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March 5, 2021

VIA UNITED STATES MAIL & EMAIL
The Honorable Judith E. Levy
U.S. District Court, Eastern District of Michigan
200 E. Liberty Street, Suite 300
Ann Arbor, MI 48104

Re: IN RE: FLINT WATER CASES – BONE SCANS
CASE NO. 16-CV-10444-JEL-EAS

Dear Judge Levy:

We write Your Honor to address the public allegations made regarding the safety and use of portable x-ray fluorescence ("XRF"). As the Court is aware, under the proposed settlement an XRF is but one method to measure the lead a claimant may have been exposed to in the Flint community. Claimants have multiple opportunities to obtain compensation that do not involve the XRF scan. Dkt. No. 1319-2. The inclusion of this provision of the settlement was negotiated over many months, and included in the Master Settlement Agreement dated August 12, 2020, the Motion for Preliminary Approval, dated November 17, 2020, and the Amended Settlement Agreement dated January 14, 2021.

We are aware that the Motion for Immediate Suspension of the Use of Portable XRF Bone Scanning Tests Pending a Further Hearing was filed (Dkt. No. 1443) and another objection filed have gained some media attention which raised concerns in the community about the safety of the XRF.[1] Although the motion was subsequently withdrawn (Dkt. No. 1449), we believe it is imperative to share essential information concerning the true nature of the XRF currently being used to measure bone lead for those individuals in the Flint community who choose to undergo the scan. We emphasize that under no circumstances would we ever expose our clients or others in the community to risk of harm. As explained below, the expert physicians and physicists who have developed and supervised the scanning process have published many studies and analyses that provide assurance that the process is without risk and, as discussed below, have received approvals from Purdue University and Harvard University to utilize the technology on humans.

In Flint, the XRF is solely being utilized as a method to quantify individual bone lead levels and is not being offered as a medical procedure nor for diagnosis or treatment purposes. XRF has

[1] Co-Liaison Counsel is also in receipt of the Objections of Dr. Lawrence A. Reynolds, M.D., FAAP Regarding the Proposed Flint Water Settlement Agreement (Dkt. No. 1436). While this letter touches upon several of the issues raised in Dr. Reynolds' Objection, Co-Liaison Counsel intend to fully respond to all objections by no later than May 27, 2021, pursuant to the Court's Schedule. *See* Dkt. No. 1399, Page ID. 54467.

been used for many years to determine the bone lead level of individuals from children to adults in a variety of different settings.[2] It can determine the level of exposure to lead on a long-term basis not available by other means.[3] The stationary XRF is a large stationary device that requires approximately 30 minutes of exposure to generate a reading. This type of XRF is used at a number of medical centers and university hospitals for the measurement of bone lead in humans. Most notably, the stationary device has not been approved by the FDA. The use of XRF has been verified in theoretical, human, animal, and lab settings using multiple methodologies for validation.[4]

The current portable XRF is being used in Flint to provide easier access to the scan technology. The portable XRF uses the same methodologies as the stationary XRF to measure lead exposure and requires only three to five minutes of exposure. The XRF in use is a model that was modified from its commercial state for human use. Without such modifications, which require proper supervision and calibration, the device would not be suitable for use in humans. The modifications applied here are consistent with modifications that have been done in studies conducted at Purdue University and Harvard University and have been approved for such use by several IRBs, including at Harvard and Purdue.[5]

In fact, both Dr. Aaron Specht and Dr. Linda Nie, have conducted other XRF programs, using the portable XRF, which have received approvals from Harvard University and Purdue University. Dr. Specht worked directly with the inventors of the portable XRF to customize the XRF calibrations specifically for these measurements as part of his validation work.

The portable XRF poses no risk to children or adults to exposure to radiation. This has been confirmed in previous radiation dose studies of this XRF. See, *Radiation dose assessments for in vivo measurements using a portable x-ray fluorescence device*. Health Physics. 2019; 116(5):590-598. That study shows the radiation dose is equivalent to that of nine (9) hours of natural background radiation sources (standing outside in the sun), or less than 1/30th of a typical chest x-

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[2] Wielopolski, Ellis et al. 1986, Bleecker, Mcneill et al. 1995, McNeill, Stokes et al. 2000, Grashow, Spiro et al. 2013, Specht, Lin et al. 2018.

[3] Rabinowitz MB. Toxicokinetics of bone lead. Environ Health Perspect. 1991 Feb;91:33-7. doi: 10.1289/ehp.919133. PMID: 2040248; PMCID: PMC1519353.

[4] Nie, Sanchez et al. 2011, Specht, Weisskopf et al. 2014, Specht, Lin et al. 2016, Specht, Parish et al. 2018, Specht, Dickerson et al. 2019, Specht, Kirchner et al. 2019.

[5] Zhang, X., Specht, A.J., Wells, E., Weisskopf, M.G., Weuve, J., and Nie, L.H., *Evaluation of a portable XRF device for in vivo quantification of lead in bone among a US population*, Sci Total Environ. 753, Jan. 20, 2021; Specht, A. J., Y. Lin, J. Xu, M. Weisskopf and L. H. Nie (2018); Specht, A. J., M. Weisskopf and L. H. Nie (2018), *Childhood lead biokinetics and associations with age among a group of lead-poisoned children in China*." Journal of Exposure Science & Environmental Epidemiology; Specht AJ, Lin Y, Weisskopf M, Xu J, Nie LH, *Bone lead levels in an environmentally exposed elderly population in shanghai, China*, The Science of the Total Environment. 2018; 626:96-98; Specht, A. J., M. Weisskopf and L. H. Nie (2014), *Portable XRF Technology to Quantify Pb in Bone In Vivo*, J Biomark 2014: 398032; Specht, A. J., Y. Lin, M. Weisskopf, C. Yan, H. Hu, J. Xu and L. H. Nie (2016). *XRF-measured bone lead (Pb) as a biomarker for Pb exposure and toxicity among children diagnosed with Pb poisoning*, Biomarkers 21(4): 347-352; McNeill, F. E., M. Fisher, D. R. Chettle, M. Inskip, N. Healey, R. Bray, C. E. Webber, W. I. Manton, L. Marro and T. E. Arbuckle (2017), *The decrease in population bone lead levels in Canada between 1993 and 2010 as assessed by in vivo XRF*, Physiol Meas 39(1): 015005; McNeill, F. E., L. Stokes, J. A. Brito, D. R. Chettle and W. E. Kaye (2000), *109Cd K x ray fluorescence measurements of tibial lead content in young adults exposed to lead in early childhood*, Occup Environ Med 57(7): 465-471.

ray, which is the most common x-ray procedure.[6] This radiation dose has been quantified using thermoluminescent dosimeters, optically stimulated luminescent dosimeters, and simulations using the exact parameters and procedures of the XRF used in Flint and in all studies using the portable XRF.[7] This publication also explains the potential risks of the procedure in comparison to known deterministic and stochastic radiation effects. The risk from radiation exposure of this amount is too small to be measured directly and is considered to be negligible when compared to everyday risks.[8] It is much less than from a dental X-ray or from an X-ray taken of a bone to find out if it is broken.

Nonetheless, in Flint additional precautions are taken. All testing is being performed under standard protocols with a medical director overseeing the program to ensure compliance. The protocols for testing were developed by Dr. Michael Weitzman and Dr. Aaron Specht. The protocols are the same as the procedures used in IRB approved studies for the use of XRF on humans.[9] The program was developed exclusively to show proof of exposure levels and now for settlement purposes under the MSA.

Under the protocols, a participant will come in to be tested in private screening rooms where trained nurses administer the test. The x-ray settings are checked prior to measurement on XRF startup. The XRF location was chosen to be the mid tibial shaft. The tibia was identified, and the nurses were trained in the operation of the XRF on site by Dr. Aaron Specht. This procedure was overseen by Dr. Michael Weitzman to verify the safety of individuals and nurses during operation and proper administration. The operators were provided standard operating procedures (SOP) of the XRF operation during training and refresher trainings, and hard copies for reference during the measurements.

Dosimetry of the XRF was completed by Dr. Aaron Specht based on calibrations previously approved by IRBs at Harvard and Purdue. The exact dose measurements were identified using optically stimulated dosimeters, thermoluminescent dosimeters, and simulation with a Monte Carlo N-Particle transport code to assess the skin and total-body effective dose typical of the XRF. Further, measurements were completed in the same way in many previous studies of bone lead. The same fitting algorithm, uncertainty estimation, and quality assurance checks used in those studies were utilized in the bone lead assessments done in Flint.

The medical director for the scanning program, Dr. Michael Weitzman, is at NYU Langone Health. He is a Board-Certified Pediatrician specializing in environmental neurotoxin exposure in children. He served as Chairman of the Department of Pediatrics at the NYU School of Medicine. He is the 2017 American Pediatric Society's John Howland Award recipient, which is considered the highest honor in academic Pediatrics. For over 20 years, Weitzman has studied the neurotoxic effects of lead exposure on children. His research on preventing childhood lead exposure has

[6] https://www.epa.gov/radiation/radiation-sources-and-doses; https://ncrponline.org/publications/reports/ncrp-report-160-2/

[7] Specht AJ, Zhang X, Goodman B, Maher E, Nie LH, Weisskopf MG. Radiation dose assessments for in vivo measurements using a portable x-ray fluorescence device. Health Physics. 2019; 116(5):590-598.

[8] *Id.*

[9] *Supra,* note 4.

influenced lead policy in several major ways, including contributing to a paradigm shift from treating lead poisoned children to a primary and secondary prevention approach that involves home investigations and abatements and screening of children to trigger home investigations and repairs. He also has contributed to the current Housing and Urban Development (HUD) and Environmental Protection Agency (EPA) dust lead clearance levels post lead abatement, as well as contributing to the Centers for Disease Control and Prevention (CDC) changing its definition of elevated blood lead levels and its lead screening and treatment guidelines. He served on the CDC Advisory Committee on Childhood Lead Poisoning Prevention from 1997-2002 and the EPA Clean Air Clean Air Scientific Advisory Committee Lead Review Panel from 2010-2013. The medical director has tight control overseeing the process meetings weekly with the team and available daily if necessary.

Dr. Aaron Specht is on the faculty at Department of Environmental Health Harvard T.H. Chan School of Public Health. He has his Doctorate in medical physics. He has a detailed understanding of the role of environmental exposures in human health. His background has a strong focus on physics and the sub disciplines of medical and health physics and exposure assessment and, in particular, x-ray fluorescence (XRF) and its uses in public health. He identifies individual exposure levels to metals and health outcomes resultant from exposures. He has worked on developing a handheld XRF for non-invasive measurement of cumulative exposure to toxicants in bone. He has written dozens of articles dealing with these type of public health assessments.

As these credentials show these experts have dedicated their careers to public health of the community, including to children. They would not, nor would we allow any risk to the community.

Finally, approval under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) is not necessary for the stationary or portable XRF because the test is not being used as a "diagnosis, prevention, or treatment of any disease." The sole purpose of the test is to quantify lead exposure for purposes of settlement. Similarly, approval is not required under the Food, Drug, and Cosmetic Act ("FDCA") because the XRF scans in Flint are not "intended for use in the diagnosis of disease or other conditions. . ." The tests are not being used to inform the recipient of any medical or diagnostic criteria beyond the test results itself for purposes of litigation and claim categorization.

We thank the Court for its attention to this matter.

Respectfully submitted,

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Co-Liaison Counsel

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/s/ Hunter J. Shkolnik
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cc: All Settling Parties via email