Mr. BRADY of Texas. Mr. Speaker, I am pleased to introduce the “Orphan Drug Tax Credit Act of 2001.” The purpose of this legislation is to remedy a problem that has arisen with regard to the Orphan Drug Tax Credit.

This credit, which Congress made permanent in 1996, was enacted in order to encourage biotechnology and pharmaceutical companies to develop therapies for rare diseases and conditions. The credit applies to 50% of qualified clinical trial expenses incurred with respect to drugs that are designated as “orphan” by the Food and Drug Administration (FDA).

The designation process requires a finding by the FDA that the drug under development meets the statutory definition of an “orphan,” that it is intended for treatment of a patient population of less than 200,000. Unfortunately, this process can take from two months to longer than a year. The end result, as in some cases, companies find themselves in the difficult position of either having to: (1) post-pone the start of their clinical trials until the designation is received, thereby delaying important research and patient access; (2) or beginning the research before the designation is granted, hereby increasing the cost of the product’s development. Neither choice is in the interest of the patient.

The “Orphan Drug Tax Credit of 2001” would solve this dilemma by providing that the credit would cover the costs of qualified clinical trial expenses of a designated orphan drug, regardless of whether such expenses were incurred before or after the designation was granted, provided the designation was actually received. This legislation would go into effect upon the date of enactment.

This bill passed both the House and Senate twice in the last Congress. It was included in H.R. 2488, the “Financial Freedom Act of 1999” which was vetoed by President Clinton for unrelated reasons. The provision was also included in H.R. 2990, which passed the House on October 6, 1999, and in H.R. 4577, the “Department of Labor, Health and Human Services, and Education, and Related Agencies Appropriations, 2001,” which passed the Senate on July 10, 2000. The time has arrived for us to move this legislation in final form and I am hopeful that it can be included in a tax package this year.

VACCINE INJURED CHILDREN’S COMPENSATION ACT OF 2001 (VICCA)

HON. DAVE WELDON
OF FLORIDA
IN THE HOUSE OF REPRESENTATIVES

Thursday, March 29, 2001

Mr. WELDON of Florida. Mr. Speaker, today, I am pleased to join Representative JERROLD NADLER and several other Members of Congress in introducing Vaccine Injured Children’s Compensation Act of 2001 (VICCA). Over the past year, the Vaccine Injury Compensation Program (VICPA) has been subject to several congressional hearings. I have met with parents, doctors, and attorneys who have been involved in the current program seeking compensation for injuries that resulted from vaccines. Serious vaccine injuries are, thankfully, very rare. However, some children suffer serious adverse reactions to vaccines. In a small number of cases these are very debilitating reactions. We must work aggressively to understand why some children suffer adverse reactions so that we may develop precautionary measures to reduce adverse reactions. I am a strong proponent of vaccination. I believe it is important that children be vaccinated against these devastating diseases. Widespread vaccination has and will continue to spare our nation from the scourge of epidemics. Our nation benefits from widespread vaccination. Those of us who are healthy are the beneficiaries of national vaccination efforts. As such, I believe very strongly that we as a nation have an obligation to meet the needs of those children who suffer adverse reactions.

I also believe that our federal public health officials should do more to ensure that we are