Testimony of Robert A. Michaels, PhD, CEP
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Health and Standing Committee on
Environmental Conservation

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As RAM TRAC Corporation President and toxicologist I specialize in assessing risks to public health potentially posed by environmental contaminants, and managing those risks via technology and regulation. What I do, most essentially, is to use medical and scientific evidence to relate people's contaminant exposure to their risk of suffering adverse health effects. Going the other way, I also relate people's adverse health effects to their exposure history to see if the exposure probably was the cause, or just a coincidental association. That is, the fundamental premise of health risk assessment is that exposure is related to risk, and risk is related to the exposure. The higher the exposure, the higher the likelihood of illness, and often the shorter time to illness.

For nearly two years I have addressed these issues in connection with PFOA for the Healthy Hoosick Water citizens group. I prepared a plain-language article about my investigations and recommendations, but time prohibits me from including the details in my oral remarks. However, the article is in press for the Summer issue of the New York State Bar Association journal, *New York Environmental Lawyer,* which kindly has given me permission to share a pre-publication draft. I am pleased to incorporate this as part of my testimony today.

The article summarizes numerous PFOA health effects. They include causation of kidney and testicular cancer, and associations with prostate and ovarian cancer and non-Hodgkins lymphoma. PFOA also is associated with numerous non-cancer effects, including effects on cholesterol, endocrine disruption, thyroid disease, immunotoxicity (including ulcerative colitis), and reproductive effects.

These findings are astonishing because they are associated with unusually low substance concentrations: parts per trillion (ppt) in drinking water and parts per billion (ppb) in blood serum, which usually have been regarded as insignificant. The properties of PFOA that give rise to this unusual toxicological potency include: essentially infinite lifetime in the environment, resistance to human metabolism, bioconcentration in the food chain, transmissibility to infants via breastfeeding, and years-long excretion half-time in the human body.

Because of these properties, PFOA and other 'emerging contaminants' are stimulating a scientific and regulatory paradigm shift: environmental clean-up programs such as Superfund no longer can automatically ignore contaminants in the ppt range, which until recent decades could not even be measured routinely. *Not all people have been quick to accept the paradigm shift stimulated by emerging contaminants such as PFOA and related perfluoroalkyl compounds (PFCs).* I will discuss five groups: companies, EPA Region 2, EPA National, DEC, and DOH.

Companies. These oversight hearings would be unnecessary, except for the actions of companies, including Honeywell International and Saint-Gobain Performance Plastics. On 30 December 2014 Saint-Gobain submitted to EPA in Washington notification of PFOA analyses in water samples taken in October and November 2014 from three wells supplying the Village of Hoosick Falls water treatment plant. The laboratory report was dated 1 December 2014. The notification was submitted as confidential business information under the Toxic Substances Control Act (TSCA).

EPA Region 2. The TSCA filing became public by September 2015. On 14 January 2016 Region 2 Administrator Judith Enck brought more than a dozen senior EPA officials to a public meeting on PFOA held here in this auditorium. The meeting also was attended by senior DOH and DEC officials. I spoke after Administrator Enck, and stated my opinion that EPA's 400-ppt advisory for PFOA was irrelevant to the Village because it applied only to 'subchronic' exposure (up to about two weeks). By the end of January, two weeks after the public meeting, EPA Region 2 had promulgated a new advisory of 100 ppt for 'chronic' exposure (about a year or longer). The EPA Region 2 response was timely, and I considered the new 100-ppt advisory to be temporary, pending EPA promulgation of a more stringent national advisory or, even better, an enforceable regulation.

EPA National. In May EPA replaced the Region 2 value of 100 ppt for 'chronic' exposure to PFOA with 70 ppt for "lifetime" exposure to the sum of PFOA and PFOS. Substitution of the term "lifetime" (usually 70 years) for "chronic" (usually one year or more) is troubling, however, because it suggests that EPA now might regard a higher value to be acceptable for a fraction of the assumed lifetime, such as 70 times higher for one year. The new 'lifetime' value of 70-ppt in that case would be less stringent than the Region 2 'chronic' value of 100-ppt that it replaces.

The latest national advisory also is supported by description of, at best, a lengthy and uncertain pathway toward enforceable regulation. EPA also failed to show that its new advisory, even if enforced, is sufficiently stringent to protect public health. Vaccination studies, discussed in the accompanying article, have suggested to some that PFOA should be

controlled down to the 1-ppt range; at the public meeting I suggested that this might translate to 1 to 10 ppt.

EPA's own peer reviewers suggested the need to base the new advisory on these vaccination studies. EPA's response was unpersuasive. Most notably, routine childhood vaccinations produced lower antibody responses in children whose serum PFOA was elevated. EPA rejected this concern, in part because the children still had attained protective levels of antibodies, and also did not exhibit elevation of incidence of the diseases against which they had been vaccinated.

This narrow view ignored the main issue: that immunosuppression is a serious clinical outcome for anyone, especially for children. Immunosuppression signifies reduced effectiveness of immunosurveillance. Immunosurveillance is the essential bodily function of maintaining vigilance to detect invading foreign pathogens, and of mounting an attack against foreign cells, or against one's own cancer cells. Most essentially, immunosurveillance protects children against childhood cancers and foreign pathogens, whether or not vaccines against them had been administered.

EPA's narrow interpretation of the vaccination studies must be viewed in the context of EPA's longstanding special mandate regarding children's health, embodied by EPA's *Children's Health Risk Initiative.* In 1997 the Office of Children's Health Protection was instituted within EPA. Its mission is *"to make children's health protection a fundamental goal of public health and environmental protection… [by] ensuring strong standards that protect children's health…"*

NYS DEC. DEC has investigated the extent, degree, and source(s) of PFOA contamination. Shortly after the January 2016 public meeting, DEC listed PFOA as a hazardous substance, and declared the contaminated area a State Superfund site. The Agency further determined that the Saint-Gobain facility is the predominant source. In February, DEC ordered Saint-Gobain and Honeywell to enter into an agreement to remediate the site.

NYS DOH. In 2015 the Village of Hoosick Falls Newsletter reported on advice sought from DOH by the Village. The response, received from the Rensselaer County DOH on 12 January 2015, read in part: *"Samples taken from the water supply wells on October 2 and November 4, 2014 were found to contain PFOA at levels ranging from 0.17 micrograms per liter (ug/L) to 0.54 ug/L… <u>These levels are below the New York State unspecified organic contaminant public drinking water standard of 50 ug/L</u>"* (50,000 ppt). This advice was based upon an enforceable standard that is 125 times higher than EPA's irrelevant 400-ppt subchronic advisory, and 500 times higher than EPA's replaced 100-ppt chronic advisory.

PFOA is the predominant PFC detected in the Village, but not the only PFC. Yet, the DOH Biomonitoring Program discloses to participants their personal PFOA serum levels, and to the public the range of PFOA serum concentrations found. DOH has not disclosed to individuals or to the public the range of serum concentrations of other PFCs. DOH should expand the scope of disclosures to individuals and the public regarding PFCs other than PFOA.

The recent DOH fact sheet regarding its Biomonitoring Program fails to acknowledge the high probability that individuals with elevated serum PFOA also are at elevated risk for adverse health effects, such as those reported in Table 6 of my article. The DOH fact sheet notes that 'association' does not necessarily mean 'causation', even though that is the most likely explanation for most if not all of the listed health effects. The fact sheet also includes excessively disarming statements, essentially disconnecting past exposure from potential future health risk. Yet, the basis for undertaking the Biomonitoring Program to begin with is that past exposure above safe levels (or 'thresholds') gives rise to future risk, even if present knowledge cannot say which particular individuals will be affected, or in what ways.

The DOH fact sheet likewise is excessively disarming in comparing *"Average PFOA Levels in Blood"* in eight populations, where the lowest is the U. S. population, at 2 ppb. The highest is in 3M workers in Decatur, Alabama, at 1125 ppb. By comparison, *"Hoosick Falls area… (all participants)"* are reported to have an average PFOA level of 23.5 ppb. Although this is nearly 12 times the U. S. average, it still understates the magnitude of the serum PFOA elevation in the population. To capture the real magnitude of the elevation, DOH should report the average PFOA level in current residents who (until recently) have consumed the PFOA-contaminated public water supply. Instead, the reported average is diluted via inclusion of relatively low serum PFOA levels of participants who not longer live in the Village, and people in the Village who have private wells located far from the PFOA source.

DOH also is conducting a cancer cluster analysis. I have several recommendations for that analysis, set forth in detail in my article. They include evaluating anecdotal evidence, which is potentially important in defining subgroups within the study area, such as the half-dozen colleagues of Michael Hickey's father who all died of cancer after working together at Saint-Gobain and predecessor companies. DOH also should consider rare cancers, whose incidence would be expected to be zero in the small Village population. DOH also should use an inclusive statistical criterion to capture possible cancer clusters, which can be analyzed further to determine whether they are PFOA-associated or statistical flukes.

Recommendations. Most essentially, an expedited pathway to enforceable regulation must be forged, with a well-supported maximum concentration of PFOA in drinking

water. Additional regulations should be considered for other PFCs, because structurally related substances tend to exert similar effects on people.

Further, the Reporting Limit (or RL) must be reduced, so that laboratories will be required to report detected concentrations all the way down to the method detection limit (or MDL). For PFOA the MDL is about 1.7 ppt, whereas the EPA RL is 20 ppt. This RL could turn out to be above a future State or Federal drinking water PFOA regulation. The State of Vermont, for example, already has adopted a drinking water advisory of 20 ppt. The EPA also should revise the basis for its most recent drinking water advisory, or otherwise justify its decision not to base it on the vaccination studies previously mentioned.

In summary. EPA has issued three successive health advisories for PFOA in drinking water, moving from a 'sub-chronic' exposure value of 400 ppt to a 'chronic' value of 100 ppt for PFOA, and now to a 'lifetime' value of 70 ppt for (PFOA + PFOS). My investigation concludes that EPA has failed to show that its latest advisory, even if enforced, is sufficiently stringent to protect public health. The time has come to conclude this process of successive approximation toward an enforceable national regulation. A defensible, enforceable regulatory value should be identified and promulgated forthwith.