September 6, 2012

The Honorable Margaret Hamburg, MD
Commissioner
Food and Drug Administration
Division of Dockets Management (HFA–305)
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

Docket No. FDA–2012–D–0384

Dear Dr. Hamburg:

On behalf of the American Academy of Pediatrics (AAP), a professional organization of 62,000 primary care pediatricians, pediatric medical subspecialists, and pediatric surgical specialists dedicated to the health, safety, and well-being of infants, children, adolescents, and young adults, we appreciate this opportunity to provide comments regarding the draft guidance on pediatric information for x-ray imaging device premarket notification. We would also like to thank you for allowing the AAP to speak at the recent public workshop on the draft guidance. The AAP values the longstanding relationship we have had with the Food and Drug Administration (FDA) on a range of pediatric issues, including the Best Pharmaceuticals for Children Act and the Pediatric Research Equity Act, and we thank you for this important step in the promotion of radiation protection for children. As you know, children are not small adults. Radiation risk in children warrants special attention because children are more radiosensitive than adults, have a longer expected lifetime for effects of radiation exposure to manifest, and are often treated with equipment and exposure settings designed for adults, which can result in excessive radiation exposure for smaller patients. Additionally, many children receive treatment from facilities that lack pediatric imaging expertise.

The AAP is encouraged that the draft guidance offers voluntary guidelines for manufacturers regarding documentation of design features and risk mitigation strategies, specifications for pediatric protocols and settings, laboratory tests for dosimetry and image quality, instructions and educational materials directed to technologists, radiologists, physicists, and other imaging professionals, and the means by which individual facilities can contact the sponsor for assistance when developing pediatric dose reduction protocols and procedures.
The AAP agrees that optimizing imaging equipment - maximizing image quality, while minimizing radiation dose - is important for all ages, but it is particularly important in pediatric patients. Improvements in the hardware and software for optimization are important, as is the accessibility of training manuals for the appropriate use of equipment for pediatric patients. Training and education of the end-users need to be understandable to all those involved in imaging and must be easily accessed.

As most pediatric imaging is conducted primarily in adult facilities, equipment manufacturers should assume that their equipment will be used both for children and adults. Children’s body size varies from the premature infant to the obese adolescent and covers the spectrum of adult body size. Devices optimized for pediatric use therefore can be appropriate for the adult population as well. As such, we support FDA efforts that promote equipment modifications that optimize radiation dose for patients of all body sizes, standardization of nomenclature, and reduction of technique variables.

Education of the end-users on optimization is important during the initial installation of the equipment, as well as on a continuing basis. Learning the dose optimization of patients of all body sizes will benefit both adult and pediatric patients. These educational materials should be easily accessible, on-line, and open source for all purchasers.

There are a few areas where further consideration and clarification may be necessary in order to prevent unintended consequences. For example, the draft guidance proposes that manufacturers label equipment with a warning not to use on children below a certain height or weight. The AAP is concerned that this could limit the choice of imaging equipment available for centers that work primarily with pediatric patients. Similarly, we are concerned about whether it would limit the ability of adult centers to provide pediatric imaging. Accessibility to imaging for all children is as important as the optimization of available equipment.

Children already face fewer medical treatment options and many medical technology advances for adults simply are not available to children due to their relatively smaller market share, cost of production, and liability and ethical considerations. As such, the draft guidance should take care to balance safety and dose optimization for pediatric patients with costs to manufacturers so that children do not face even fewer options. Off-label use of medical technologies is an unfortunate, but necessary, standard of care in pediatrics. As the FDA finalizes the draft guidance, careful attention should be paid to the unintended consequence of increasing, rather than decreasing, off-label use of imaging devices in children.

The AAP agrees with the FDA that standardized dose information for pediatric patients is the ideal. However, real questions exist about the evidence base for measuring such a standardized dose. Similarly, the goal of radiation equipment that displays patient dose or dose index is a good one, but how would accuracy be assured and are there quality assurance tools to track radiation
dose management? More research is needed to better understand and measure dose optimization. The AAP encourages the Agency to pursue this needed investment and we would welcome the opportunity to pursue this further with the Agency.

The AAP strongly encourages the FDA to clarify how the guidance affects the use of “home grown” pediatric positioning aids that are not included in the vendor’s 510(k) application but are developed by the end user. While we would be concerned if such a modification caused a device to be unsafe or caused injury to a child, these types of end-user modifications can be critical to the care we give our patients. Further clarification on their use in the final guidance document would be helpful.

The AAP applauds the FDA for this thoughtful initiative to protect unnecessary exposure to radiation in children. We are grateful for the opportunity to comment on the draft guidance. If the AAP can be of further assistance, please do not hesitate to contact Tamar Magarik Haro in AAP’s Department of Federal Affairs at 202-347-8600.

Sincerely,

Robert W. Block, MD, FAAP

President

RWB/bd