

From: Susan Masten <masten@egr.msu.edu>

Sent: Tuesday, September 17, 2019 10:11 PM

To: mlapoin1@hfhs.org; CTOResearch@hfhs.org; HFAHClinicalTrials@hfhs.org; jbirk@umich.edu; cshindle@umich.edu; monica.malian@wayne.edu

Cc: OswaldE1@Michigan.gov; khdunj@michigan.gov; 'Amy Pruden' <apruden@vt.edu>; Marc Edwards <edwardsm@vt.edu>; 'Siddhartha Roy' <sidroy@vt.edu>

Subject: Questions regarding publication entitled Bacterial colonization of drinking water: implications for an aging U.S. water infrastructure

Dear Drs. LaPointe, Birk, Malian, and Shindledecker:

We are writing to request a copy of IRB protocols and approvals, for a research study conducted by Drs. Maki, Zervos, Misikir, and Perri of the Henry Ford System, Dr. McElmurry of Wayne State, and Dr. Love of University of Michigan on bacterial colonization of drinking water. These research results were published in ***the International Journal of Infectious Diseases***, Feb 2019, Vol 79, Supplement 1, pages 30-31 at the following location:

[https://www.ijidonline.com/article/S1201-9712\(18\)34667-8/fulltext](https://www.ijidonline.com/article/S1201-9712(18)34667-8/fulltext)

Details of our request and cause for concern are provided in the attached letter.

We thank you for your time and look forward to your response.

Sincerely,

Marc Edwards, Ph.D.
Siddhartha Roy, Ph.D.
Susan Masten, Ph.D.
Amy Pruden, Ph.D.

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Susan J. Masten, Ph.D., P.E.
Professor

Associate Chair for Undergraduate Studies Department of Civil and
Environmental Engineering Engineering Building
428 S. Shaw Ln., Room 3546
East Lansing, MI 48824

Phone: 517 355-2254
Fax: 517 355-0250

9/17/2019

Re: IRB Approval for Frontline POU Filter Bacteria Infection Research Study

Dear Dr. LaPointe and IRB Officers of Henry Ford, Wayne State, and the University of Michigan:

We are writing to request a copy of IRB protocols and approvals, for a research study conducted by Drs. Maki, Zervos, Misikir, and Perri of the Henry Ford System, Dr. McElmurry of Wayne State, and Dr. Love of University of Michigan on bacterial colonization of drinking water. These research results were published in ***the International Journal of Infectious Diseases***, Feb 2019, Vol 79, Supplement 1, pages 30-31 at the following location:

[https://www.ijidonline.com/article/S1201-9712\(18\)34667-8/fulltext](https://www.ijidonline.com/article/S1201-9712(18)34667-8/fulltext)

<https://doi.org/10.1016/j.ijid.2018.11.088>

The stated objective of the research in the paper, was to study POU filter ***“effects on bacterial infections.”***

An alarming conclusion from the study was that ***“Residents of 7/10 homes in Flint had severe pneumonia, 1 sepsis, and 1 folliculitis. 5/10 patients died.”***

A generalizable published conclusion of this research study is that: ***“These results have important implications for immune compromised patients, and other cities with aging infrastructure where PoU filters are being considered.”***

We have just discovered, that this alarmist study, was actually designed by PBS “Frontline,” and PBS has disclosed that they were the ones collecting the samples used in the research (APPENDIX 1 and 2). Moreover, this study is now being used to imply that the POU filtered water in Flint is not safe (see attached press release by PBS with supporting comments by the study authors).

We have never heard of PBS designing, and actually collecting samples, for an IRB approved human subjects experiment, the health implications and generalizable results of which have now been distributed internationally by PBS and the study authors. Moreover, the fact that PBS reporters designed this study, and/or collected the samples, was never disclosed by the authors of the research paper.

We would like documentation approving all aspects of this research study. We do not believe that the study design, supports the implied conclusion that the use of the POU filters resulted in the deaths of 5 Flint residents, or that they caused the cited infections. In our attached email to Frontline, we even question the timing of the POU filter installation, relative to the reported deaths and illnesses of study participants.

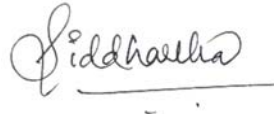
We would also like to read, how these results, were communicated to the Flint residents that experienced these infections, and the families of those test subjects who died. As such, in addition to the IRB protocols and approvals, please provide us with copies of all documentation presented to the residents involved in this study, including the informed consent form.

Sincerely,

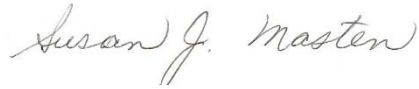


Marc Edwards, Ph.D.

Virginia Tech



Siddhartha Roy, Ph.D.
Virginia Tech



Susan Masten, Ph.D.

Michigan State University



Amy Pruden, Ph.D.
Virginia Tech

Cc: Eric Oswald, Director Drinking Water and Environmental Health Division, MI Department of Environment, Great Lakes, and Energy

Dr. Joneigh S. Khalidun, Director Public Health Division, MI Department of Health and Human Services

APPENDIX 1:

From: edwardsm@vt.edu <edwardsm@vt.edu>

Sent: Tuesday, September 17, 2019 8:06 AM

To: 'Kayla Ruble' <kayla.ruble@gmail.com>

Subject: RE: PBS journalist reaching out about Genesee County Legionnaires Outbreak

Hi Kayla,

Unfortunately, I never did hear from Frontline, about the fact checking on the story.

I do have a question for Frontline editors and journalists in relation to the logic presented in the story below, and the methods Frontline used for the sampling.

According to the logic presented in the peer reviewed paper and the article below, it would appear that people in Flint died (or are dying) from pneumonia, by drinking water from POU filters, because they are loaded with toxic and antibiotic resistant bacteria. The article actually states that 5 of 10 people died in the homes sampled.

Our question is related to the Frontline study design and interpretation. When were the filters first used in these homes?

The reason I ask, is that we did not start recommending filters until late 2015, which was after the excess deaths documented by Frontline and others occurred in 2014-2015. Did these homes of infected patients, actually have filters installed before the patients were infected? And if not, how can the filters cause the deaths reported in the paper?

So what I am asking, is a Table, indicating the following:

1. What date did the people in the Flint homes that had filters sampled for Frontline, actually die or get infected?
2. What is the first date, that each home, actually started using the filters?
3. When were the filters sampled in relation to events #1 and #2?

Also, for the 10 control homes in Detroit sampled by Frontline, can you tell me the type of residence that was sampled, and when the sampling was conducted.

Also, can we have the exact sampling protocol that Frontline reporters used, and also understand the training that was done, before they collected all these samples? o

Finally, can we obtain the materials, that were used to inform the consumers who participated, as to the purposes of the study, and a copy of the information that went to them describing the results? Can we also get a copy of IRB approval, that the researchers obtained, to do this human subjects experiment, which resulted in the scientific publication cited by Frontline?

Also, don't you think that the authors should have disclosed in their paper, that these samples were collected by Frontline reporters, in association with a Frontline investigation?

Marc

From: Kayla Ruble <kayla.ruble@gmail.com>

Sent: Friday, July 19, 2019 1:16 PM

To: Amy Pruden <apruden@vt.edu>

Cc: Marc Edwards <edwardsm@vt.edu>

Subject: Re: PBS journalist reaching out about Genesee County Legionnaires Outbreak

Thanks Amy. Appreciate you getting back to me on vacation and thanks for looping in Marc. Great to connect with you both.

To give you both a little background, myself and two other reporters have been working in Flint the last few years investigating various aspects of the crisis, but for this documentary in addition to specifically focusing on legionella, we have really zeroed in on reporting into pneumonia deaths during the crisis/outbreak. Last summer we published a pretty straight forward article with our preliminary reporting. I believe my reporting partner Jacob may have shared some of his raw data with you very early on when he first started digging.

Anyways, earlier this year we linked up with epidemiologists at Emory to do a statistical analysis of both pneumonia deaths and the spatial distribution of those deaths. I've attached the analysis plan we drafted for reference. They completed the analysis earlier this summer and we're in the process of getting outside experts to review/vet the work (as in, experts independent of both Emory and Flint), but we're also eager to share with experts who have worked in Flint for more informed insight/interpretations/critiques of our analysis. With the legionella research you've done and of course your overall knowledge of everything in Flint, if you were able to take a look at our findings we'd be really interested to hear what you guys think. Also, we'll be publishing an in-depth article about it in September and would love to include comments from you.

If you're interested and willing to take a look, please let me know and I can follow up with an analysis summary we've compiled. Thanks so much! - Kayla

Kayla B. Ruble

APPENDIX 2:

https://www.pbs.org/wgbh/frontline/article/epa-says-flints-water-is-safe-scientists-arent-so-sure/?utm_source=twitter&utm_medium=social&utm_campaign=share_button

According to epidemiologists and microbiologists, without access, accountability and peer-reviewed science, it will be difficult to prove to Flint residents their water is safe.

“We don’t know if it’s safe, because the proper studies haven’t been done,” said Marcus Zervos, an infectious disease doctor who sat on the Flint Area Community Health and Environment Partnership (FACHEP), a group hired by the state in 2016 to investigate the Legionnaires’ outbreak. That fall, the team tested the water of 188 randomly selected Flint-area households and found legionella in 12 percent of them.

The state ultimately rejected the team’s work, saying the scientists had “only added to the public confusion,” and that an outside consulting firm the state hired had been critical of their work.

Zervos continued working on water issues in Flint. **In 2018, a team including Zervos tested water filters from 10 Flint residents’ homes that they suspected were infected, using samples collected by FRONTLINE. The results, published early this year in the *International Journal of Infectious Diseases*, announced that they had found toxic, often antibiotic-resistant bacteria in some filters.**

“By us saying that the filters potentially have a problem with them, we were also getting push back [from the state],” Zervos told FRONTLINE. “There are people going around that are saying that it’s normal to have bacteria in the water and that the filters are the solution to this. There are still a lot of questions.”

One of his FACHEP colleagues, University of Michigan professor Nancy Love, said that while the filters distributed in Flint are efficient at removing lead, [research suggests](#) they can also harbor harmful bacteria. “Whether the level of those bacteria that end up in filtered water, consumed over long periods of time, is a health risk has, to my knowledge, not been evaluated,” Love said.

Another problem, she said, is that emphasizing filters as the only barrier between safe and unsafe water pushes all maintenance and treatment responsibility onto residents.