REGULATORY DEVELOPMENTS

U.S. SENATE HOLDS APRIL HEARING ON REGULATION OF PHARMACEUTICALS IN DRINKING WATER— REVIEW OF RECENT FEDERAL EFFORTS DEALING WITH EMERGING CONTAMINANTS IN DRINKING WATER

Recent media and Congressional attention on the issue of pharmaceuticals in the environment, known as "PIE," has brought into greater focus whether and how federal regulators can and should address through existing or new regulations a category of water contaminants grouped under the moniker "emerging contaminants." These emerging contaminants include a wide variety of chemicals and substances contained in and derived from the use of commercial and consumer products, and typically are discussed as including pharmaceuticals, agricultural chemicals and food additives. Examples include human and veterinary prescription and over the counter drugs, as well as diagnostic agents used in medicine, fragrances, and inert ingredients in consumer products, among others. Although the emerging contaminant issue arose initially in the context of surface water, it has recently become a drinking water focus, as well. (For background, *see*, 11 *Env. Liability, Enforcement & Penalties Rptr.* 61 (Jan. 2001); 11 *Env. Liability, Enforcement & Penalties Rptr.* 86 (Feb. 2001).)

March News Article

The recent flurry of activity arose following a widely publicized Associated Press (AP) story, which reported in early March that a variety of pharmaceutical product residuals were present at parts-per-billion and parts-per-trillion levels in the drinking water supplies in two dozen municipalities across the country. The AP reporting asserted that there are no federal requirements for testing, limiting or treating these small amounts of product residuals in drinking water supplies, though it also acknowledged these levels are well below dosages considered safe for medicinal purposes.

U.S. Senate Reacts

In response to the AP report, the Senate Committee on Environment and Public Works—Subcommittee on Transportation Safety, Infrastructure Security and Water Quality (EPW Subcommittee) held a hearing on April 15, 2008, at which the Environmental Protection Agency (EPA), the U.S. Geological Survey (USGS), the pharmaceutical industry trade association, environmental interests and the public water utility community provided testimony. The primary focus of questions by EPW Subcommittee members was on the status and progress of EPA's efforts regarding the assessment and regulation of emerging contaminants in surface water under the Clean Water Act (CWA), and in particular the scope of EPA's Contaminant Candidate List (CCL) under the Safe Drinking Water Act (SDWA), which, as proposed for public comment earlier this year, contained no pharmaceutical compounds based on EPA's screening and assessment of potential risks.

This article summarizes the federal efforts to date on the emerging contaminant issue generally and the framework under the CWA and SDWA for possibly regulating emerging contaminants that present potential human health or environmental risks warranting regulatory controls.

Background

The emerging contaminant issue arose in earnest when the USGS published the results of surface water quality monitoring from dozens of rivers and streams in several states and regions. The USGS report included data regarding levels of personal care and consumer products (PCCPs) and other "unregulated contaminants" (steroids, antidepressants, antibiotics, antibacterial agents, pharmaceuticals, fragrances, fire retardants, *etc.*) in various surface water settings. USGS also reported a growing concentration of PCCPs in urban waterways and pesticides in rural waterbodies. Although these matters had been studied since the 1990s, the USGS report drew much attention.

In response, EPA, USGS and other affected federal agencies formed a federal strategy group, the focus of

which initially was to further develop and advance the science around these issues and, ultimately, to address whether pharmaceuticals and PCCPs found in surface water presented risks for human health and the environment warranting regulatory attention. The premise of the strategy group was that the USGS data demonstrated that pharmaceuticals and PCCPs were "ubiquitous but unregulated" in the environment, a conclusion with which not all interested groups concurred. Federal agencies involved in this effort to look at research needs and regulatory needs include EPA, USGS, the Food and Drug Administration, the Centers for Disease Control and Prevention, the National Institute for Environmental Health Sciences, the National Oceanic and Atmospheric Administration, the Department of Agriculture and the U.S. Fish & Wildlife Service. In June 2005, the White House Office of Science and Technology subcommittee on policy established a task force to develop an integrated approach to identify research needs for PCCPs entering waterways.

Discussion and Analysis

Many of the writings stemming from these federal efforts over the last several years recognize that the detections of these substances reported are in the part-per-billion and part-per-trillion range, well below levels deemed safe for human exposure, use and consumption. They also acknowledge that, rather than documenting a previously non-existent issue, the use of new testing and laboratory analytical methods allowing detection of more contaminants at these lower levels may simply reflect a new and better ability to identify the presence of these compounds, rather than a sudden emergence of the compounds in the environment. Nevertheless, these efforts have also acknowledged that the potential environmental and health effects may not be well-understood except on a compound-specific basis for which extensive scientific study has been completed, usually in the form of data and studies developed for products undergoing Food and Drug Administration (FDA), EPA or other regulatory review and approval.

In addition to the efforts in increase the scientific understanding of emerging contaminants in surface water, many states and communities have enacted or sponsored drug take-back programs in which centralized facilities are used to collect and properly dispose of unused prescription and over the counter drugs. In February 2007, the White House issued guidelines addressing federal policy on the proper disposal of prescription drugs, emphasizing best practices to remove unused and unwanted drugs from wastewater streams (*e.g.*, by not disposing of these items via sinks and toilets) and to place them instead into household garbage in a protected manner for landfill or incineration.

As noted, the recent media and Capitol Hill attention have focused on whether and how EPA could regulate emerging contaminants under the CWA and SDWA.

The CWA provides EPA with authority to regulate both industry and domestic wastewater discharges. The SDWA provides EPA with authority to require monitoring and treatment of constituents in public water supplies that pose a risk to human health through consumption of or other exposure (*e.g.*, dermal) to drinking water.

Much of the recent discussion of pharmaceuticals suggests that most of the constituents observed in surface and drinking water derive from residues of human use/consumption and disposal of unused drugs in the wastewater stream, rather than from manufacturing processes. Thus, the resulting focus in recent weeks has been on whether further controls at wastewater and drinking water utilities are warranted.

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Wastewater

On the wastewater side, EPA issued effluent limitations for pharmaceutical manufacturing in 1998, followed by guidance for permit writers in 2006. In addition, EPA is evaluating the discharge of pharmaceuticals from hospitals as a possible effluent limitation guideline (ELG) category. This effort is focused on mercury and silver as well as "emerging contaminants" such as endocrine-disrupting chemicals and pharmaceuticals for which EPA states that it and regulated publicly owned treatment works (POTWs) have little data. EPA is attempting to quantify this data and to review available treatment, pollution prevention and process issues for possible regulation. In addition, EPA could presumably look at its CWA 403 "pass-through" authority as a starting point for assessing possible regulatory approaches.

Drinking Water

On the drinking water side, EPA has authority under the SDWA to list "candidate contaminants" on the CCL list (noted above), which coincidentally was open for public comment when the AP story broke. In simple terms, if a constituent is listed on the CCL, it becomes part of a structured study process to determine if there is sufficient human health risk to warrant regulating the constituent in public drinking water supplies by limiting allowable levels and requiring treatment and monitoring to assure safe levels. EPA could also use its "unregulated contaminant" monitoring program under the SDWA to require drinking water utilities to collect data for further definition and assessment of the issue.

Both EPA and the utility testimony at the April 15, 2008 EPW Subcommittee hearing summarized the lack of human health risk presented by the available data in concluding and urging that further regulation of wastewater and drinking water utilities is not warranted given other, higher priority risks.

Conclusion and Implications

The CWA and SDWA regulatory programs for controlling the presence of constituents in surface and drinking water are based on robust data collection and assessment protocols and evaluations of risk to human health and, under the CWA, the environment. EPA, wastewater utilities and drinking water utilities are all of the view that the best current science indicates the emerging contaminants issue is not a priority for regulation based on risk of harm. Time will tell as to whether media and political attention drive a different outcome. (K. Hanson/R. Davis)