Ohio House of Representatives

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83rd House District

Sponsor Testimony
Substitute House Bill 290
Senate Health and Human Services Committee
September 27, 2016

Chair Jones, Vice Chair Lehner, Ranking Member Tavares, and members of the Senate Health and Human Services Committee, thank you for giving me the opportunity to offer sponsor testimony on Substitute House Bill 290. Substitute House Bill 290 is Ohio's Right to Try legislation.

Annually, millions of Americans suffer from a terminal illness. Although there are some alternative ways to try new treatments, access to new and potentially life-saving treatment is limited. Clinical trials are somewhat rare and qualifying to participate can be extremely difficult. The United States Food and Drug Administration offers an expanded access program, which allows terminally ill individuals to access investigational medications, but there are only about 1,000 annual participants. The program has an extensive application process that most individuals cannot successfully complete. In addition to required manufacturer paperwork, the program previously required physicians to complete an application that can take about 100 hours. Earlier this year, the United State Food and Drug Administration began trying to streamline the application process and introduced a new physician form and guidance documents. It's estimated the form can take about 45 minutes to complete, so this is a positive step in the right direction. Once all potential questions are answered, the Food and Drug Administration has up to a month to review applications. Following this step, if an application is approved by the United States Food and Drug Administration, the Institutional Review Board has to approve the application. The Institutional Review Board can also take up to thirty days to approve or deny an application. If any questions or issues arise during the process, the application can be delayed for additional weeks or months.

In response to these barriers, we introduced House Bill 290. Substitute House Bill 290 will allow Ohioans that are suffering from a terminal condition to have increased access to investigational drugs, biological products, or devices that have passed Phase I of a United States Food and Drug Administration clinical trial and are still being considered for full approval. After exhausting all approved treatment options, or if treatments are not satisfactory or comparable, treating physicians and their patients will have the opportunity to utilize an investigational drug. Before beginning treatment, the legislation requires informed consent and

treatment information to be presented to patients or individuals that are legally responsible. Furthermore, Substitute House Bill 290 provides certain protections for parties that will be involved in the treatment process.

After Representative Anielski and I received feedback on the introduced version of House Bill 290, the House Health and Aging Committee reported Substitute House Bill 290 out of committee. Substitute House Bill 290 includes the following differences from the introduced version of House Bill 290:

- The language revises the term of "terminal illness" and includes "terminal conditions" that can be longer acting than the original provision that required the illness to possibly cause death within a short period of time. These conditions include progressive musculoskeletal disorders, progressive neurological disorders, and progressive cancer.

- The substitute version requires a second physician to confirm that the patient has a terminal condition.

- Substitute House Bill 290 requires the treating physician to attest that the investigational treatment is the best chance of survival.

- Before accessing investigational medications, in the event of a clinical trial being offered in their resident or adjoining counties, patients must attempt to enter the clinical trial.

- We clarified language to ensure that participation by insurance companies is permissive.

- The bill authorizes the patient or legally responsible party to revoke therapy, at any time and in any manner.

- At the request of the Board of Pharmacy, to ensure proper handling, investigational medication will be subject to the same licensing requirements applied to approved treatments regarding possession, purchase, distribution, and sale

- The bill includes language that states nothing in the bill condones, authorizes, or approves of assisted suicide or any action that is considered mercy killing or euthanasia.

Nearly two years ago, when we started drafting the language for House Bill 290, we were only aware of four other states that were actively working on similar bills. At the time of our sponsor testimony in the House Health and Aging Committee, there were 24 states that had a Right to Try law. Currently, there are 31 states with this type of law in place. Furthermore, S.2912 and H.R.3012, implementing the national Right to Try Act, are being reviewed on the federal level. I feel that the national movement by states and federal officials to implement a Right to Try law is beginning to push the Food and Drug Administration to streamline their expanded access process and also approve medication that could be helpful to people with terminal conditions. As an example, last week, the Food and Drug Administration approved eteplirsen to treat Duchenne muscular dystrophy. The approval was against adviser panel recommendations, because there is not clear evidence whether it actually helps patients. Due to

how the Food and Drug Administration approval process is structured, the drug's risks are known; the drug's effectiveness is not confirmed.

A physician from Texas has used the state's Right to Try law to treat 78 patients with neuroendocrine, a form of cancer. The physician was conducting clinical trials on the investigational treatment, but when the trial ended, there were patients with nowhere to turn. He waited until the state's Right to Try law was effective and continued his work with patients suffering from neuroendocrine. To date, there have not been any adverse reactions. Moreover, many of his patients were given three to six months to live. Quality of life improved and many of those same patients have been alive for more than a year. Furthermore, the medication that he's been using has been used by the medical community in Europe for nearly 30 years.

This year, the American Cancer Society is predicting an estimated total of 1,685,210 new cancer cases and 595,690 cancer-related deaths. Cancer is one of many devastating terminal conditions that individuals and their families are struggling to fight.

Participation in the Right to Try process is permissive for all parties, and due to limited access to other avenues of treatment, Substitute House Bill 290 could give some Ohioans an opportunity to live another day or improve their quality of life. Representative Anielski and I heard directly from individuals that continue to look for other options, and this bill could result in those opportunities.

Thank you for your time and consideration. I am happy to answer any questions that the committee might have.