

PENN STATE



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The College of Medicine

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Division of Nephrology and Hypertension

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Docket Management Branch (HFA-305)
Food and Drug Administration
5630 Fisher's Lane
Room 1061
Rockville, MD 20857

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RE: THE PEDIATRIC RULE

Dennis Ebright, MSW, CNSW
Nephrology Social Worker
dgebright@psu.edu

Dear Sirs:

Veronica Parkhill
Staff Assistant
vparkhill@psu.edu

I am writing to support the continuation of the PEDIATRIC RULE. This is vital to the appropriate practice of pediatrics and pediatric therapeutics. PEDIATRIC RULE insures that children are no longer a therapeutic afterthought by the pharmaceutical industry. Waving this rule allows the pharmaceutical industry to avoid performing studies on this important part of our population. I should note that the PEDIATRIC RULE includes biological products in addition to the drugs and without this rule there is no mechanism to assure that pediatric studies are conducted on these important medications. The PEDIATRIC RULE captures drug and age populations that the BEST PHARMACEUTICALS for CHILDREN ACT cannot. The BPCA can be applied only once during the life cycle of a drug and cannot be expanded later if additional studies are needed in very young children or newborns or if a new use is discovered for the drug. In addition, when studies have been completed and the incentive has been granted, there is no obligation on the part of the participating companies to generate additional pediatric data. I should note that the PEDIATRIC RULE is ongoing whereas the BPCA is time limited and sunsets in 2007. Finally, the PEDIATRIC RULE is mandatory while the BPCA is voluntary.

Specialists in the care of infants, children and adolescents with:

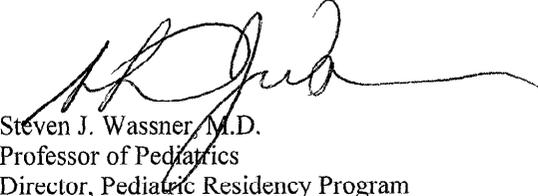
- Hematuria/Proteinuria
- Nephrotic Syndrome
- Glomerulonephritis
- Hypertension
- Renal Tubular Disorders
- Voiding Dysfunction
- Urinary Tract Infections
- Congenital Renal Malformations
- Acute and Chronic Renal Failure

For all these reasons, I strongly urge you to continue this rule in effect. Thank you for your interest.

Services Offered:

- Pediatric Nephrology Clinics at:
 - PSU Children's Hospital & Women and Babies Hosp. Lancaster, PA
 - Pediatric Dialysis Clinic
 - Voiding Dysfunction Clinic
 - Post-Renal Transplant Care
 - Renal Biopsy
 - Ambulatory Blood Pressure Monitoring
 - Renal Replacement Therapy
 - Peritoneal dialysis
 - Hemodialysis
 - Hemofiltration

Sincerely,


 Steven J. Wassner, M.D.
 Professor of Pediatrics
 Director, Pediatric Residency Program
 Vice Chairman for Education
 Chief, Division of Pediatric Nephrology and Hypertension

SJW:vp

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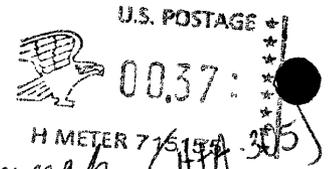
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