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BOTTLED WATER

FDA Safety and Consumer Protections Are Often Less Stringent Than Comparable EPA Protections for Tap Water

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Mr. Chairman and Members of the Subcommittee:

I am pleased to be here today to discuss the quality and safety of bottled water and its environmental impacts. Over the past decade, the per capita consumption of bottled water in the United States has more than doubled—from 13.4 gallons per person in 1997 to 29.3 gallons per person in 2007. With this increase have come several concerns, raised by public interest groups in recent years, over bottled water’s quality and safety. For example, water quality testing conducted by some of these groups, and others, has shown that bottled water does not necessarily have lower levels of contamination than tap water. Furthermore, bottled water’s potential environmental impact has also come under scrutiny. Several organizations have raised concerns about a low recycling rate for plastic water bottles, the amount of energy used to manufacture and transport the product, and the impact of groundwater extraction on local resources. My testimony is based on our June 2009 report,¹ which is being publicly released today and addresses three issues: (1) the extent to which federal and state authorities regulate the quality of bottled water to ensure its safety, (2) the extent to which federal and state authorities regulate the accuracy of labels or claims regarding the purity and source of bottled water, and (3) the environmental impacts of bottled water.

To address these questions, we reviewed relevant Food and Drug Administration (FDA) documents, policies, and guidance, as well as related laws and regulations pertinent to the oversight of bottled water at the federal and state levels; analyzed data from the FDA databases that track inspections, import examinations, and recalls; conducted a survey of all 50 states and the District of Columbia; and conducted interviews with Environmental Protection Agency (EPA) and FDA officials and a variety of experts from nonprofit organizations and industry associations. We also examined bottled water labels and contacted companies to determine what information they provide to consumers.² Finally, we interviewed

¹GAO, *Bottled Water: FDA Safety and Consumer Protections Are Often Less Stringent Than Comparable EPA Protections for Tap Water*, [GAO-09-610](#) (Washington, D.C.: June 22, 2009).

²A total of 83 unique bottled water labels were examined after removing duplicate labels, or labels that were not for bottled water. Labels were collected from GAO staff in each of our 11 field offices and at headquarters.

experts and other knowledgeable officials and reviewed the literature regarding the environmental impacts of bottled water. A full description of our scope and methodology is included in appendix I of our report.

We conducted this performance audit from June 2008 to June 2009, in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Mr. Chairman, the following summarizes our findings on each of the three issues discussed in our report:

- *Federal and state regulation of the quality of bottled water.* FDA's bottled water standard of quality regulations generally mirror EPA's national primary drinking water regulations under the Safe Drinking Water Act, as required by the Federal Food, Drug, and Cosmetic Act (FFDCA) as amended, although the case of DEHP (an organic compound widely used in the manufacture of polyvinyl chloride plastics) is a notable exception. Specifically, FDA deferred action on DEHP in a final rule published in 1996, and has yet to either adopt a standard or publish a reason for not doing so, even though FDA's statutory deadline for acting on DEHP was more than 15 years ago. More broadly, we found that FDA's regulation of bottled water (including its implementation and enforcement), particularly when compared with EPA's regulation of tap water, reveals key differences in the agencies' statutory authorities. Of particular note, FDA does not have the specific statutory authority to require bottlers to use certified laboratories for water quality tests or to report test results, even if violations of the standards are found. Among our other findings, the states' requirements to safeguard bottled water often exceed those of FDA, but are still often less comprehensive than state requirements to safeguard tap water.
- *Federal and state regulation of the accuracy of labels or claims of purity.* FDA and state bottled water labeling requirements are similar to labeling requirements for other foods, but the information provided to consumers is less than what EPA requires of public water systems under the Safe Drinking Water Act. Public water systems must annually provide consumer confidence reports that summarize local drinking water quality information about the water's sources, detected contaminants, and compliance with national primary drinking water regulations as well as information on the potential health effects of certain drinking water contaminants. FDA does not require bottled water companies to provide

this information. Rather, as in the case of other foods, bottled water labels are required to list ingredients and nutritional information and are subject to the same prohibitions against misbranding. In 2000, FDA concluded that it was feasible for the bottled water industry to provide the same types of information to consumers that public water systems must provide. However, the agency was not required to conduct a rulemaking requiring that manufacturers provide such information to consumers, and has yet to do so. Nevertheless, our work suggests that consumers may benefit from such additional information. For example, when we asked cognizant officials in a survey of the 50 states and the District of Columbia whether their consumers had misconceptions about bottled water, many replied that consumers often believe that bottled water is safer or healthier than tap water. Their responses were consistent with a 2002 EPA-sponsored Gallup survey, which found that the main reason consumers either filtered tap water or purchased bottled water was due to health-related concerns. We also found that information comparable to what public water systems are required to provide to consumers of tap water was available for only a small percentage of the 83 bottled water labels we reviewed, companies we contacted, or company Web sites we reviewed.

- *The environmental impacts of bottled water.* Among the environmental impacts of bottled water are its effects on U.S. municipal landfill capacity and U.S. energy demands. Regarding its impacts on landfill capacity, we found that about three-quarters of the water bottles produced in the United States in 2006 were discarded and not recycled, on the basis of figures compiled by an industry trade association and an environmental nonprofit organization.³ Regarding the impact on U.S. energy demands, a recent peer-reviewed article noted that while the production and consumption of bottled water comprises a small share of total U.S. energy demand, it is much more energy-intensive than the production of public drinking water.⁴

Our report released today recommends that the Secretary of Health and Human Services direct the Commissioner of FDA to issue a standard of quality regulation for DEHP, or publish in the *Federal Register* the agency's reasons for not doing so 1 year after the conclusion of its task force study on the issue. FDA generally concurred with the recommendation, agreeing that it should reassess whether to issue the

³The two organizations are the American Beverage Association and the Container Recycling Institute.

⁴P. H. Gleick and H. S. Cooley, Pacific Institute, "Energy Implications of Bottled Water," *Environmental Research Letters*, vol. 4, no. 014009 (2009).

regulation for DEHP as soon as possible after the conclusion of the task force study on phthalates.⁵ The report also recommends that FDA implement its findings on methods that are feasible for conveying information about bottled water to customers. FDA agreed that bottled water should be labeled with contact information allowing consumers to more easily contact the manufacturer to obtain comprehensive information about the product, and said it intends to pursue this issue with bottled water manufacturers.

Despite the concerns our report raised regarding FDA's regulation of bottled water under the FFDCA (particularly in comparison with EPA's regulation of drinking water under the Safe Drinking Water Act), we concluded that its observations must be viewed in the context of the legal limitations placed by the act on FDA, and the constrained resources that have affected FDA's overall capabilities in recent years. The legal limitations arise because while the Safe Drinking Water Act authorizes EPA to require water samples to be tested by certified laboratories, and violations of national primary drinking water regulations to be reported within certain time frames to EPA or the state agency with primary enforcement responsibility, the FFDCA does not grant FDA similar authority. Rather, the FFDCA requires FDA to regulate bottled water as a "food." As such, it does not specifically authorize FDA to require that bottled water be tested by certified laboratories or that violations of the standard of quality be reported to FDA.

In addition to these legal constraints, bottled water's status as a food has subjected it to many of the same problems more generally affecting FDA oversight of food safety. As we noted in January 2007,⁶ for example, when we designated federal oversight of food safety as a "high-risk" area affecting public health and the economy, federal oversight of food safety is fragmented, with about 15 agencies having food safety roles. We specifically cited FDA's resource constraints, noting in 2008⁷ that while the number of domestic firms under FDA's jurisdiction increased from fiscal

⁵Phthalates are a class of chemical compounds primarily used as a plasticizer, added to plastics to increase flexibility, transparency, durability, and longevity and found in a variety of food containers and packaging.

⁶GAO, *High-Risk Series: An Update*, [GAO-07-310](#) (Washington, D.C.: January 2007).

⁷GAO, *Food Labeling: FDA Needs to Better Leverage Resources, Improve Oversight, and Effectively Use Available Data to Help Consumers Select Healthy Foods*, [GAO-08-597](#) (Washington, D.C.: Sept. 9, 2008).

years 2001 through 2007 from about 51,000 firms to more than 65,500, the number of firms inspected declined from 14,721 to 14,566 during the same period. We cited resource constraints as a contributing factor, noting that the number of full-time-equivalent positions at FDA devoted to food safety oversight had decreased by about 19 percent from fiscal years 2003 through 2007.

Ultimately, as our January 2007 report recommended, a fundamental reexamination of the federal food safety system will be needed to look across the activities of individual programs within specific agencies with responsibilities related to food safety. Toward that end, we had previously recommended in 2001 that the Congress, among other things, enact comprehensive, uniform, and risk-based food safety legislation and commission the National Academy of Sciences or a blue-ribbon panel to analyze alternative organizational food safety structures in detail.⁸ We continue to believe that such a fundamental reexamination is needed, and believe that FDA's lack of authority and resources to effectively regulate bottled water should be part of it.

Mr. Chairman, this concludes my statement. I would be pleased to respond to any questions you or other Members of the Subcommittee may have.

Contacts and Acknowledgments

For questions about this statement, please contact John Stephenson at (202) 512-3841 or stephensonj@gao.gov. Individuals who made key contributions to this testimony include Steve Elstein, Assistant Director; Brian M. Friedman; Nathan A. Morris; Kelly A. Richburg; and Jeanette Soares.

⁸GAO, *Food Safety and Security: Fundamental Changes Needed to Ensure Safe Food*, [GAO-02-47T](#) (Washington, D.C.: Oct. 10, 2001).

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