that were sequelae of serious COVID-19 could not be identified and therefore remain included in our calculations. Because the vaccines prevent SAEs from COVID-19 while adding SAE risks of their own, this inclusion makes it impossible to separately estimate SAEs due to the vaccine from SAEs due to COVID-19 in the available Moderna data, as must be done to extrapolate harm-benefit to other populations. These study limitations all stem from the fact that the raw data from COVID-19 vaccine clinical trials are not publicly available. [45,46].

We emphasize that our investigation is preliminary, to point to the need for more involved analysis. The risks of serious AESIs in the trials represent only group averages. SAEs are unlikely to be distributed equally across the demographic subgroups enrolled in the trial, and the risks may be substantially less in some groups compared to others. Thus, knowing the actual demographics of those who experienced an increase in serious AESI in the vaccine group is necessary for a proper harm-benefit analysis. In addition, clinical studies are needed to see if particular SAEs can be linked to particular vaccine ingredients as opposed to unavoidable consequences of exposure to spike protein, as future vaccines could then be modified accordingly or sensitivities can be tested for in advance. In parallel, a systematic review and meta-analysis using individual participant data should be undertaken to address questions of harm-benefit in various demographic subgroups, particularly in those at low risk of serious complications from COVID-19. Finally, there is a pressing need for comparison of SAEs and harm-benefit for different vaccine types; some initial work has already begun in this direction. [47].

Full transparency of the COVID-19 vaccine clinical trial data is needed to properly evaluate these questions. Unfortunately, as we approach 2 years after release of COVID-19 vaccines, participant level data remain inaccessible. [45,46].

Author contributions

All authors had full access to all of the data in the study (available at https://doi.org/10.5281/zenodo.6564402), and take responsibility for the integrity of the data and the accuracy of the data analysis.

Study concept and design: All authors.
Acquisition of data: Doshi.
Analysis and interpretation: All authors.
Statistical analysis: Jones, Greenland.
Drafting of the manuscript: Fraiman, Doshi.
Critical revision of the manuscript for important intellectual content: All authors.

Data availability

All of the data in the study is available at https://doi.org/10.5281/zenodo.6564402

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Ethical review statement

This research was confirmed to be Not Human Subjects Research (NHSR) by University of Maryland, Baltimore (HP-00102561).

Conflicts of interest

JF, JE, MJ, SG, PW, RK: none to declare. PD has received travel funds from the European Respiratory Society (2012) and Uppsala Monitoring Center (2018); grants from the FDA (through University of Maryland M-CERSI; 2020), Laura and John Arnold Foundation (2017-22), American Association of Colleges of Pharmacy (2015), Patient-Centered Outcomes Research Institute (2014-16), Cochrane Methods Innovations Fund (2016-18), and UK National Institute for Health Research (2011-14); was an unpaid IMEDS steering committee member at the Reagan-Udall Foundation for the FDA (2016-2020) and is an editor at The BMJ. The views expressed here are those of the authors and do not necessarily reflect those of their employers.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.vaccine.2022.08.036.

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EXHIBIT 4

Danish Health Authority, *Vaccination against covid-19*

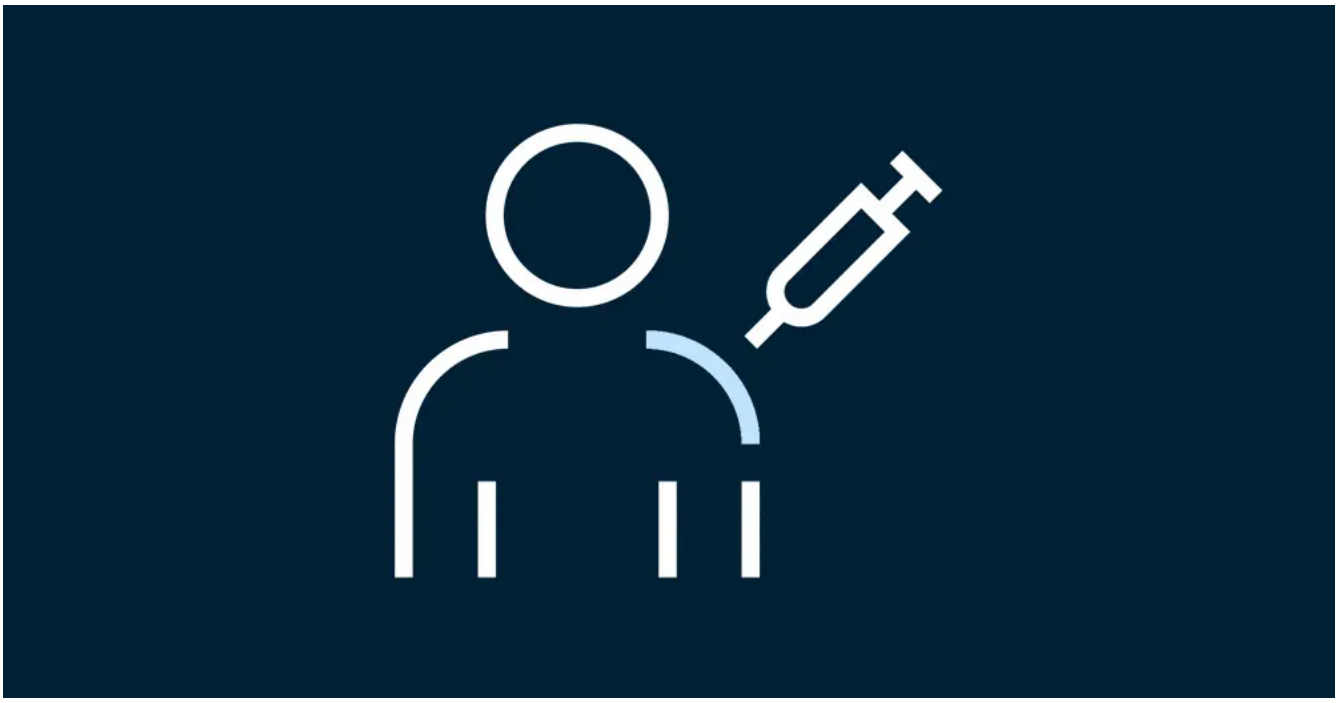
See attached.

DANISH HEALTH AUTHORITY

COVID-19

Vaccination against covid-19

The Danish Health Authority expects that the number of covid-19 infections will increase during autumn and winter. Therefore, we recommend vaccination of people aged 50 years and over as well as selected risk groups. Read more about the autumn vaccination programme here.



With the autumn vaccination programme, we aim to prevent serious illness, hospitalisation and death. The risk of becoming severely ill from covid-19 increases with age. Therefore, people who have reached the age of 50 and particularly vulnerable people will be offered vaccination. We expect that many people will be infected with covid-19 during autumn and winter. It is therefore important that the population remembers the guidance on how to prevent infection, which also applies to a number of other infectious diseases.

> See the guidance here: Prevent being infected with covid-19

On this page, you can read who will be offered vaccination, which vaccines we plan to use and when the programme will begin.

Q&A about vaccination

Who will be offered vaccination against covid-19?

People aged 50 years and over will be offered vaccination.

People aged under 50 who are at a higher risk of becoming severely ill from covid-19 will also be offered vaccination against covid-19.

Staff in the healthcare and elderly care sector as well as in selected parts of the social services sector who have close contact with patients or citizens who are at higher risk of becoming severely ill from covid-19 will also be offered booster vaccination against covid-19.

In addition, we recommend that relatives of persons at particularly higher risk accept the offer of vaccination to protect their relatives who are at particularly higher risk.

Why do we need to re-vaccinate?

We have achieved very high population immunity in Denmark. This is due both to the high adherence to the vaccination programme and to many people previously having been infected with covid-19. However, we expect that this immunity will gradually decrease over time. In addition, we know that covid-19 is a seasonal disease and that the number of infections are expected to increase during autumn and winter. We expect that a large part of the population will become infected with covid-19 during the autumn, and we therefore want to vaccinate those having the highest risk so that they are protected from severe illness if they become infected.

When will I be offered vaccination?

Nursing home residents and people aged 85 and over will be offered vaccination from mid-September. For others, the vaccination programme against covid-19 will begin on 1 October 2022.

I have a specific disease or condition – will I be offered vaccination?

People aged under 50 who are at higher risk of becoming severely ill are recommended vaccination against covid-19. This may, for example, be people who have a severely impaired immune system.

> Read more here

Will i get an invitation for vaccination?

If you are offered vaccination based on your age, you will receive an invitation in e-Boks/mit.dk. You will be offered vaccination against covid-19, influenza and pneumococci. For nursing home residents, there will be a special offer of local vaccination without appointment.

If you are in the target group for vaccination based on your illness/condition or your work, you will not receive an invitation. When the programme starts on 1 October, you can instead either:

- Fill in a solemn declaration and booking an appointment for vaccination on www.vacciner.dk. If you are in doubt about whether you are in the target group for vaccination, you can fill in a guiding questionnaire, which is also available on www.vacciner.dk, and then book an appointment if you are in the target group.
- Talk to your doctor, who can set up a vaccination process at www.vacciner.dk for you with the vaccines you are offered. You can then book an appointment yourself. In some cases, your doctor will be able to vaccinate you immediately.

If you are a healthcare professional or elderly care worker or employed in selected parts of the social services sector, your workplace can inform you about whether they offer vaccination of their staff.

Why are people aged under 50 not to be re-vaccinated? +

The purpose of the vaccination programme is to prevent severe illness, hospitalisation and death. Therefore, people at the highest risk of becoming severely ill will be offered booster vaccination. The purpose of vaccination is not to prevent infection with covid-19, and people aged under 50 are therefore currently not being offered booster vaccination.

People aged under 50 are generally not at particularly higher risk of becoming severely ill from covid-19. In addition, younger people aged under 50 are well protected against becoming severely ill from covid-19, as a very large number of them have already been vaccinated and have previously been infected with covid-19, and there is consequently good immunity among this part of the population.

It is important that the population also remembers the guidance on how to prevent the spread of infection, including staying at home in case of illness, frequent aeration or ventilation, social distancing, good coughing etiquette, hand hygiene and cleaning.

Variant-updated vaccines

What does it mean that a vaccine is variant updated? +

The Danish Health Authority will offer variant-updated mRNA vaccines in the autumn vaccination programme. These vaccines have been approved by the European Medicines Agency.

The vaccination, which will be offered during autumn/winter 2022-2023, consists of a variant-updated vaccine. The influenza vaccines are updated every year, and the covid-19 vaccines have likewise also been updated to target the Omicron variant more effectively.

The variant-updated vaccines have been adapted to the variant that is dominant in society.

What side effects do the vaccines have?

All vaccines cause side effects, including the covid-19 vaccines. In general, the side effects are mild and transient, and we consider the vaccines to be very safe and highly documented.

Studies of the variant-updated vaccines have shown that the side effects do not differ from those seen in connection with the vaccines we have previously used in Denmark.

Mild side effects

Most people will experience pain at the injection site. Other common side effects include fatigue, headache, pain in muscles and joints, chills, a slight fever as well as redness and swelling at the injection site. These are generally signs that your body's immune system is reacting as it should to the vaccine. You do not need to call your doctor if you experience these known and transient side effects. If you are among those who do not experience side effects, you should not worry that the vaccine is not working, because it will regardless of whether you experience side effects.

We know from other vaccines that almost all side effects occur within the first six weeks of vaccination. It is very rare for them to occur later than this. Both Danish and European medicines agencies monitor the vaccines closely after they have been approved both in relation to how well they work and how many side effects they cause.

However, there is a difference in how well the immune system of older and younger people responds to vaccines. Elderly people will typically have poorer-responding immune systems, and they will therefore typically experience fewer side effects.

Rare side effects

In rare cases, severe immediate allergic reactions (anaphylaxis) may occur, which may be caused by, for example, allergy to the additives in the vaccine. If you have previously had a severe allergic reaction immediately after being vaccinated or after being injected with a medicinal product, you should contact your doctor before being vaccinated against covid-19. If you have a known allergy to macrogols/PEG/polyethylene glycol, you should not be vaccinated with the mRNA vaccines.

Vaccination of children against covid-19

Children and adolescents rarely become severely ill from the Omicron variant of covid-19.

From 1 July 2022, it was no longer possible for children and adolescents aged under 18 to get the first injection and, from 1 September 2022, it was no longer possible for them to get the second injection.

A very limited number of children at particularly higher risk of becoming severely ill will still be offered vaccination based on an individual assessment by a doctor.

Should I be vaccinated?

Can I tolerate being vaccinated?

Can I tolerate being vaccinated?

Situations in which you should not be vaccinated

You should not be vaccinated against covid-19 if you have:

- A known, ascertained allergy to the vaccine (for example an immediate allergic reaction (anaphylaxis) in connection with the first injection)
- A known allergy to one of the excipients in the vaccine

Situations in which you should postpone vaccination

- You are acutely ill with a fever above 38°. You can be vaccinated if you only have a slight fever or light infections such as a common cold. However, you should always consider whether you might have covid-19 in this connection.
- You have covid-19 or suspect that you have covid-19.
- You have had covid-19 within one month before vaccination.
- You have been tested due to suspicion of covid-19 or because you are a close contact of an infected person.
- You are to undergo surgery within one week before or after vaccination.

Situations in which you should consult a doctor before being vaccinated

- You have been informed that there is a suspicion of allergy to macrogol/PEG/polyethylene glycol.
- You have previously had an immediate allergic reaction (anaphylaxis) after vaccination or after injection of another medicinal product.
- You have previously repeatedly had an immediate allergic reaction (anaphylaxis) after ingestion of other medicinal products (for example laxatives, stomach acid drugs).
- You have mastocytosis (a rare disease of the body's mast cells).

Situations in which you can be vaccinated

Most people tolerate the vaccine well. You can be vaccinated even if:

- You are waiting for the result of a covid-19 test
- You have developed a skin rash after taking other medicinal products (for example penicillin, ibuprofen).
- You cannot tolerate or experience discomfort from strong pills (for example painkillers).
- You have experienced common, known side effects after the first injection of the vaccine.
- You are allergic to foods (for example eggs, shellfish, nuts).
- You are allergic to insecticides, latex or the like.

- You have pollen allergy/hay fever, allergy to animals or asthma eczema.
- You are undergoing fertility treatment.
- You have received another vaccine (for example against influenza or pneumococci) on the same day/recently.
- You are a cancer patient and are undergoing treatment
- You have an impaired/weakened immune system1
- A family member has had an allergic reaction after vaccination.
- You do not want to consume products made from pigs.
- You have previously had treatment with botox.
- You are on ordinary blood-thinning medication.
- You have previously had a blood clot or there is a tendency to blood clots in your family.

[1]People with impaired/weakened immune system may have a poorer effect of the vaccine and should pay special attention to following

> The Danish Health Authority's guidance on how to prevent infection

Need further advice?

Healthcare professionals can contact Statens Serum Institut or the regional pharmacovigilance units/side effect managers.

CanI be vaccinated if I am ill?

If you have a fever of 38 degrees or more or have an acute severe infection such as pneumonia, your vaccination must be postponed.

You can be vaccinated if, for example, you only have a slight fever or a light infection such as a common cold, but you must always consider whether you may have covid-19.

Publications, etc.

Please click on the arrow to view our current publications, etc. on COVID-19 vaccination.

vaccination COVID-19

EXHIBIT 5

Emergency Executive Order 62, March 4, 2022

See attached.

THE CITY OF NEW YORK
OFFICE OF THE MAYOR
NEW YORK, N.Y. 10007

EMERGENCY EXECUTIVE ORDER NO. 62
March 24, 2022

WHEREAS, the COVID-19 pandemic has severely impacted New York City and its economy, and is addressed effectively only by joint action of the City, State, and Federal governments; and

WHEREAS, the state of emergency to address the threat and impacts of COVID-19 in the City of New York first declared in Emergency Executive Order No. 98, issued on March 12, 2020, and extended most recently by Emergency Executive Order No. 46, issued on February 28, 2022, remains in effect; and

WHEREAS, this Order is given because of the propensity of the virus to spread person-to-person, and also because the actions taken to prevent such spread have led to property loss and damage; and

WHEREAS, athletes and performing artists frequently conduct their work at venues both inside and outside of the City, without regard to their residence in the City, and their work benefits the City's economic recovery from the pandemic, often attracting large numbers of visitors to the City; and

WHEREAS, New York City athletic teams have been, and continue to be, at a competitive disadvantage because visiting teams can field unvaccinated players, and this competitive disadvantage has negatively impacted, and continues to negatively impact, New York City teams' success, which is important to the City's economic recovery and the morale of City residents and visitors; and

WHEREAS, additional reasons for requiring the measures continued in this Order are set forth in my prior Emergency Executive Order No. 50, issued on March 4, 2022;

NOW, THEREFORE, pursuant to the powers vested in me by the laws of the State of New York and the City of New York, including but not limited to the New York Executive Law, the New York City Charter and the Administrative Code of the City of New York, and the common law authority to protect the public in the event of an emergency:

Section 1. I hereby direct that section 1 of Emergency Executive Order No. 59, dated March 19, 2022, is extended for five (5) days.

§ 2. I hereby order that section 3 of Emergency Executive Order No. 50, dated March 4, 2022, is amended to read as follows.

§ 3. I hereby direct that:

a. Covered entities that had been covered by the Key to NYC program shall continue to require that a covered worker provide proof of vaccination, unless such worker has received a reasonable accommodation. Covered entities shall continue to keep a written record of their protocol for checking covered workers' proof of vaccination and to maintain records of such workers' proof of vaccination, as described in subdivisions d and e of section 2 of Emergency Executive Order No. 317, dated December 15, 2021.

b. Records created or maintained pursuant to subdivision a of this section shall be treated as confidential.

c. A covered entity shall, upon request by a City agency, make available for inspection the records required to be maintained by this section, consistent with applicable law.

d. For the purposes of this Section:

(1) "Covered entity" means any entity that operates one or more "covered premises," except that "covered entity" does not include pre-kindergarten through grade twelve (12) public and non-public schools and programs, houses of worship, childcare programs, senior centers, community centers.

(2) "Covered premises" means any of the following locations, except as provided in subparagraph (iv) of this paragraph:

> **(i) Indoor Entertainment and Recreational Settings, and Certain Event and Meeting Spaces**, including indoor portions of the following locations, regardless of the activity at such locations: movie theaters, music or concert venues, adult entertainment, casinos, botanical gardens, commercial event and party venues, museums, aquariums, zoos, professional sports arenas and indoor stadiums, convention centers and exhibition halls, hotel meeting and event spaces, performing arts theaters, bowling alleys, arcades, indoor play areas, pool and billiard halls, and other recreational game centers;
>
> **(ii) Indoor Food Services**, including indoor portions of food service establishments offering food and drink, including all indoor dining areas of food service establishments that receive letter grades as described in section 81.51 of the Health Code; businesses operating indoor seating areas of food courts; catering food service establishments that provide food indoors on its premises; and any indoor portions of an establishment that is regulated by the New York State Department of Agriculture and Markets offering food for on-premises indoor consumption; and

(iii) Indoor Gyms and Fitness Settings, including indoor portions of standalone and hotel gyms and fitness centers, gyms and fitness centers in higher education institutions, yoga/Pilates/barre/dance studios, boxing/kickboxing gyms, fitness boot camps, indoor pools, CrossFit or other plyometric boxes, and other facilities used for conducting group fitness classes.

(iv) "Covered premises" does not include houses of worship or locations in a residential or office building the use of which is limited to residents, owners, or tenants of that building.

(3) "Covered worker" means an individual who works in-person in the presence of another worker or a member of the public at a workplace in New York City. "Covered worker" includes a full- or part-time staff member, employer, employee, intern, volunteer, or contractor of a covered entity, as well as a self-employed individual or a sole practitioner.

"Covered worker" does not include:

(i) an individual who works from their own home and whose employment does not involve interacting in-person with co-workers or members of the public;

(ii) an individual who enters the workplace for a quick and limited purpose;

(iii) a performing artist, or an individual accompanying such performing artist, while the performing artist is in a covered premises for the purpose of such artist's performance; or

(iv) a professional athlete, or an individual accompanying such professional athlete or such athlete's sports team, who enters a covered premises as part of their regular employment.

(4) "Proof of vaccination" means proof of receipt of a full regimen of a COVID-19 vaccine authorized for emergency use or licensed for use by the U.S. Food and Drug Administration or authorized for emergency use by the World Health Organization, not including any additional recommended booster doses. Such proof may be established by:

(i) A CDC COVID-19 Vaccination Record Card or an official immunization record from the jurisdiction, state, or country where the vaccine was administered, or a digital or physical photo of such a card or record, reflecting the person's name, vaccine brand, and date administered; or

(ii) A New York City COVID Safe App (available to download on Apple and Android smartphone devices); or

(iii) A New York State Excelsior Pass; or

(iv) CLEAR's digital vaccine card; or

(v) Any other method specified by the Commissioner of Health and Mental Hygiene as sufficient to demonstrate proof of vaccination.

(5) I hereby order that section 20-1271 of the Administrative Code of the City of New York is modified by adding the following provision to the definition of "just cause:" Notwithstanding any provision of this chapter, a fast food employer shall be deemed to have just cause when a fast food employee has failed to provide proof of vaccination required by an emergency executive order issued in response to the COVID-19 pandemic and shall not be required to follow progressive discipline procedures prior to terminating the employee, provided that the employee shall have 30 days from the date when the employer notified the employee of the requirement to submit such proof and the employee shall be placed on leave following such notification until such proof is provided. This provision shall not excuse the employer from the responsibility to provide a reasonable accommodation where required by law.

e. An individual who meets the requirements of subparagraph (iii) or (iv) of section 3(d)(3) of this Order shall be exempt from the Order of the Commissioner of Health dated December 13, 2021, relating to requiring COVID-19 vaccination in the workplace.

§ 3. I hereby direct the Fire and Police Departments, the Department of Buildings, the Sheriff, and other agencies as needed, to enforce the directives set forth in this Order in accordance with their lawful authorities, including Administrative Code sections 15-227(a), 28-105.10.1, and 28-201.1, and section 107.6 of the Fire Code. Violations of the directives set forth in this Order may be issued as if they were violations under Health Code sections 3.07 and 3.11, and enforced by the Department of Health and Mental Hygiene or any other agency.

§ 4. This Emergency Executive Order shall take effect immediately and shall remain in effect for five (5) days unless it is terminated or modified at an earlier date.

Eric Adams
Mayor

THE COUNCIL
THE CITY OF NEW YORK

Appearance Card

I intend to appear and speak on Int. No. _____ Res. No. _____

☐ in favor ☐ in opposition

Date: _____

(PLEASE PRINT)

Name: BUDGET JUSTICE

Address: FY DRIVE

I represent: JUST A FEW

Address: QUESTIONS

THE COUNCIL
THE CITY OF NEW YORK

Appearance Card

I intend to appear and speak on Int. No. _____ Res. No. _____

☐ in favor ☐ in opposition

Date: _____

(PLEASE PRINT)

Name: Laura Lugo

Address: _____

I represent: _____

Address: _____

THE COUNCIL
THE CITY OF NEW YORK

Appearance Card

I intend to appear and speak on Int. No. _____ Res. No. _____

☐ in favor ☐ in opposition

Date: _____

(PLEASE PRINT)

Name: GOLD, MARIBEL

Address: FOR DRIVE

I represent: MyPSE

Address: _____

Please complete this card and return to the Sergeant-at-Arms

THE COUNCIL
THE CITY OF NEW YORK

Appearance Card

I intend to appear and speak on Int. No. _____ Res. No. _____

☐ in favor ☐ in opposition

Date: _____

(PLEASE PRINT)

Name: JANAY SPENCER

Address: [redacted] East 6th St. [redacted] NY NY 10009

I represent: _____

Address: _____

THE COUNCIL
THE CITY OF NEW YORK

Appearance Card

I intend to appear and speak on Int. No. _____ Res. No. _____

☐ in favor ☐ in opposition

Date: _____

(PLEASE PRINT)

Name: ROSEMARIE VARGAS

Address: [redacted] East 6th St. [redacted] NY NY 10009

I represent: _____

Address: _____

THE COUNCIL
THE CITY OF NEW YORK

Appearance Card

I intend to appear and speak on Int. No. _____ Res. No. _____

☐ in favor ☐ in opposition

Date: _____

(PLEASE PRINT)

Name: Javita Santiago

Address: [redacted] F.D.R. Drive

I represent: Jacob Riis Housing

Address: _____

Please complete this card and return to the Sergeant-at-Arms

THE COUNCIL
THE CITY OF NEW YORK

Appearance Card

I intend to appear and speak on Int. No. _____ Res. No. _____

☐ in favor ☐ in opposition

Date: _____

(PLEASE PRINT)

Name: Debra Medina

Address: [redacted] Ave B

I represent: GOLES

Address: _____

THE COUNCIL
THE CITY OF NEW YORK

Appearance Card

I intend to appear and speak on Int. No. _____ Res. No. _____

☐ in favor ☐ in opposition

Date: _____

(PLEASE PRINT)

Name: ALBERTO MERCADO

Address: [redacted] Columbia St ; [redacted] NY 10002

I represent: GOLES & SELF - Baruch Houses

Address: Resident

THE COUNCIL
THE CITY OF NEW YORK

Appearance Card

I intend to appear and speak on Int. No. _____ Res. No. _____

☐ in favor ☐ in opposition

Date: 1/23/22

(PLEASE PRINT)

Name: _____

Address: _____

I represent: _____

Address: _____

Please complete this card and return to the Sergeant-at-Arms

THE COUNCIL
THE CITY OF NEW YORK

Appearance Card

I intend to appear and speak on Int. No. _____ Res. No. _____

☐ in favor ☐ in opposition

Date: 9/23/22

(PLEASE PRINT)

Name: YESENIA VARGAS

Address: 152 AVENUE D, #2B, NYC 10009

I represent: GOLES and ALL Rio TENANTS

Address: _____

THE COUNCIL
THE CITY OF NEW YORK

Appearance Card

I intend to appear and speak on Int. No. _____ Res. No. _____

☐ in favor ☐ in opposition

Date: _____

(PLEASE PRINT)

Name: Rev. Kevin McCall

Address: 407 Rockaway Ave

I represent: Crisis Action Center

Address: 407 Rockaway Ave

THE COUNCIL
THE CITY OF NEW YORK

Appearance Card

I intend to appear and speak on Int. No. _____ Res. No. _____

☐ in favor ☐ in opposition

Date: 9/23/22

(PLEASE PRINT)

Name: Sanford Rubenstein Esq

Address: 40 Wall Street

I represent: 172 Victims while at Rio Hotel

Address: _____

Please complete this card and return to the Sergeant-at-Arms

THE COUNCIL
THE CITY OF NEW YORK

Appearance Card

I intend to appear and speak on Int. No. _____ Res. No. _____

☐ in favor ☐ in opposition

Date: _____

(PLEASE PRINT)

Name: Danielle Green

Address: _____

I represent: NYCHA - SVP

Address: _____

THE COUNCIL
THE CITY OF NEW YORK

Appearance Card

I intend to appear and speak on Int. No. _____ Res. No. _____

☐ in favor ☐ in opposition

Date: _____

(PLEASE PRINT)

Name: Lisa Bova-Hiatt

Address: _____

I represent: NYCHA - Interim CEO

Address: _____

THE COUNCIL
THE CITY OF NEW YORK

Appearance Card

I intend to appear and speak on Int. No. _____ Res. No. _____

☐ in favor ☐ in opposition

Date: _____

(PLEASE PRINT)

Name: Eva Trimble

Address: _____

I represent: NYCHA - COO

Address: _____

Please complete this card and return to the Sergeant-at-Arms

THE COUNCIL
THE CITY OF NEW YORK

Appearance Card

I intend to appear and speak on Int. No. _____ Res. No. _____

☐ in favor ☐ in opposition

Date: 9.23.2022

(PLEASE PRINT)

Name: DANETTE L CHAVIS

Address: _____

I represent: LAGUARDIA TA President

Address: 250 CLINTON ST, NY, NY, 10002

THE COUNCIL
THE CITY OF NEW YORK

Appearance Card

I intend to appear and speak on Int. No. _____ Res. No. _____

☐ in favor ☐ in opposition

Date: _____

(PLEASE PRINT)

Name: Rebecca Perkins

Address: FDR Drive

I represent: _____

Address: _____

THE COUNCIL
THE CITY OF NEW YORK

Appearance Card

I intend to appear and speak on Int. No. _____ Res. No. _____

☐ in favor ☐ in opposition

Date: _____

(PLEASE PRINT)

Name: Daniel Greene

Address: _____

I represent: NYCHA

Address: _____

Please complete this card and return to the Sergeant-at-Arms

THE COUNCIL
THE CITY OF NEW YORK

Appearance Card

I intend to appear and speak on Int. No. _____ Res. No. _____

☐ in favor ☐ in opposition

Date: _____

(PLEASE PRINT)

Name: Vincent Sapienza

Address: Le frak City, Qns.

I represent: DEP

Address: _____

THE COUNCIL
THE CITY OF NEW YORK

Appearance Card

I intend to appear and speak on Int. No. _____ Res. No. _____

☐ in favor ☐ in opposition

Date: _____

(PLEASE PRINT)

Name: Corinne Schiff

Address: _____

I represent: NYC Health Department

Address: _____

THE COUNCIL
THE CITY OF NEW YORK

Appearance Card

I intend to appear and speak on Int. No. _____ Res. No. _____

☐ in favor ☐ in opposition

Date: _____

(PLEASE PRINT)

Name: Albert Negron

Address: Jackson St NY 10002

I represent: VLADECK HOUSES - R.A. President

Address: _____

Please complete this card and return to the Sergeant-at-Arms

THE COUNCIL
THE CITY OF NEW YORK

Appearance Card

I intend to appear and speak on Int. No. _____ Res. No. _____

☐ in favor ☐ in opposition

Date: _____

(PLEASE PRINT)

Name: Crystal Glover

Address: [redacted] E. 99 st.

I represent: myself, a tenant

Address: _____

THE COUNCIL
THE CITY OF NEW YORK

Appearance Card

I intend to appear and speak on Int. No. _____ Res. No. _____

☐ in favor ☐ in opposition

Date: _____

(PLEASE PRINT)

Name: Daphne Williams

Address: _____

I represent: TA PRESIDENT

Address: Rii's Houses

THE COUNCIL
THE CITY OF NEW YORK

Appearance Card

I intend to appear and speak on Int. No. _____ Res. No. _____

☐ in favor ☐ in opposition

Date: _____

(PLEASE PRINT)

Name: David Brusvell

Address: [redacted] Ave D NYC 10009

I represent: GOLES

Address: 179 Ave B NYC 10009

Please complete this card and return to the Sergeant-at-Arms

THE COUNCIL
THE CITY OF NEW YORK

Appearance Card

I intend to appear and speak on Int. No. _____ Res. No. _____

☐ in favor ☐ in opposition

Date: _____

(PLEASE PRINT)

Name: Robert Sanderman

Address: 89-00 Sutphin Blvd. 5th Floor

I represent: Queens Legal Services

Address: Same as above

THE COUNCIL
THE CITY OF NEW YORK

Appearance Card

I intend to appear and speak on Int. No. _____ Res. No. _____

☐ in favor ☐ in opposition

Date: _____

(PLEASE PRINT)

Name: MARTHA LOZANO

Address: [redacted] East 10th Street

I represent: _____

Address: _____

THE COUNCIL
THE CITY OF NEW YORK

Appearance Card

I intend to appear and speak on Int. No. _____ Res. No. _____

☐ in favor ☐ in opposition

Date: _____

(PLEASE PRINT)

Name: Elizabeth Reyes

Address: [redacted] Commonwealth Ave Bronx NY 1046

I represent: WE ACT for Environmental Justice

Address: 1854 Amsterdam Ave NY 10032

Please complete this card and return to the Sergeant-at-Arms