



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

JUL 26 2000

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The Honorable Deborah Pryce
House of Representatives
Washington, D.C. 20515-3515

Dear Ms. Pryce:

Thank you for your letter of June 9, 2000, lending your support to comments submitted to the Food and Drug Administration (FDA) by the Cancer Leadership Council regarding the pediatric exclusivity program.

FDA is committed to ensuring the proper implementation of the pediatric exclusivity provisions of the FDA Modernization Act of 1997 and the mandatory pediatric study rule. As you may be aware, we are in the process of drafting a report to Congress regarding the program, and have published a Federal Register notice (Docket Number 00N-1266) seeking public comment on the program. We will carefully consider all comments regarding implementation of the pediatric exclusivity provisions as we draft our report, and will include your comments in the public docket.

We appreciate you sharing your thoughts and comments regarding this matter. Please be assured that FDA will consider all aspects of this issue as it pertains to public health.

Thanks again for contacting us concerning this matter. If you have further questions, please let us know.

Sincerely,

Melinda K. Plaisier
Associate Commissioner
for Legislation

cc: Dockets Management Branch
(Docket No. 00N-1266)

00N-1266

C13 /ANS

Congress
of the
United States
House of Representatives

DEBORAH PRYCE
OHIO
15th DISTRICT



June 9, 2000

Jane E. Henney
Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Commissioner Henney,

I am writing to lend my support to the comments submitted to the FDA by the Cancer Leadership Council regarding the pediatric exclusivity program. For your reference, I have enclosed a copy of these comments.

As part of the Food and Drug Administration Modernization Act of 1997 (FDAMA), Congress provided an incentive to encourage greater private investment in research on the use of drugs to treat pediatric diseases. Specifically, FDAMA provides an additional six months of market exclusivity to sponsors of new or approved drugs if they conduct pediatric studies that may produce benefits for children. Unfortunately, it appears that this policy and its implementation have proven ineffective in stimulating research or providing additional information about drugs that may prove useful in treating pediatric cancer.

The Cancer Leadership Council points to a number of problems and makes some constructive suggestions about how the pediatric exclusivity program can be improved to benefit children who are diagnosed with cancer. I hope that the FDA will seriously consider these comments and use its authority to make changes where appropriate. Specifically, I encourage the FDA to reevaluate Section 111 of the Act and revisit its decision to impose a requirement that sponsors file a new drug application or supplemental new drug application, which is not required by statute. The burdens the FDA's interpretation of the law poses for drug sponsors has undermined the incentive for additional research that Congress intended to create. In addition, I strongly support greater consultation by the FDA with pediatric oncology experts in developing priorities for clinical trials and a list of priority drugs for study.

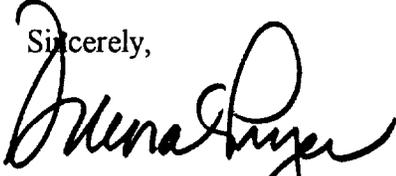
Please know that as I encourage the FDA to work on behalf of the 10,000 children who are diagnosed with cancer annually, I also stand ready to do my part as a legislator to improve upon the pediatric exclusivity policies embodied in FDAMA, specifically as they apply to pediatric cancer.



I look forward to working with you and the cancer community to develop strategies that will improve treatments toward a cure for childhood cancer.

Thank you for your consideration of these views. If I can provide additional information regarding this matter, please do not hesitate to let me know.

Sincerely,

A handwritten signature in black ink, appearing to read "Deborah Pryce". The signature is fluid and cursive, with a large initial "D" and "P".

DEBORAH PRYCE
Member of Congress