

Addendum to Pediatric Priorities

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Addendum

PEDIATRIC PRIORITIES: LEGISLATIVE AND REGULATORY INITIATIVES TO EXPAND RESEARCH ON THE USE OF MEDICINES IN PEDIATRIC PATIENTS

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After this article was set for printing there was a significant development in the Ass'n of American Physicians and Surgeons case. As noted in the article, there was a December 16, 2002 deadline for the government to file a notice of appeal from the court's ruling invalidating the Pediatric Rule. Prior to that deadline, the American Academy of Pediatrics and the Elizabeth Glaser Pediatric AIDS Foundation filed a motion to intervene in the case. These groups explained that they wished to intervene in order to file an appeal should the government ultimately elect not to appeal. On December 13, 2002, the court granted the motion to intervene and the American Academy of Pediatrics and the Elizabeth Glaser Pediatric AIDS Foundation became Intervenor-Defendants in the case. On December 16, 2002, the government announced that it would not file an appeal, and instead would pursue legislation to provide FDA with new statutory authority to require pediatric studies in certain circumstances. That same day, the intervenors filed a notice of appeal. It remains to be seen whether the appeal will be able to move forward given that the government elected not to appeal. It also remains to be seen whether any legislation will pass that might moot the case.

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