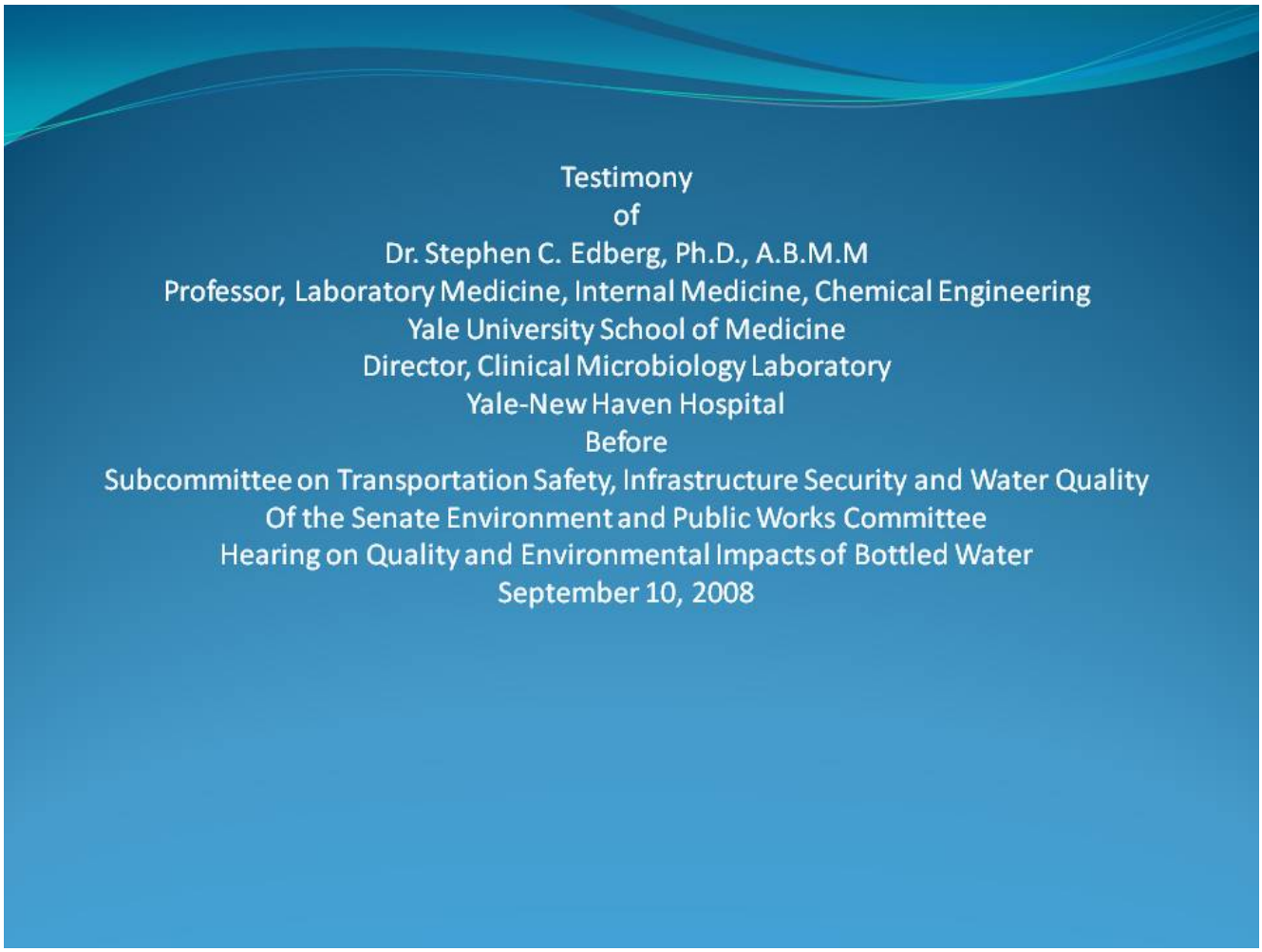


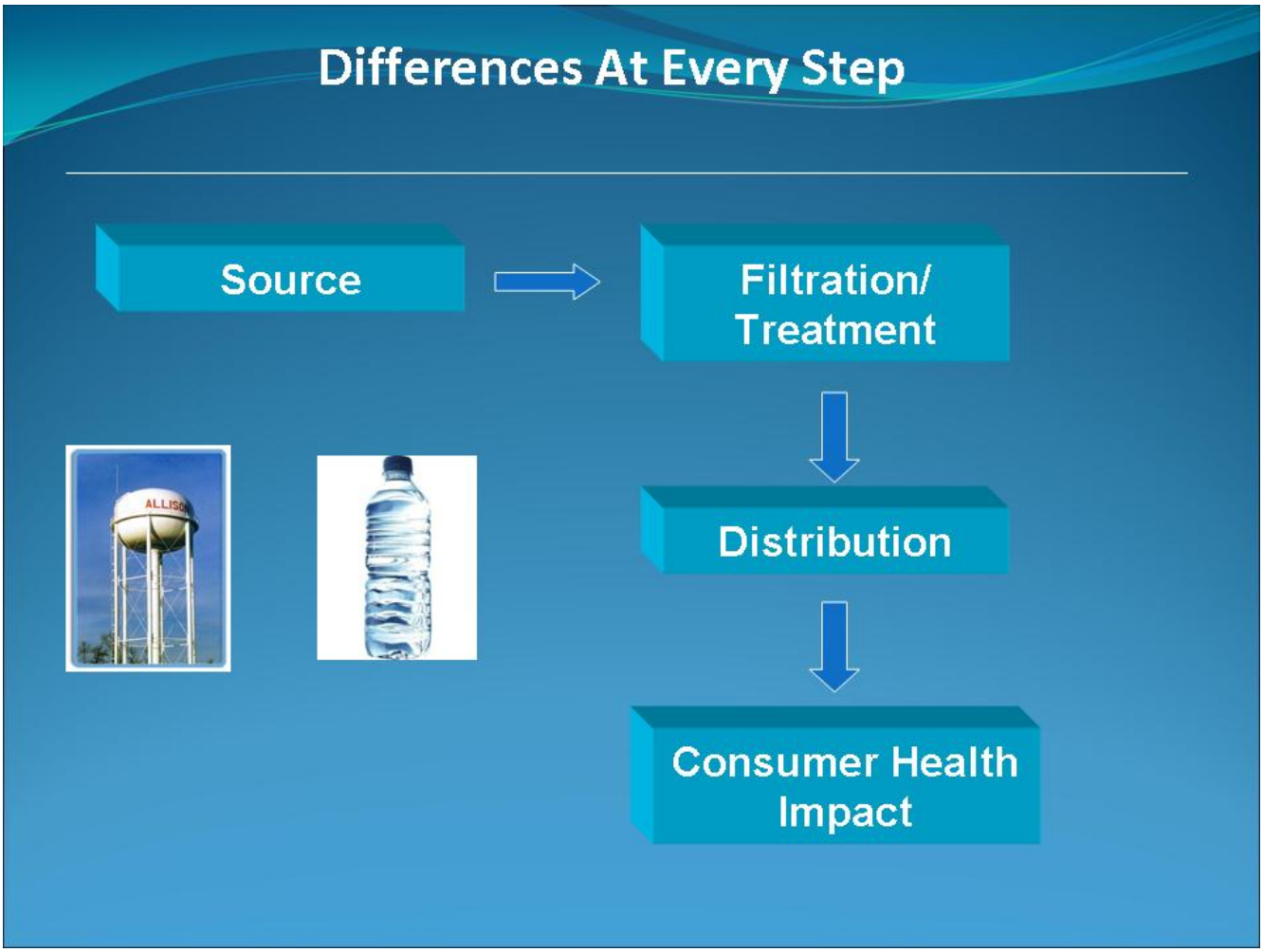
Dr. Stephen C. Edberg is a professor in the Department of Laboratory Medicine and Internal Medicine at the Yale University School of Medicine, and the director of the Clinical Microbiology Laboratory at Yale-New Haven Hospital. He has received the following degrees: B.A. Lehigh University, Bethlehem, Pennsylvania, 1967, Major in Biology, Minor in Chemical Engineering; M.A. Hofstra University, Hempstead, New York, 1968, Major in Bacteriology, Minor in Chemistry; Masters thesis entitled: "The Effect of Calcium and Strontium on the Heat Resistance of Bacillus subtilis and Bacillus megaterium"; Ph.D. State University of New York at Buffalo Medical School, 1971, Department of Microbiology and Immunology, Dissertation entitled: "The Valency of IgM and IgG Antidextran Antibody"; Post-doctoral, University of Washington, Seattle, Washington, 1972, Medical Microbiology under Dr. J. Sherris and Dr. F. Schoenknecht; M.A. (Honorary), Yale University, New Haven, Connecticut, 1989.

Among Dr. Edberg's research activities that have found their way into usage in clinical microbiology laboratories are constitutive enzyme testing for rapid identification of gram-negative species, the refinement of immunoglobulin coating of latex particles for the direct detection of antigens, and the use of hydrolysable substrates to directly identify bacterial and mycotic isolates within one hour. His most significant contribution to global well-being was his development of the "Colilert" test for the detection and enumeration of Escherichia coli in drinking water.

Dr. Edberg has received the Becton Dickenson (BD) Award for Research in Clinical Microbiology. This award, which has been supported by BD Diagnostic Systems for 30 years, recognizes a distinguished scientist for research accomplishments that form the foundation for important application in clinical microbiology.

There are fundamental differences between bottled water and water from a municipal water system and the regulatory framework that governs them. These regulatory frameworks are properly tailored to the particular production of drinking water. In the case of bottled water, it is regulated by FDA as a food product, similar to other beverages. The production, labeling, standards of quality and standards of identity are all prescribed in FDA regulations. As a food product, the bottled water quality requirements apply to each container. Violations of the regulations, including standards of quality, can lead to product recalls and FDA enforcement action.

Municipal water systems are regulated by the Environmental Protection Agency, which has promulgated regulations that prescribe the production and quality of the drinking water that they produce. There are substantial differences between bottled water and municipal water systems in compliance with the quality standards. For example, municipal water systems may average the monthly tests for disinfection by-products. Thus, public drinking water may exceed the maximum contaminant level (MCL) in some months, but be substantially lower in other months and not be in violation. If there are violations for exceeding the MCL, the water continues to flow, but corrective action and public notice are required. This is appropriate because much of the water produced by municipal water systems is not consumed by humans and is vital to the economic health of the communities they serve.



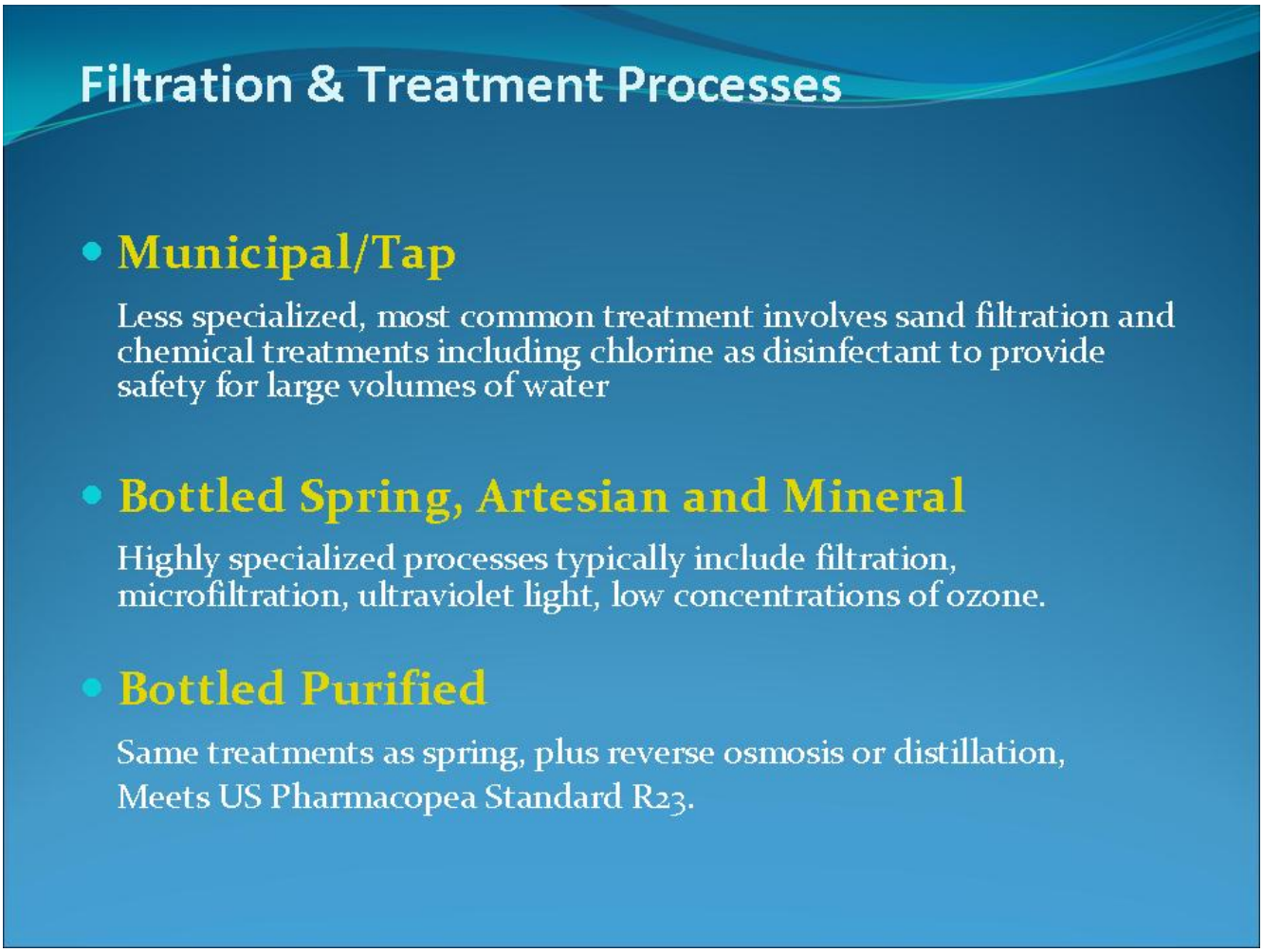
There are substantive differences from sources to treatment to distribution and most importantly to consumer health. Although there are a number of differences, consumers in the United States have access to the best drinking water in the world.

Municipal Water Sources

Approximately 75% of the population is serviced by municipal water systems that have surface water as their source. Surface water is subject to run-off and other pollution intrusion into the water source that are not as abundant, difficult to manage or present in groundwater sources. Micro-organisms, such as *Cryptosporidium*, *Legionella, Giardia,* and viruses can be present in surface water, but are not present in groundwater. In addition, municipal water systems are limited by their geography on potential water sources that can be used.

Bottled Water Sources

Two thirds of bottled water sources are groundwater and one third is purchased from municipal water systems. If a source becomes contaminated or the aquifer becomes stressed during a drought period, bottled water companies can locate new sources or purchase bulk water from another company. Spring sources are selected on the basis of quality, sustainability, flow, stability and taste, which is a function of the composition of the water source. By law, springs must continue to flow naturally to the surface in order for the bottled water product to be labeled as spring water.



The primary differences in the filtration and treatment processes between municipal water systems and bottled water are related to scale. Municipal water systems must be designed to produce large quantities of water every day to satisfy the demand on their systems. They commonly use sand filtration and chemical treatment, including chlorine, to disinfect water, both in the treatment plant and through the distribution system.

Bottled water production is done on a much smaller scale and as a result can be more specialized. The average bottled water plant produces less than 100,000 gallons per day. The common multi-barrier approach employed in most bottling facilities is source protection, filtration, microfiltration, ultraviolet light and low dose ozonation in a closed environment. For purified or sterile water, the additional treatment of reverse osmosis or distillation or de-ionization or de-mineralization is used to meet the U.S. Pharmacopeia 23rd revision standards. Although many purified bottled waters use a municipal water system as the source, the finished bottled water produced is a very different composition than the source. There is not one municipal water system in this country that meets the standard USP standard for purified water.

The United States has one of the best drinking water production and distribution systems in the world that delivers quality water at a low cost to citizens of communities throughout the country. However, one stark difference between municipal water systems and bottled water is the distribution system. Municipal water is distributed through miles of pipe, some of which is centuries old. These pipes are susceptible to leaking and municipal water systems loose between 18% and 44% of the water they produce through these pipes.

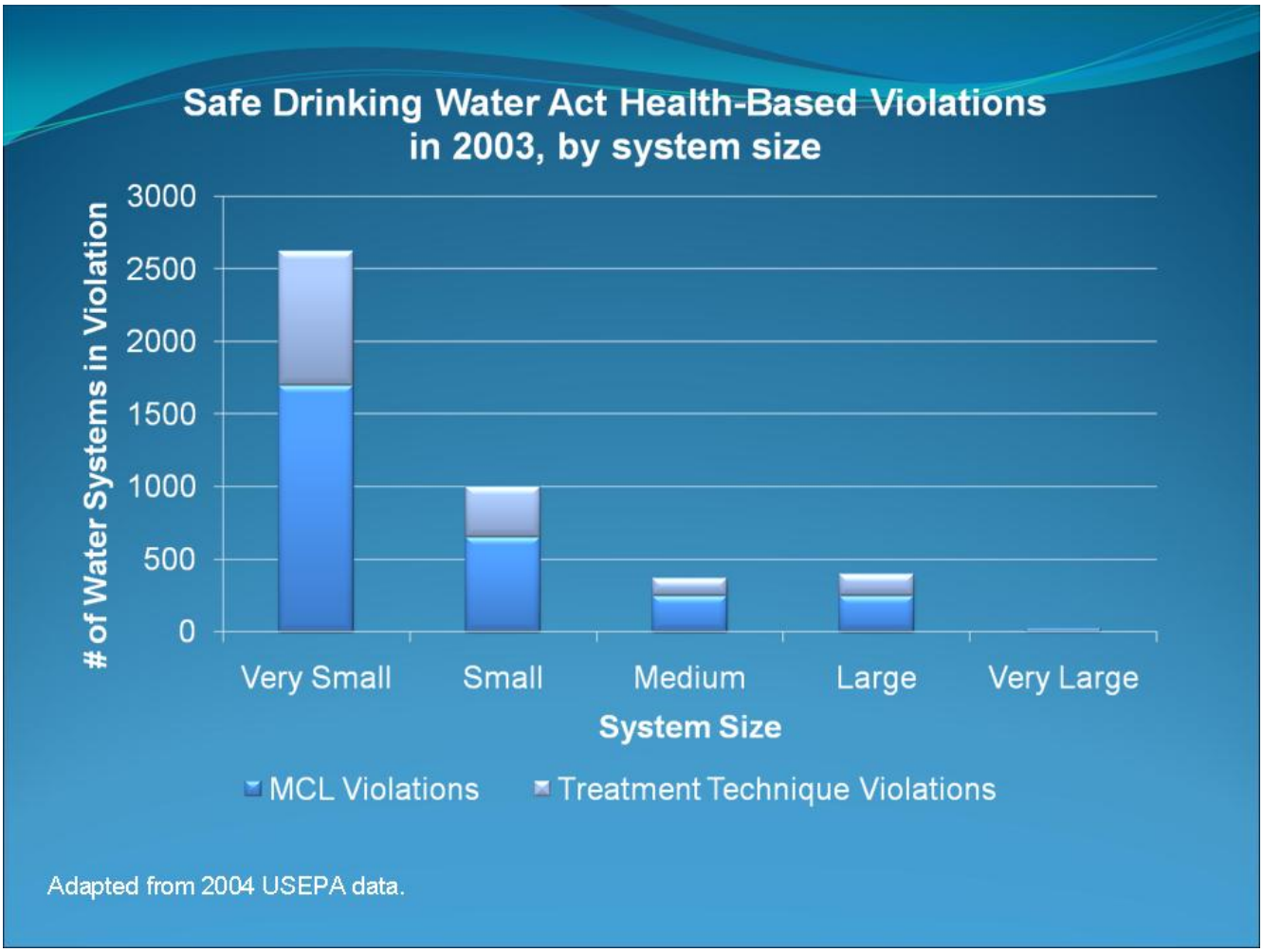
Drinking water pipes are often buried near waste water pipes, which are also susceptible to leaking. Because of pressure changes within the drinking water system, the drinking water pipes are vulnerable to intrusion from the surrounding environment. This has been shown in a study by Mark W. Lechevallier that highlights the risk to the distribution systems because of pressure changes and environmental intrusion. Thus, drinking water may be fully compliant when it leaves the municipal water treatment plant, but can be subject to change as it travels through the distribution systems. The water delivered to the tap may contain contaminants that entered through the distribution system. Such vulnerability places consumers at a much greater health risk than from the production process of drinking water. The infrastructure of our municipal water systems needs to be improved to help ensure the reduction of health risks to the citizens of communities around the country.

Bottled water is distributed in sealed containers that are made of materials approved by FDA for food contact. During the bottling process, the containers are sanitized, filled and immediately sealed with FDA approved closures. The containers help ensure that there is no contamination and quality is not compromised after production.

As a food product, there is the added benefit of being able to tracking products to permit them to be recalled because of the coding required of all food products. If a container of bottled water is found to exceed the Standards of Quality that FDA has established, the lot (production run) of products can be tested. If it is found to be out of compliance, it can be removed from the market place. This safeguard minimizes the health risk to consumers. Depending upon the circumstances, the recall notice can go to consumers notifying them that a particular lot is a health risk and should not be consumed. We have seen such notices on a variety of food products.

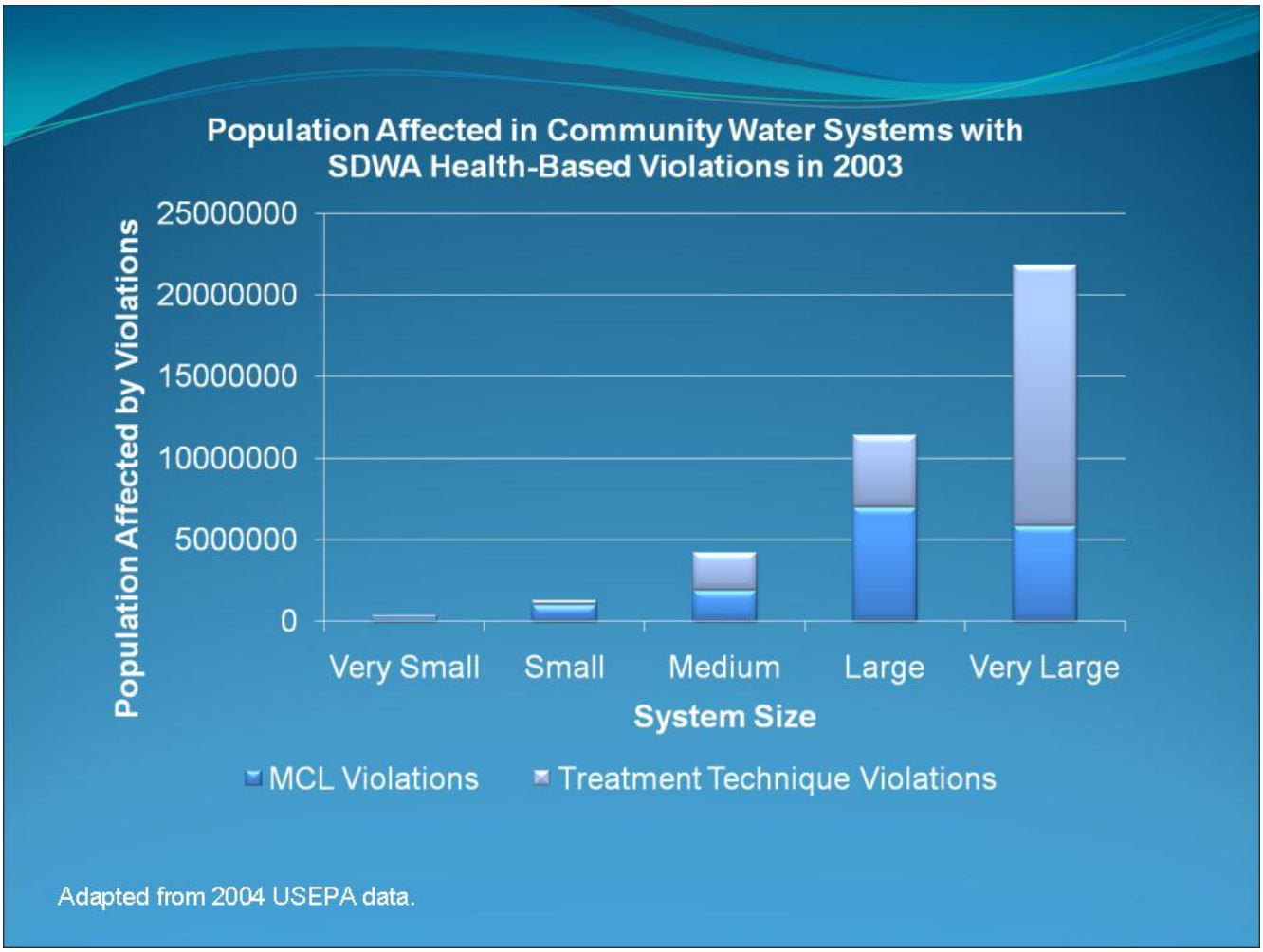
As stated earlier, the healthiest means of hydration is the consumption of water and public policy should encourage consumers to choose water to drink. However, there are differences in the health impact between bottled water and water from a municipal water system. There were an estimated 16.4 million cases of acute gastro-intestinal illnesses in 2006 associated with tap water. On the other hand, there have been less than 10 incidents resulting in possible illness from the consumption of bottled water in the past 35 years.

This difference is primarily related to the issues of source, treatment and distribution between municipal water systems and bottled water.



The challenges faced by small municipal water systems are substantial, particularly in lowering of MCL's. The expense incurred to meet those standards often exceeds the financial resources of the system. However, it is important to understand the assumptions used in establishing MCL's by the EPA. They assume a consumption of two liters per day over a 70 year life span.

Also, it is important to note that under Section 410 of the Food, Drug, and Cosmetic Act, FDA is required to review all EPA National Primary Drinking Water Standards for their applicability to bottled water and to regulate bottled water as stringently and as protective of public health as public drinking water. Some bottled water recalls are related to exceeding the FDA Standards of Quality, which are applied to each container.



As you saw in the previous chart, small systems have a numerically higher number of MCL violations, than larger systems, but the populations affected by larger systems' violations is far greater.

As I indicated earlier, exceeding the FDA Standard of Quality for bottled water subjects the product to recall or FDA enforcement action. The FDA Standards are an absolute standard that is applied to each container. Bottled water companies are not granted waivers or allowed to average, as municipal water systems are permitted to do. For example, FDA and EPA have established standards for disinfection by-products. Most bottled water companies use ozone as a disinfection and some municipal water systems are also using it. When ozone interacts with bromide (a naturally occurring compound in water), it converts it to bromate. The FDA Standard of Quality and the EPA MCL for bromate is 10 ppb. If a bottled water container has more than 10 ppb, it is violation of FDA regulations and subject to recall and enforcement action by FDA. If a public water system has a 25 ppb level for two months, the municipal water system has not exceeded the MCL, so long as the 12 month average is below 10 ppb. Thus, the consumers of that public water system can be consuming much higher levels of bromate than if they were drinking bottled water.

The true public policy question should be: “How do we encourage more people to drink more water?” With obesity and diabetes a true public health concern, drinking more water can be very beneficial to a healthier diet. Water, whether from a municipal water system or in a bottle, is one of the best options for people to meet their hydration needs. If people would drink more water, their health will be improved, particularly if they reduce the number of calories consumed and exercise. People have available to them some of the best drinking water in the world, even with the challenges the municipal water systems and bottled water face to improve the quality.

I would be glad to answer any questions from the Committee. My email address is: Stephen.Edberg@yale.edu.