Testimony for Public Hearing Senate Standing Committee on Health Senate Standing Committee on Environmental Conservation Assembly Standing Committee on Health Assembly Standing Committee on Environmental Conservation

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Good Morning. My name is Dr. Howard Freed. I am a licensed and board certified physician with 35 years of experience practicing medicine, with an interest in the health effects of man-made environmental chemicals. I graduated from the Mount Sinai School of Medicine in 1971 and after training I worked at Albany Med from 1978 to 1996 in a variety of patient care and administrative roles. Prior to working at the NYS Department of Health, I was Chairman and Chief of Emergency Services at D.C. General Hospital and a Professor at Howard University and the Georgetown University School of Medicine. In 2008 I was appointed the Director of the NYS Department of Health's Center for Environmental Health, also known as CEH. In New York State government, CEH is the unit responsible the evaluation of the health effects of man-made chemicals, including PFOA. The bureau of state government now involved in the issues surrounding PFOA is CEH's Bureau of Water Supply Protection, which I directly supervised for my 3.5 years at DOH.

In my role as Director, I worked to change the institutional culture at CEH from an agency that found reasons to *not* act, to a culture that would more aggressively provide public health protection. It was a significant and daily challenge to change a workplace culture that has been in place for decades. I received much less than full support from the staff in this effort.

<u>Section 1</u> Minimizers vs. The Precautionary Principle

In the field of respected physicians and scientists evaluating the health effects of environmental chemicals there are 2 main schools of thought. One, which has a tendency to downplay the human health effects of environmental chemicals, I call the minimizers. Minimizers are concerned about unnecessarily alarming the public, and believe it is an error to take government action when a risk to human health has, in their judgment, not been sufficiently demonstrated.

The other school of thought takes a more precautionary approach, and uses a version of the *Precautionary Principle*, which essentially holds that regulators and other decision makers responsible for public health should act to protect the public when there is evidence of harm, and not wait for conclusive proof, especially when conclusive proof is unlikely to become available in the foreseeable future.

With these two schools of thought there are two ways to describe the current scientific literature on the health effects of PFOA: one minimizing the risks, the other more precautionary. As an example, both of the following very different statements are true:

First a description minimizing the health risks of PFOA:

"Human studies show that increased exposure to PFOA might increase the risk for some health effects but those studies have scientific limitations. Human studies are difficult to interpret, and we cannot be sure that PFOA caused the observed health effects."

Now a precautionary interpretation of the same scientific literature: "Studies both in people and in animals have shown a link between PFOA exposure and testicular and kidney cancer. There is a distinct probability that such an association exists."

Both of those statements are true.

Section 2 How CEH Operates

Since its beginning around 1980, after the Love Canal incident, CEH has adopted the minimizing approach, which means trying to avoid governmental action unless a chemical has a demonstrable risk, and the risk of harm has been proven to its satisfaction. That has been the nature of CEH for many years and through many administrations. CEH's evaluation of PFOA in the Hoosick Falls municipal water supply occurred in this minimizing context.

The minimizing by CEH is usually subtle, and DOH never says anything untrue. The scientists are highly professional and know the peer-reviewed scientific literature. DOH's minimizing health risks is not in changing the facts, but in evaluating and interpreting facts. When there is nothing proven, CEH *has always* emphasized scientific uncertainty over what many others see are clear warnings of real risk to the public.

DOH has informed the public that there are studies associating PFOA with serious health effects, including cancer, and DOH has advised the public to try to limit their intake of PFOA. But the question before us today is not about the facts. It is about how CEH communicates health risk to the public, and about how DOH always downplays the risk to the public, and always emphasizes the scientific uncertainties of any papers that suggest that PFOA may be causing major health problems.

Here are two examples of CEH minimization: the first is from a December 2015 DOH PFOA Fact Sheet ¹ and the second is from a brochure² DOH issued in June 2016 about its PFOA Blood Testing Program.

In the December 2015 Fact Sheet DOH listed all the known major health effects that several studies found to be associated with PFOA. But DOH also minimized their importance by adding the following statements:

"The studies have scientific limitations, and the results have not been consistent." "Data on the effects of PFOA on children are mixed," and "The human studies are difficult to interpret because results are not consistent."

DOH concluded, "We do not expect health effects to occur from normal use of the In that same Fact Sheet, DOH asked and answered the following question:

DOH Question: "Are health effects expected given the PFOA level found in the Hoosick Falls public water system? DOH Answer: "No." [Followed by an explanation.]

DOH later revised the fact sheet and took out the word "No."

The second example of how CEH minimizes the health risks of PFOA was in an informational brochure² about DOH's PFOA Blood Testing Program. In the brochure DOH posed and answered the following question:

DOH Question: "What do the studies show about health effects and PFOA exposure?"

DOH Answer: "Some human health studies have found associations between PFOA exposure and health effects and others have not. In addition, the studies that found associations were not able to determine with certainty if the health effects were caused by PFOA or some other factors.

That was the extent of DOH's answer about what the scientific studies show, and in my judgment that so emphasizes the scientific uncertainty and so underplays the risks of PFOA that it does not accurately reflect the scientific literature. Essentially, DOH said, "Some studies show risk and others don't. It's hard to say," and that is true. However, CEH answered the question as if the 2012 C8 Science Panel Report³ did not exist, when in fact it was a ground-breaking, years-long set of studies on the health effects of PFOA in more than 60,000 exposed individuals. The C8 Science Panel (C8 is another name for PFOA.) consisted of three senior academic epidemiologists. It was funded by DuPont as part of the settlement of a class action lawsuit against DuPont for PFOA contamination of drinking water in West Virginia. The C8 Science Panel's report is one of most comprehensive studies of the health risks of any toxic chemical ever conducted. The work is currently the gold standard for assessing the health risks of PFOA. The panel of ndependent epidemiologists concluded that even though there are scientific incertainties, there is a probable link between PFOA exposure and the development of *wo* types of cancer (kidney cancer and testicular cancer), and other major ailments.

1 a revised version of their PFOA blood sampling brochure⁴ DOH states *three times* that me studies have shown associations between PFOA exposure and health effects and hers have not, but makes no mention that:

1- In 2006, EPA's Science Advisory Board convened a PFOA Risk Assessment Review Panel. After their deliberations, three-quarters of the panel concluded that PFOA is, "likely to be carcinogenic" in humans.⁵

2- Studies of PFOA's effects in animals include body weight changes, reduced survival, altered puberty, retarded mammary gland development, liver toxicity, kidney effects, effects on immunity, and cancer.⁶

3- PFOA is known to be transmitted to babies in human breast milk,⁶ and,

4- At least one large epidemiologic study suggests a probable link between blood PFOA and kidney and testicular cancers among members of the general population.^{7,8,9}

It has been emphasized repeatedly that there are significant differences between the three statements: "PFOA causes cancer," "PFOA is associated with cancer," and "PFOA is linked with cancer." It is unclear whether those distinctions make much practical difference to the residents of Hoosick Falls. Here is an analogy:

You are in a room and there is a plate of cookies on a table. Someone offers you a cookie. Does it matter to you if the person says, "Those cookies cause cancer of the kidney and testicle," or "These cookies are associated with cancer of the kidney and testicle," or, "There is a link between those cookies and cancer of the kidney and testicle?" In any of those situations, do you want to eat the cookies?

<u>Section 3</u> How could it happen that DOH knew the Hoosick Falls drinking water was contaminated with PFOA for over a year and did not act?

Here's NOT how it happened: DOH did NOT say internally: *"The water the families of Hoosick Falls are drinking could cause cancer. <u>Let's not tell</u> <u>them.</u>" That is NOT how it happened.*

Here is how it happened:

Understandably, the people of Hoosick Falls don't want any PFOA in their water but, as always, DOH policy is that it is permissible to drink any toxin, as long as the concentration does not exceed its drinking water standards. For so-called unregulated chemicals like PFOA, DOH follows what DOH calls the Unspecified Organic Contaminant (UOC) standard, which essentially means that if we know very little or nothing about a particular contaminant then it's OK to drink it, as long as the

concentration does not go over 50,000 parts per trillion (ppt). That's how the allowable limit for PFOA got to be 50,000 ppt and that explains how six months after the discovery of PFOA in Hoosick Falls' public water supply, CEH declared that the situation "does not constitute an immediate health hazard." The Hoosick Falls water did not exceed 50,000 ppt, so as far as DOH was concerned, their allowable limit was not exceeded, and that is why there was no health protective action by DOH. One problem with that is that DOH's cutoff is nowhere near the cutoff of other regulatory agencies. While DOH's upper allowable limit of PFOA is 50,000 ppt, EPA's advisory limit was 400 ppt and now is 70 ppt. Vermont's upper acceptable limit is 20 ppt.

In this case of PFOA pollution, DOH's limit of 50,000 ppt was not exceeded so they

didn't act. EPA's limit of 400 ppt was exceeded, so they did act.

Section 4 Conclusions

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The problems in CEH are not caused by incompetence or corruption. CEH staff are not complicit with industry, they are not bought off, and no one is telling them to put their thumbs on the scale. The staff scientists are highly competent, experienced, knowledgeable, and professional. CEH is filled with ethical and well-meaning scientists. It's just that they are minimizers in a workplace where that is the dominant culture. They can be wrong, and in my judgment, by always minimizing the health risks of environmental pollution, they are.

CEH staff has known about the much lower PFOA health advisory threshold recommended by EPA, but dismissed the evidence as not strong enough. At the time, they were aware that the C8 studies concluded that there is a probable link between [>]FOA exposure and certain types of cancer and other serious ailments. The situation

was discussed internally, and with EPA, and it was, and still is, the opinion of many in CEH that dangers posed by PFOA have not been proven to their satisfaction.

Unfortunately, always minimizing the risk of ingesting toxins in drinking water is a pattern of behavior doomed to fail the people of New York. Routine reassurance cannot be justified in the face of our profound scientific ignorance about the health effects of long-term exposure to PFOA.

The public has a First Amendment right to "petition the Government for a redress of grievances," but until very recently has had virtually no ability to question or comment on CEH's work, because CEH staff did not attend meetings where they could be questioned by the public, or explain in public how or why they come to their conclusions.

Section 5 Recommendations

1- There should be a permanent, impartial Advisory Panel of Experts to review and advise the Commissioner of Health about CEH public health standards and recommendations.

2- CEH should adopt a precautionary approach to protecting public health, such that they act to protect the public when there is *evidence* of harm, and not wait for *conclusive proof* of harm, especially when conclusive proof is unlikely to become available in the foreseeable future. In other words, as Dr. Courtney Carignan of the Harvard School of Public Health has suggested, let's treat the scientific studies finding harm as if they are true rather than the opposite.

3- A medical monitoring program should be established for people who have elevated PFOA levels in their blood. With the costs borne by the polluter, these people should be identified by making blood PFOA testing widely available and free to concerned and exposed individuals.

4- The medical monitoring program should be put in place and patterned on the thoughtfully designed, exemplary program in New York State established under the James Zadroga 9/11 Health and Compensation Act of 2010.

5- DOH should provide written justification for its standards for acceptable intake where those standards differ from those of other regulatory agencies and multi-state groups, including but not limited to EPA, the World Health Organization's International Agency for Research on Cancer (IARC), and the Great Lakes Consortium for Fish Consumption.

6- DOH should require and fund continuing professional education of CEH staff scientists, such as that provided through organizations like the National Registry of Environmental Professionals, the National Environmental Health Association, and the National Association of Environmental Professionals, with the goal being to become nationally certified.

7- DOH should increase transparency, and CEH staff should appear when invited to public forums and meetings convened by local officials and/or the media to address health concerns caused by exposure to toxins in our living and working environments.

Thank you for the opportunity to submit this testimony to the Legislature.

Respectfully submitted,

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References

1. http://www.villageofhoosickfalls.com/Media/PDF/NYS-DOH-PFOA%20Fact%20Sheet-1215.pdf

2. https://www.health.ny.gov/environmental/investigations/hoosick/docs/qandabl

3.

http://www.c8sciencepanel.org/

4.

http://www.health.ny.gov/environmental/investigations/hoosick/docs/pfoa_bloo d sampling q and a 8-1-16.pdf

5.

https://yosemite.epa.gov/sab/sabproduct.nsf/A3C83648E77252828525717F004 B9099/\$File/sab_06_006.pdf

6.

https://www.epa.gov/sites/production/files/2016-05/documents/pfoa health advisory final-plain.pdf Page 9

7.

http://escholarship.org/uc/item/9zr6d0jj#page-1

8.

http//:www.c8sciencepanel.org/pdfs/Probable_Link_C8_Cancer_16April2012_v2.p

9.

http://ehp.niehs.nih.gov/121-a340/