

Testimony of Aaron A. Rosenblatt

Date: March 5, 2021
To: PA Senate Democratic Policy Committee
Re: The Legionnaires' Disease Prevention and Reporting Act SB 1285 of the 2019-2020 Legislative Session

INTRODUCTION

I thank Chairwoman Muth and the honorable members of the Pennsylvania Senate Democratic Policy Committee for the opportunity to provide written testimony in connection with the proposed legislation SB 1285 from the 2019-2020 legislative session.

I am a *Principal* of Gordon & Rosenblatt, consultants in water and public health. Our practice centers on the prevention of disease associated with human-made water systems. Our clients include both healthcare and non-healthcare facilities. (See our *Statement of Qualifications*, attached.) I have prepared this testimony at my own time and expense, without any compensation from any other party.

I serve on a number of Standard making committees involved in issues of water and public health, including as a voting member on the American Society of Heating Refrigeration & Air Conditioning Engineers (“ASHRAE”) Standing Standard Project Committee (“SSPC”) 188, which is responsible for the development of ANSI/ASHRAE Standard 188 *Legionellosis: Risk Management for Building Water Systems* and ASHRAE Guideline 12-2020 *Managing the Risk of Legionellosis Associated with Building Water Systems*. I also serve on ASHRAE Standard Project Committee (“SPC”) 514P *Minimizing Risk of Injury and Disease Associated with Building Water Systems*, on the American Water Works Association (“AWWA”) Standards Committee on *Disinfection of Facilities* and on the American Society of Testing Materials (“ASTM”) Committee D-19, *Water*. In the past, I have served on the AWWA *Disinfectants* and *Disinfection By-products* Committees, on the Board of the International Ozone Association/Pan American Group, and on the Advisory Council for the US Centers for Disease Control and Prevention (“CDC”) program *Development and Dissemination of an Online Training for Environmental Health Professionals: Legionellosis Prevention and Response*.

NOTE – I also served as a non-voting member on the working group that developed ASSE/IAPMO/ANSI 12080, *Professional Qualifications Standard for Legionella Water Safety and Management Personnel* (“ASSE 12080”) which is included in the proposed legislation SB 1285. While it is an ANSI Standard, procedures for the ASSE 12080-development process were far less rigorous than the ANSI process as managed by ASHRAE. The Standard published by ASSE fell far short of its objectives and, I believe, has fundamental flaws. At my request, ASSE removed my name from Standard 12080. (See my letter to ASSE of March 4, 2021, attached). I understand that other members of the ASSE 12080 working group have also asked to have their names be removed from ASSE 12080. In my estimation, ASSE 12080 does not have broad support, and much of the support it may have had initially has diminished.

The proposed legislation addresses an important public health issue, waterborne disease associated with human made water systems, particularly (1) potable water systems in buildings and (2) cooling tower systems used in connection with comfort cooling of buildings. With certain amendments and adjustments, I believe that SB 1285 could help advance practices that would afford significant protection the of public health at reasonable cost. Without such amendments and adjustments, I believe SB 1285 could cause more harm than good, at significant, unjustifiable expense.

CONTEXT

The issues at hand benefit from consideration of carefully developed consensus standards, accreditation requirements and CDC guidance, summarized here.

ANSI/ASHRAE 188. In 2015, after nearly a decade of work and thoughtful deliberation, the American Society of Heating, Refrigeration and Air Conditioning Engineers (ASHRAE) published ANSI/ASHRAE 188, the first industry-consensus standard addressing waterborne disease caused by *Legionella* bacteria. ASHRAE 188 was the product of many years of work by a carefully balanced group of stakeholders including but not limited to renowned chemists, microbiologists, engineers and public health experts. ANSI/ASHRAE 188, updated in 2018, is an essential part of SB 1285.

The ANSI/ASHRAE 188 risk-management methodology, which centers on the management of conditions that, in the absence of control support microbial growth, is consistent with CDC Guidance and with CMS/TJC Requirements.

ASHRAE 188 does not require testing for *Legionella* by spread plate culture (ISO 11731) or by any other method. The primary means for confirming (a/k/a “validating”) that an ASHRAE-188 compliant water management plan is effectively maintaining control of the growth-supportive environmental conditions throughout the building water system is to measure physical-chemical parameters (e.g., temperature, disinfectant residual) at representative points throughout the system. The appropriate use of *Legionella* (and other microbial) testing is to provide an additional means to confirm that a water management plan, when implemented as designed, is effectively maintaining control of the growth-supportive environmental conditions throughout the building water system.

In addition to the option of testing for *Legionella* and other pathogens, far less expensive microbial test methods, such as for total heterotrophic aerobic bacteria (THAB or HPC) may be sufficient for validating a water management plan, especially in non-healthcare facilities.

ASHRAE 188 was written to stand alone. It states explicitly: “This standard does not use or require compliance, training, or certification in any additional hazard analysis, risk assessment or risk management methodologies.” The requirement in SB 1285 that water management team members be certified under ASSE 12080 is inconsistent with the provisions and intent of ASHRAE 188. It also adds unnecessary cost. For water management team members seeking additional training, considerable resources are readily available at little to no cost, including CDC’s *Development and Dissemination of an Online Training for Environmental Health Professionals: Legionellosis Prevention and Response*.

ASHRAE Guideline 12-2020. ASHRAE Guideline 12-2020 *Managing the Risk of Legionellosis Associated with Building Water Systems* is a guidance document developed by ASHRAE SSPC 188. It provides substantive information on the scientific considerations and water management practices for the prevention of legionellosis, information which is useful for implementing ANSI/ASHRAE 188. Though a guideline and not a standard, ASHRAE Guideline 12-2020 was developed under similarly rigorous procedures used for the development of ANSI/ASHRAE Standard 188, including formal consideration of public comments and requirements for committee consensus

CDC Guidance. CDC has participated actively in the development of the ANSI/ASHRAE Standard 188 and ASHRAE Guideline 12. CDC also has published guidance, including “toolkits”, to support the development of water management programs consistent with ANSI/ASHRAE Standard 188 and ASHRAE Guideline 12. CDC also has published guidance on facility-associated waterborne pathogens other than *Legionella*, including pathogens that cause disease across all types of facilities (i.e., healthcare and non-healthcare) and others that are particularly significant in healthcare settings.

BSR/ASHRAE 514-P. Owing to the significant disease burden caused by waterborne pathogens other than *Legionella*, ASHRAE is developing ASHRAE SPC 514P *Risk Management for Building Water Systems: Physical, Chemical and Microbial Hazards*, which is based on the same risk management methodology as ASHRAE 188 and is designed as a complement to ASHRAE 188. A draft of ASHRAE 514P was issued for First Advisory Public Review in March 2021.

CMS/TJC Requirements. On March 19, 2021, The Joint Commission (TJC) issued its New Requirements for Water Management in Healthcare Facilities, which go into effect on January 1, 2022. The TJC requirements were approved by the US Centers for Medicare and Medicaid Services. The new requirements closely follow the methodology of ANSI/ASHRAE 188 (and BSR/ASHRAE 514P). The scope of the new requirements includes *Legionella* and other waterborne pathogens associated with building water systems. Consistent with ASHRAE 188 and CDC guidance, the CMS/TJC Requirements do not require testing for *Legionella* or other pathogens of concern, either by spread plate culture or by any other method.

BACKGROUND

Growth, Transmission and Infection. Regulation-compliant drinking water is not sterile; it contains a rich, diverse, dynamic microbial community. Biofilm-associated environmental-source pathogens, such as *Legionella*, are ubiquitous in the environment and are generally present in the public water supply, albeit often at very low (even undetectable) concentrations. In the absence of control of certain physical-chemical conditions, building water systems can act as “incubators” in which even very small numbers of pathogens in the water supplied to the building can grow to very large numbers, then be released from the building water system in microscopic droplets (e.g., through showers, whirlpool spas, cooling towers). When susceptible persons are exposed, they can become infected.

Multiple Pathogens. There are several biofilm-associated environmental-source pathogens that cause a significant disease burden; they must all be addressed in order to protect the public health. Focus on only one—e.g., *Legionella*—may result in the increase in the disease burden associated with the others, resulting in the overall increase in danger to the public health. For example, some treatment chemicals, such as monochloramine, used to control *Legionella* can promote the growth of other dangerous pathogens.

- *Legionella* is a one of several families (“genera”) of biofilm-associated environmental-source bacteria with at least some members that cause a substantial amount of disease, both in healthcare and non-healthcare facilities. The *Legionella* species that causes more than 90% of Legionnaires' disease associated with potable water systems, and essentially all Legionnaires' disease associated with cooling tower systems, is *L. pneumophila*.
- *Pseudomonas* is another family of bacteria with some members that cause a substantial amount of disease, both in healthcare and non-healthcare facilities. The *Pseudomonas* species that causes most *Pseudomonas* disease is *P. aeruginosa*.
- *Mycobacteria* is another family of bacteria with some members that cause a substantial amount of disease, both in healthcare and non-healthcare facilities. The *Mycobacteria* species that cause most mycobacterial disease is a group of organisms collectively known as Non-Tuberculous Mycobacteria (“NTM”).
- According to a recent CDC publication, the disease burden attributable to each of *P. aeruginosa* and NTM is comparable to that of *Legionella*. Determining which microbial pathogens are of concern is situation specific. For example, for cooling towers the only pathogen of concern is *L. pneumophila*. In potable water systems in non-healthcare environments, *L. pneumophila* is the primary *Legionella* species of concern; other pathogens of concern that should be considered include *P. aeruginosa* and NTM.

Special Considerations for Healthcare. In addition to *Legionella*, *Pseudomonas* and NTM, there a number of biofilm-associated environmental-source pathogens that are of concern primarily in healthcare facilities. These include, without limitation, *Acinetobacter*, *Burkholderia*, *Elizabethkingia*, *Klebsiella*, *Sphingomonas* and *Stenotrophomonas*. Patients in healthcare environments often are more susceptible to infection by these pathogens than the general population. Even within healthcare environments, the susceptibility of different patient populations varies, for example populations such as bone marrow transplant, solid organ transplant and burn patients are at the highest risk of infection. Additionally, there are devices and equipment that use water, such as heater-cooler units, that are found exclusively in healthcare facilities. Other equipment used in both healthcare and non-healthcare facilities, such as ice machines, have healthcare-specific uses.

While there are more complex considerations, challenges and regulatory/accreditation requirements associated with the management of *building water systems* in healthcare environments, healthcare facilities also have unique resources and capabilities that are not generally available in non-healthcare environments. These include specialized personnel, such as clinicians, infection preventionists and facility engineers with advanced, healthcare-specific training. Consistent with ASHRAE 188 and CDC guidance, we suggest that requirements for water management in healthcare facilities should be different than for non-healthcare facilities.

Microbial Test Methods. The proposed legislation mandates testing for all *Legionella* species by culture on spread plates, an expensive, laboratory-based procedure that is heavily dependent on the skill of the technician, and the results of which are typically available 10-14 days after sampling. Inter- and intra-laboratory variation in results is significant. Other than culture on spread plates, methods for analysis of all or a sub-set of *Legionella* species include culture in liquid media, culture on field-inoculated media and qPCR. In many circumstances, these methods offer significant advantages over testing for all *Legionella* species by culture on spread plates, including being faster, less expensive, more sensitive to the pathogen of concern, less dependent on technician proficiency, and able to screen simultaneously for multiple pathogens of concern. Relative advantages of different methods vary from application to application.

Appropriate Use of Microbial Analysis of Water Samples. In the absence of disease, multi-pathogen microbial screening (for example, by qPCR) can help focus and establish a baseline for water management plans. Microbial analysis of environmental water samples by any of a number of methods—spread plate culture, liquid culture, qPCR—also can be useful for confirming that a water management program is successfully managing physical-chemical conditions that, in the absence of control, support microbial growth of the target pathogens of concern. Importantly, microbial testing of water samples is an essential tool for investigating suspected cases of disease. However, the limitations of microbial analysis of water samples must be recognized. According to CDC, the results of microbial analysis of water samples, including by *Legionella* culture, do not predict disease and do not correlate with risk of disease. Consistent with CDC guidance, ASHRAE 188 and TJC/CMS do not require microbial analysis of environmental water samples. TJC/CMS, ASHRAE 188, and CDC do not recommend *against* microbial analysis of environmental water samples. Rather, they recognize that decisions on whether, when, how and where to test and for which pathogens is situation specific and should be left to the judgement of each building’s water management team.

RECOMMENDATIONS

Based on the foregoing, we respectfully suggest that the proposed legislation SB 1285 be simplified and harmonized with the growing consensus recommendations and requirements of ASHRAE, CDC and CMS/TJC as follows:

- Rename the legislation to broaden the scope beyond *Legionella*, for example: “The Waterborne Disease Prevention and Reporting Act”
- Add language that expands the scope to include additional waterborne pathogens
- Remove the requirement for ASSE 12080 certification
- Remove the requirement for water sampling and testing for *Legionella spp.* by spread plate culture
- Separate requirements for healthcare and non-healthcare facilities
- Adopt ASHRAE 188-2018 in its entirety, by reference

Thank you for your time and attention.

Sincerely,

Aaron Rosenblatt

Aaron Rosenblatt
Principal

GORDON & ROSENBLATT

Statement of Qualifications

Gordon & Rosenblatt is a consulting firm founded by Gilbert Gordon and Aaron Rosenblatt in April 2009. Scott Deitchman joined the firm in May 2017. Christopher Crawford joined the firm in September 2019. We advise our clients on matters involving water and public health, with emphasis on prevention of Legionnaires' disease (infection by *Legionella* bacteria) and infection by other waterborne pathogens associated with building water systems.

Scott Deitchman, MD, MPH, RADM (Ret)

Dr. Deitchman joined Gordon & Rosenblatt in May 2017. Previously, he was Associate Director for Environmental Health Emergencies, National Center for Environmental Health, US Centers for Disease Control and Prevention (CDC); an Assistant Surgeon General of the United States; and Chief Medical Officer of the National Center for Environmental Health and the Agency for Toxic Substances and Disease Registry. Dr. Deitchman joined CDC and was commissioned as an officer in the US Public Health Service in 1987. Dr. Deitchman coordinated CDC preparedness for chemical, radiological and natural disasters, and led CDC's responses to the public health consequences of hurricanes Katrina, Rita, Dolly, and Ike, the 2010 Deepwater Horizon oil spill, and the 2011 Fukushima nuclear power plant disaster. In 2006-2007, he served at the White House as the Vice President's Medical Advisor for Homeland Security Affairs. Dr. Deitchman is a graduate of the Ohio State University (BS, Zoology), Northeastern Ohio Universities College of Medicine (MD), and the Johns Hopkins University School of Hygiene and Public Health (Master's degree in Public Health). He completed residency training in General Preventive Medicine at Johns Hopkins and in Occupational Medicine at the University of Cincinnati. He is board certified in both specialties. He was promoted to the rank of Rear Admiral in the US Public Health Service in 2009.

Gilbert Gordon, PhD

Gilbert Gordon, co-founder of Gordon & Rosenblatt, is *Distinguished Research Professor Emeritus* at Miami University of Ohio, where he was the *Volwiler Distinguished Research Professor of Chemistry*, taught and conducted research for more than thirty-five years. Professor Gordon is known internationally for his leadership in drinking water research, including his groundbreaking work on dynamics of chemical reactions, reactions of chlorine dioxide, chlorine and ozone and associated analytical chemistry. In connection with this work, he co-edited the definitive, 800-page review "Disinfectant Residual Measurement Methods" used by drinking water utilities in the United States, Canada and Europe. He has served as a member of national and international committees, including the *Standard Methods for the Examination of Water and Wastewater*

committees on Ozone, Chlorine Dioxide and Total Oxidants. Professor Gordon is a past President of the International Ozone Association (IOA). He also has served as a member of the Disinfectant/ Disinfection By-Products (D/DBP) Technical Advisory Workgroup for the *American Water Works Association (AWWA)*. Professor Gordon is a graduate of Bradley University (BS) and Michigan State University (PhD). He did postdoctoral work with Professor Henry Taube at the University of Chicago.

Aaron Rosenblatt

Aaron Rosenblatt, co-founder and a *Principal* of Gordon & Rosenblatt, is an advisor to healthcare institutions, real estate firms, insurers and non-governmental organizations. He is a member of ASHRAE Standing Standard Project Committee 188, *Legionellosis: Risk Management for Building Water Systems*, a member of ASHRAE Standard Project Committee 514, *Minimizing Risk of Injury and Disease Associated with Building Water Systems*, a member of the AWWA Standards Committee on *Disinfection of Facilities*, a member of the ASTM Committee D-19, *Water* and the technical lead on the ASTM working group on *Point of Use (POU) Filters*. He served on the Advisory Council for the CDC program *Development and Dissemination of an Online Training for Environmental Health Professionals: Legionellosis Prevention and Response*. He is the co-inventor of more than twenty-five US patents. Mr. Rosenblatt has served on the Board of the International Ozone Association-Pan American Group (IOA-PAG). He also has taught workshops for AWWA, and has served on AWWA *Disinfection* and *Disinfectants* Committees and the *Microbial and Disinfection By-Product (M/DBP) Technical Advisory Workgroup* during regulatory negotiations for USEPA M/DBP Rule II. He is a past Trustee of the Chemists' Club of New York and past Chairman of the Chemists' Club Library. He is a graduate of The Johns Hopkins University (BA).

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March 4, 2021

Marianne C. Waickman
Professional Qualifications Director
ASSE International
18927 Hickory Creek Drive, Suite 220
Mokena, IL 60448

Re: ASSE Standard 12080

Dear Ms. Waickman,

On May 29, 2019, while ASSE Standard 12080 was under development, I sent you a note (with a copy to the other members of the Working Group), expressing concern about the way the standard-making process was being managed and the apparent imbalance of the group charged with developing the Standard.

“The stated purpose of this standard (§10-1.2) is to provide minimum criteria, identified by industry consensus. The implication of “industry consensus” is balance of different viewpoints. However, looking at the membership of the ASSE committee through the lens of on my experience over the years on ASHRAE SSPC188 and other committees, I don’t see the kind of balance needed to develop a true consensus standard... I suggest that ASSE address the balance issue now, while we are still early in the process of developing this potentially important standard. The first step would be to open up committee membership, get the word out and rebalance the committee.”

I was particularly concerned about the dominance of one group, Dr. Stout and her colleagues, especially those that have a commercial interest in monochloramine systems being promoted for the supplemental disinfection of potable water systems in buildings. Others on the working group joined me in the concerns about balance and suggested that ASSE take steps to address the balance issue, but our concerns were ignored.

On August 12, 2020, I sent you a letter expressing my concerns about the publication of ASSE 12080.

“When I agreed to participate on the Working Group developing Standard 12080 under the auspices of the American Society of Sanitary Engineers (“ASSE”), it was my clear understanding that the objective was to produce a standard with fully developed content. When the outline was circulated, I understood it to be an interim step on the way to developing substantive course and exam content on all topics covered. To be clear, my expectation from the outset was that all members of the Working Group would have the opportunity to consider, discuss and debate all substantive scientific, technical and other materials until reaching consensus on a comprehensive, content-rich document. This expectation was based on my many years of service on the ANSI/ASHRAE Standard 188 committee and other standard making committees. I never expected the outline to be rushed out and published as a “standard” in its present form.

I believe ASSE Standard 12080, as published, is far from finished. It gives to each and any course developer completely unchecked latitude in shaping the material that would constitute the course. There is no means for authorities having jurisdiction, public health agencies or any of the Working Group members to determine whether a course taught and certification given under 12080 is consistent with their policies and positions on the subject matter. In fact, there is nothing to prevent any course developer from teaching things within the sparse framework of 12080 that are driven by commercial agendas and may damage, rather than protect, public health. In any event, the course content will undoubtedly vary from one developer to the next, and at least some of the content will probably be inconsistent or even conflict with Working Group members' (or their organizations') policies and positions on scientific, technical and other matters. Yet, by affixing the names of the Working Group members to the standard, it may give the false and misleading impression that they endorse whatever material is being taught and for which certification is being independently developed and given, even though they've never seen it."

On information and belief, I understand that the potential problems about which I had expressed to you during development of ASSE Standard 12080 and after publication, have been realized. For example, in courses given recently by Special Pathogens Lab and IAPMO, information about supplemental disinfection was omitted or distorted in a way that promoted monochloramine and discredited alternatives.

The way in which supplemental disinfection and other topics were covered is wholly inconsistent and conflict with my positions on these matters. I believe that being listed as a member of the 12080 Working Group gives the false and misleading impression that I endorse the material being taught and may cause irreparable harm to my reputation.

Please remove my name and that of my firm from Standard 12080 immediately.

Sincerely,

Aaron

Aaron Rosenblatt
Principal