

# CLIENT ALERT



April 17, 2009

**Authors:**

**Mark N. Duvall**

1350 I Street, N.W.  
Suite 700  
Washington, DC 20005  
(202) 789-6090  
mduvall@bdlaw.com

**Linda Tsang**

1350 I Street, N.W.  
Suite 700  
Washington, DC 20005

For more information  
about our firm, please visit  
[www.bdlaw.com](http://www.bdlaw.com)

If you do not wish to  
receive future Client Alerts,  
please send an e-mail to:  
[jmilitano@bdlaw.com](mailto:jmilitano@bdlaw.com)

## THE ROAD AHEAD FOR FDA: CHANGES IN LEADERSHIP AND CHALLENGES

On March 14, 2009, President Obama nominated former New York City Health Commissioner Margaret Hamburg as his new Food and Drug Administration (“FDA”) Commissioner and appointed Baltimore City Health Commissioner Joshua Sharfstein as FDA Deputy Commissioner. Once confirmed, the FDA Commissioner nominee Dr. Hamburg will have to address food and drug issues inherited from the prior FDA leadership while rebuilding the public trust and raising health and safety standards. FDA has faced inadequate funding and declining public confidence from recent food-borne illnesses such as peanut products contaminated with salmonella and drug controversies.

In addition to the nominations, President Obama announced the creation of a Food Safety Working Group to reassess and upgrade the federal food safety laws. Chaired by the Secretaries of Health and Human Services and the Department of Agriculture, this Food Safety Working Group will advise President Obama on improving enforcement and coordination across federal agencies and revising food safety laws.<sup>1</sup>

Some in the pharmaceutical industry and health care organizations, and some members of Congress are pushing to change FDA’s structure, management, and enforcement authority in an effort to tackle food and drug safety challenges. In addition to those well-publicized challenges, FDA faces questions about its handling of two chemicals widely used in FDA-regulated products, bisphenol A and phthalates.

### BACKGROUND ON THE FDA COMMISSIONER NOMINEE AND DEPUTY COMMISSIONER

Dr. Hamburg’s career has focused on public health, bioterrorism defense, and disease control. Dr. Hamburg is currently the Senior Scientist for the Nuclear Threat Initiative (“NTI”). According to the White House press release, before joining NTI, she was the Assistant Secretary for Planning and Evaluation, Department of Health and Human Services. Prior to this, she served for six years as the Commissioner of Health for the New York City and as the Assistant Director of the National Institute of Allergy and Infectious Diseases. As Health Commissioner for New York City, she developed innovative programs for boosting childhood immunization rates and controlling the spread of tuberculosis and AIDS. The pharmaceutical industry has praised the selection of Dr. Hamburg. The Senate has not started the confirmation process for Dr. Hamburg.

---

<sup>1</sup> Press Release, Office of the Press Secretary, The White House, President Barack Obama Announces Key FDA Appointments and Tougher Food Safety Measures (March 14, 2009), available at [http://www.whitehouse.gov/the\\_press\\_office/weekly-address-president-barack-obama-announces-key-fda-appointments-and-tougher-food-safety-measures](http://www.whitehouse.gov/the_press_office/weekly-address-president-barack-obama-announces-key-fda-appointments-and-tougher-food-safety-measures).

Dr. Sharfstein is currently the FDA Acting Commissioner until a permanent Commissioner is confirmed by the Senate. His position as Deputy Commissioner does not require Senate confirmation. Prior to his recent position at FDA, Dr. Sharfstein was the Commissioner of Health for Baltimore City. Dr. Sharfstein has led efforts to eliminate lead hazard from children's jewelry, increase immunization of healthcare workers, expand access to substance abuse treatment, and improve oversight of children's medications. Dr. Sharfstein, who has previously criticized pharmaceutical companies, successfully petitioned FDA in March 2007 to restrict the use of over-the-counter cough-and-cold medications. That petition led to the voluntary recall by manufacturers of those products. In January 2008, FDA issued a Public Health Advisory recommending that these products not be used in children under the age of two because of the risk of serious and potentially life-threatening side effects.<sup>2</sup> Dr. Sharfstein has also been a proponent of drugs such as buprenorphine to treat heroin addiction and vaccines for children.

Dr. Sharfstein also worked for several years on Capitol Hill for Rep. Henry Waxman (D-CA) on health policy issues, tobacco control, and FDA oversight. As an investigator on Rep. Waxman's previous House Committee on Government Reform and Oversight, Dr. Sharfstein worked on giving FDA regulatory control over tobacco products. In March 2009, Rep. Waxman introduced a bill, H.R. 1256, that would grant FDA the authority to reject new tobacco products, restrict tobacco advertising, eliminate additives, regulate nicotine levels, and prohibit terms like "light" and "mild" in product descriptions.<sup>3</sup> On April 2, 2009, H.R. 1256 passed the House with a vote of 298 to 112 and is now in the Senate.

#### Legislation that Would Address FDA Management Structure and Recall Powers

Members of Congress are considering splitting FDA into two separate agencies, one for food safety and one for drugs and medical devices. Rep. Rosa DeLauro (D-CT) has introduced legislation (H.R. 875) that would separately regulate drugs and medical devices under a new entity, the Federal Drug and Device Administration, and transfer FDA's food safety responsibilities to a separate entity, the Food Safety Administration, that would have additional authority and responsibility to order product recalls and increase food inspections.<sup>4</sup>

Currently, FDA does not have the authority to order a recall of a food or dietary supplement, with the exception of infant formula. FDA is seeking the power to issue mandatory recalls of food products through dialogue with the Department of Health and Human Services and Congress. In March 2009, Steven Solomon, Assistant Commissioner for FDA Compliance Policy, testified before the House Subcommittee on Regulations and Healthcare of the House Committee on Small Business on how FDA currently manages food product recalls and the need for expanded enforcement powers.<sup>5</sup>

---

<sup>2</sup> FDA, Public Health Advisory, Nonprescription Cough and Cold Medicine Use in Children (Jan. 17, 2008), available at [http://www.fda.gov/CDER/drug/advisory/cough\\_cold\\_2008.htm](http://www.fda.gov/CDER/drug/advisory/cough_cold_2008.htm).

<sup>3</sup> Family Smoking Prevention and Tobacco Control Act, H.R. 1256, 111th Cong. (2009), available at <http://thomas.loc.gov/cgi-bin/query/z?c111:H.R.1256>:

<sup>4</sup> Food Safety Modernization Act of 2009, H.R. 875, 111th Cong. (2009), available at <http://thomas.loc.gov/cgi-bin/query/z?c111:H.R.875>:

<sup>5</sup> Testimony of Steven M. Solomon, Assistant Commissioner for Compliance Policy, FDA Office of Regulatory Affairs before House Subcommittee on Regulations and Healthcare of the House Committee on Small Business (March 11, 2009), available at <http://www.fda.gov/ola/2009/recalls031109.html>.

In addition to H.R. 875, there are five other bills introduced in 2009 that would expand FDA's enforcement authority to include mandatory food product recalls. S. 510, introduced by Senator Richard Durbin (D-IL),<sup>6</sup> H.R. 1332, introduced by Representative Jim Costa (D-CA),<sup>7</sup> and H.R. 999, introduced by Representative Peter Roskam (R-IL),<sup>8</sup> include provisions that would give FDA the authority to issue a mandatory recall of adulterated or misbranded food products that may cause serious adverse health consequences if the producer refuses to recall voluntarily the food product. A bill introduced by Representative John Dingell (D-MI), H.R. 759, would expand FDA's recall authority for both adulterated food products and drugs.<sup>9</sup> H.R. 841, "Protect Consumers Act of 2009," introduced by Representative Betty Sutton (D-OH), proposes the most expansive mandatory recall authority of the proposed bills. Under that bill, the Secretary of Health and Human Services would have the authority to implement a mandatory recall of any product regulated by FDA if she "determines that it is necessary."<sup>10</sup>

## BISPHENOL A

The new FDA Commissioner will have to address the increasing public and scientific attention that has been focused on exposure to bisphenol A ("BPA") from food-contact materials. As indicated in a previous client alert, [available here](#), FDA maintained in a draft report in October 2008 that products containing BPA are safe at current levels of exposure. However, an FDA Science Board subcommittee said that the FDA's assessment was inadequate.

Since then, FDA has been reviewing its previous assessments of BPA and devising new studies. On January 30, 2009, FDA and Health Canada's Health Products and Food Branch held a meeting of representatives of U.S. and Canadian manufacturers and users of food packaging materials to discuss current efforts to help minimize the levels of BPA in food.<sup>11</sup> At the FDA Science Board meeting on February 24, 2009, FDA provided its Science Board with an update on the agency's safety review of BPA.<sup>12</sup> FDA is currently analyzing and conducting a series of studies to determine how the chemical affects babies and whether current levels found in medical devices, such as in dental products, are safe. For more information BPA, see our client alert "Bisphenol A Ban Proposals Proliferate" [here](#).

## PHTHALATES

The renewed attention on phthalates resulting from the Consumer Product Safety Improvement Act of 2008, which bans certain phthalates in children's toys and

---

<sup>6</sup> FDA Food Safety Modernization Act, S. 510, 111th Cong. (2009), available at <http://thomas.loc.gov/cgi-bin/query/z?c111:S.510>:

<sup>7</sup> Safe Food Enforcement, Assessment, Standards, and Targeting Act of 2009, H.R. 1332, 111th Cong. (2009), available at <http://thomas.loc.gov/cgi-bin/query/z?c111:H.R.1332>:

<sup>8</sup> Keeping America's Food Safe Act of 2009, H.R. 999, 111th Cong. (2009), available at <http://thomas.loc.gov/cgi-bin/query/z?c111:H.R.999>:

<sup>9</sup> Food and Drug Administration Globalization Act of 2009, H.R. 759, 111th Cong. (2009), available at <http://thomas.loc.gov/cgi-bin/query/z?c111:H.R.759>:

<sup>10</sup> Protect Consumers Act of 2009, H.R. 841, 111th Cong. (2009), available at <http://thomas.loc.gov/cgi-bin/query/z?c111:H.R.841>:

<sup>11</sup> FDA Statement: Regulatory Meeting with Manufacturers and Users of Bisphenol A-containing Materials (Feb. 9, 2009), available at <http://www.fda.gov/bbs/topics/NEWS/2009/NEW01955.html>.

<sup>12</sup> For more information regarding FDA's update on BPA to the Science Board, see the FDA Science Board Meeting Transcript (Feb. 24, 2009), available at <http://www.fda.gov/ohrms/dockets/ac/oc09.html#ScienceBoard>.

products above a threshold level, will bring additional pressure on FDA to address phthalates in medical devices and cosmetics. Phthalates are primarily used as plasticizers in polyvinyl chloride (“PVC”) and polyvinylidene chloride (“PVDC”) polymers to increase their flexibility. Di-(2-ethylhexyl) phthalate (“DEHP”) is used to produce flexible versions of PVC and PVDC polymers for medical devices such as IV bags and tubing, catheters, respiratory tubing, and nutrition feeding bags.

FDA has studied the health effects from exposure to medical devices that use DEHP. In 2002, FDA issued a public health notification that warned that certain high risk patients may be harmed by DEHP exposure from vinyl medical devices and recommended the use of alternatives in high risk circumstances.<sup>13</sup> In 2006, the National Toxicology Program concluded that certain intensive medical treatments of male infants may result in DEHP exposures levels that affect development of the male reproductive tract.<sup>14</sup>

Unsatisfied with FDA’s effort to regulate DEHP in medical devices, in 2007, Health Care Without Harm, a coalition of hospitals and health care providers, petitioned FDA to require labeling of medical devices containing DEHP so that health care providers know whether the device that they are choosing or buying contains the chemical.<sup>15</sup> Under 21 C.F.R. § 10.30(e)(2), FDA is required to respond to a citizen petition within 180 days but FDA has not issued a response.

FDA has not changed its assessment that DEHP does not require further regulation. In June 2008, Dr. Norris Alderson, Associate FDA Commissioner for Science, testified before the House Subcommittee on Commerce, Trade and Consumer Protection of the House Committee on Energy and Commerce to the health effects of DEHP in medical devices. Dr. Alderson stated:

While toxic and carcinogenic effects of DEHP have been demonstrated in laboratory animals, there are no studies in humans that are adequate to serve as the basis for regulatory decision-making. Further, health care providers should not avoid performing certain medical procedures simply because of the possibility of health risks associated with DEHP exposure. In these cases, the risk of not doing a needed procedure is far greater than the risk associated with exposure to DEHP.<sup>16</sup>

Phthalates are also widely used in cosmetics, serving as solvents for fragrances, antifoaming and suspension agents, skin emollients, and plasticizers in nail products. FDA does not believe that phthalates in cosmetics pose a health risk but is planning a more extensive survey of a larger number of cosmetic products to better determine to what extent cosmetic products contribute to total human exposure to phthalates.<sup>17</sup>

---

<sup>13</sup> FDA Public Health Notification: PVC Devices Containing the Plasticizer DEHP (July 12, 2002), available at <http://www.fda.gov/cdrh/safety/dehp.html>.

<sup>14</sup> National Toxicology Program, Center for the Evaluation of Risks to Human Reproduction, “NTP Brief on the Potential Human Reproductive and Developmental Effects of Di(2-ethylhexyl) Phthalate (DEHP)” (May 2006), available at <http://cerhr.niehs.nih.gov/chemicals/dehp/DEHP%20Brief%20Draft1.pdf>.

<sup>15</sup> Healthcare Without Harm, Citizen Petition for a Food and Drug Administration Regulation or Guideline to Label Medical Devices That Leach DEHP Plasticizers (July 24, 2007), available at <http://www.noharm.org/details.cfm?ID=1660&type=document>.

<sup>16</sup> Testimony of Norris Alderson, Associate FDA Commissioner for Science, FDA Associate Commissioner for Science, before House Subcommittee on Commerce, Trade and Consumer Protection of the House Committee on Energy And Commerce (June 10, 2008), available at <http://www.fda.gov/ola/2008/BPA061008.html>.

<sup>17</sup> Id.

In light of the change in leadership at FDA with Commissioner nominee Hamburg and Deputy Commissioner Sharfstein, companies should expect the potential for a significant shift from the previous FDA policies, practices, and enforcement of the Bush Administration.

\* \* \* \*

For more information, please contact Mark Duvall ([mduvall@bdlaw.com](mailto:mduvall@bdlaw.com)). Linda Tsang assisted in the preparation of this article.

**Office Locations:**

Washington, DC

Maryland

New York

New Jersey

Massachusetts

Texas

California