



AMERICAN ACADEMY OF
ORTHOPAEDIC SURGEONS

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August 4, 2015

Stephen Ostroff, MD
Acting FDA Commissioner
Food and Drug Administration (FDA)
10903 New Hampshire Ave.
Silver Spring, MD 20993

RE: Docket No. FDA-2015-D-1376

Dear Dr. Ostroff,

On behalf of more than 18,000 board-certified orthopaedic surgeons, the American Academy of Orthopaedic Surgeons (AAOS/Academy) welcomes the opportunity to comment on the draft guidance “Leveraging Existing Clinical Data for Extrapolation to Pediatric Uses of Medical Devices.” AAOS champions the interests of patients by improving treatment options through education and research. We are dedicated to the development of sound federal health care policy that fosters patient access to the highest quality orthopaedic care. AAOS is committed to keeping the world in motion through the prevention and treatment of musculoskeletal conditions.

AAOS supports the FDA’s ongoing efforts to make device regulation clearer and more predictable. We believe these improvements will stimulate a medical device development environment that promotes collaboration and ultimately benefits patients. We appreciate the inclusion of examples to aid surgeons in their understanding of how this guidance may be implemented by manufacturers and the Agency.

This guidance and others recently released addressing patient preference and risk-benefit determinations set a patient-focused tone for the regulation of medical devices. With support from standards and post-market data, we believe this approach can greatly accelerate access to treatments for pediatric populations.

AAOS members actively engage in the creation and maintenance of standards for orthopaedic products. Existing standards should be assessed for any necessary changes in the context of expanding extrapolation to safety data. New standards may be needed to inform testing and applications of materials in pediatric populations.

We would like to again encourage FDA to review the definition of “pediatric patients” as described in section 520(m)(6)(E)(i) of the Federal Food, Drug, and Cosmetic Act. While chronological age may be the most functional descriptor of maturity for many therapeutic considerations, we believe that it should not be the only factor used when assessing skeletal maturity. We encourage the FDA to consider options to expand this definition to include radiographic, anthropometric, and other measures of skeletal maturity when determining the intended treatment population for orthopaedic devices.



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AAOS looks forward to the final guidance. Each time data can be extrapolated and applied to pediatric populations is one more opportunity to help parents make more informed decisions about their children's care. This guidance will also help to reduce the number of children and adolescents enrolled in clinical trials.

AAOS thanks the FDA for considering our suggestions and hearing our concerns. We look forward to working with the FDA and other stakeholders to continue to advance the science of orthopaedic care and continuously improve patient safety and outcomes.

Sincerely,

A handwritten signature in black ink that reads "David Teuscher MD". The signature is written in a cursive style with a large initial 'D'.

David Teuscher, MD

President, American Academy of Orthopaedic Surgeons