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## **Bioethics Position Statement: Pediatric Medicine and Device Clinical Development**

When a medicine or device is studied and approved specifically for use in adults, the risk-benefit profile for children is relatively unknown. Therefore, when it can be reasonably anticipated that an Eli Lilly and Company medicine or device may be frequently prescribed for a specific pediatric illness or condition, Lilly believes it is appropriate and may even be necessary to investigate such uses via clinical studies. Specifically, Lilly pediatric clinical research is conducted to assess whether children with specific diseases could safely benefit from Lilly medicines or devices. The ultimate goals for conducting pediatric clinical studies are 1) to provide potential treatment benefit for the individual pediatric patients enrolled in the studies and 2) to potentially help other children with the same illness or condition by publicly disclosing the research results and, when medically appropriate, incorporating the study results into product labeling.

Lilly considers potential pediatric uses of its medicines and devices early in clinical development. Thus, when appropriate, pediatric research is integrated into the overall clinical development program. Important considerations in Lilly's planning for a potential pediatric medicine or device are the seriousness of the illness or condition, the unmet medical need, and the availability of approved pediatric treatments. Ultimately, Lilly will determine the extent and timing of any pediatric clinical studies based upon discussions with regulatory agencies.

Lilly ensures special protections are in place whenever children are involved in research. Children must not be placed at a disadvantage by being enrolled in research, either through exposure to excessive risks or by failing to receive necessary health care. In addition, the risks to an individual child generally must be minimal, except in special circumstances that are defined by local regulations. Therefore, Lilly enrolls children in a clinical study only if 1) it is scientifically necessary, and 2) there are sound reasons to anticipate a favorable balance of benefit to risk—both for the individual child and for the pediatric patient population with the disease.

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