New and persisting drug shortages of critical pediatric drugs are routinely impacting the care of children. The next administration should prioritize action to prevent and mitigate drug shortages and protect child health. Absent new legislative solutions, FDA must work within its existing authorities to proactively respond to potential shortages to ensure that patients have the therapies they need.

High and rising costs of drugs and devices. In recent years, the high and rising costs of drugs and devices have caused financial hardship for families. Every child’s health and safety is of equal importance, and no parent should have to worry about how to pay for access to life-saving medications. Urgent solutions to the skyrocketing price of drugs are needed. The next administration should act quickly to convene stakeholders including families, doctors, manufacturers, distributors, payers and government agencies like the FDA to develop and implement solutions to the high and rising cost of drugs and devices for families.

Data and labeling for drugs used during pregnancy and lactation. Each year, almost four million women in the United States give birth and 75 percent of them breastfeed their infants. There are 73.7 million women of childbearing age in the United States, and nearly all of these women will take a medication or receive a vaccine during pregnancy. Yet, not enough is known about the effect of most drugs on a woman and her pregnancy, or the ways in which pregnancy may alter the uptake, metabolism, and effect of medication. As more women with chronic diseases such as diabetes, hypertension, depression, and asthma are becoming pregnant, safe and effective medications to manage these ongoing conditions throughout their pregnancy and beyond are needed. The next administration should expand efforts to generate data for use in improving the labeling of drugs and biologics with respect to their safety and efficacy during pregnancy and lactation. FDA should work collaboratively with other federal agencies to promote a coordinated strategy that will advance clinical data about drugs and biologics used during pregnancy and lactation.

Pediatric device labeling. The next administration should prioritize the development of medical devices that are appropriately labeled for children. Medical device innovation continues to lag about a decade behind that for adults. As a result, providers must use medical devices off-label, an unapproved use of a medical device. In other cases, providers must “jury-rig” devices to make them appropriate for a small and growing child. To assist with promotion of pediatric labeling of medical devices, an internal pediatric infrastructure to promote and provide consultation on pediatric medical device labeling within FDA is needed.
Regulate tobacco products. The administration must prioritize FDA’s newly instituted authority to regulate all tobacco products, including e-cigarettes and cigars. As such, it must develop new regulations to restrict the sale and marketing of tobacco products to children. It must guarantee (using appropriate scientific evidence) that any e-cigarette products allowed on the market will benefit the public health and will not be attractive to non-smokers and adolescents. The agency must take quick action to prohibit candy flavors in all tobacco products (including e-cigarettes and cigars) and should immediately prohibit menthol in cigarettes. FDA should also develop companion regulations to the Consumer Product Safety Commission’s current authority to require child-resistant packaging of liquid nicotine used to refill e-cigarettes. Finally, FDA should publish a new rule establishing graphic cigarette warning labels as required by law.

Provide accurate information about nutrition. Foods high in sodium can contribute to higher blood pressure in children and adolescents, which is a risk factor for health challenges like obesity and cardiovascular disease. Foods high in sodium are also incredibly common in the diets of children and adolescents. The next administration should continue the progress made to update the nutrition facts label and ensure the final rules are fully implemented and enforced. Similarly, the next administration should move forward with finalizing the voluntary, phased-in targets for industry intended to help Americans gradually reduce their sodium intake.

Reduce child caffeine intake. Caffeine and other stimulant substances contained in energy drinks have no place in the diet of children and adolescents. Furthermore, frequent or excessive intake of caloric sports drinks can substantially increase the risk for overweight or obesity in children and adolescents. The inappropriate marketing to children and consumption by children of beverages, foods, or dietary supplements (including sports and energy drinks and powdered caffeine) is a major public health concern that should be addressed by the next administration. The next administration should take stronger action to reduce consumption of caffeine by our nation’s children.

Take aggressive action to combat antibiotic resistance. Overuse of antibiotics in food animal production is a dire public health problem. Approximately 80 percent of the overall tonnage of antimicrobial agents sold in the United States in 2012 was for animal use, and approximately 60 percent of those agents are considered important for human medicine. Most of the use involves the addition of low doses of antimicrobial agents to the feed of healthy animals over prolonged periods to promote growth and increase feed efficiency, or at a range of doses to prevent disease. These nontherapeutic uses contribute to resistance and create new health dangers for humans. FDA has implemented voluntary programs to incentivize animal antibiotic manufacturers to discontinue growth promotion use of antibiotics in agriculture. FDA should promulgate regulations prohibiting even disease prevention uses of medically important antibiotics, as recommended by the Preservation of Antibiotics for Medical Treatment Act (H.R. 1552 in the 114th Congress).

Recommended Congressional Actions

Strengthen BPCA and PREA. Congress should continue to build on the success of BPCA and PREA by making legislative changes to improve the programs. To ensure that the pediatric study requirements apply to innovative, targeted therapies—like those developed for cancer—PREA must be amended to lift the orphan drug exemption and to allow FDA to require studies of a drug if the drug’s molecular target is relevant in a pediatric disease. Congress must also add transparency to the programs, encourage earlier pediatric study of drugs for serious and life-threatening diseases, and ensure that pediatric study requirements are completed in a timely manner.

Over-the-counter monograph reform. Congress should enact legislation to reform and streamline the current monograph system for regulating old, grandfathered over-the-counter (OTC) drugs so that FDA can act quickly to respond to new and existing information about safety and efficacy concerns. A reformed system should give FDA the authority to address gaps in data on safety and efficacy and to facilitate innovations that protect public health. Congress must establish a new user fee program to provide greater certainty to industry and support the ability of FDA to address public health needs.

Pediatric Device Consortia Program reauthorization. Congress should reauthorize the FDA Pediatric Device Consortia (PDC) Program. The PDC Program has assisted more than 650 device innovators on more than 770 would-be pediatric device projects since the program’s inception in 2009. In fact, there are seven new devices available for children as a result of the program.

Pediatric Humanitarian Device Exemption incentive. Congress should reauthorize the pediatric Humanitarian Device Exemption (HDE) incentive that allows manufacturers of pediatric HDEs that are approved by FDA to make a profit on the sale of those devices.

Promise for Antibiotics and Therapeutics for Health (PATH) Act. Congress should enact legislation to establish a new, limited population antibacterial drug approval pathway through FDA for antibiotics to treat serious or life-threatening infections for which there exists an unmet medical need. Antibiotic resistance remains a serious patient safety, public health, and national security concern, particularly for children. Unfortunately, antibiotic development has dwindled, with many pharmaceutical companies leaving this market. One key reason has been the lack of a clear, feasible regulatory pathway for FDA approval of a new antibiotic for some of the most serious infections caused by multidrug-resistant (MDR) pathogens. Congress should enact legislation that provides for the limited pathway, and also help guide the appropriate use of antibiotics approved under this new pathway.

Antibiotics resistance legislation. Congress should pass PAMTA, which requires a drug manufacturer applying for approval of a new animal drug that is a medically important antimicrobial to
demonstrate that there is a reasonable certainty of no harm to human health from antimicrobial resistance attributable to the nontherapeutic use of the drug. PAMTA would also begin to address the antibiotic resistance crisis by prohibiting a medically important antimicrobial from being administered to a food-producing animal for disease control unless there is a significant risk that a disease or infection present on the premises will be transmitted to the animal.

**Funding Priorities**

**Pediatric Device Consortia Program.** The PDC Program should be funded at its fully authorized level, which will allow the program to support additional consortia and, in turn, more pediatric device projects.

**Implementation of Food Safety Modernization Act.** Foodborne illness is a preventable public health threat. Children are particularly vulnerable to the pathogens that cause foodborne illness, and are at unique risk of severe infection and more serious outcomes. The 2011 Food Safety Modernization Act (FSMA) was a once-in-a-generation overhaul of FDA’s authorities to prevent foodborne illness before it happens, rather than reacting after children and others have been sickened. However, without adequate funding for all of the requirements of the law, FSMA’s protections will remain theoretical. FDA needs to fill a budget gap of approximately $172 million in order to fully implement the law. We urge Congress to close this budget gap so that FDA may implement FSMA as intended.

**About this Document**

*This document is an excerpt from* Blueprint for Children: How the Next President Can Build a Foundation for a Healthy Future ([http://aap.org/blueprint](http://aap.org/blueprint)), which was produced by the American Academy of Pediatrics in September 2016 and has also been endorsed by the following organizations: the Academic Pediatric Association, the American Pediatric Society, America’s Promise Alliance, the Association of Medical School Pediatric Department Chairs, Family Voices, the National Association of Pediatric Nurse Practitioners, the Pediatric Policy Council, the Society for Adolescent Health and Medicine, the Society for Pediatric Research and ZERO TO THREE.