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The Ohio House of Representatives

HB 190 – Proponent Testimony on the Cure Bill, February 3rd, 2021

Chair Nelson, Vice Chair Pierucci, and Members of the House Health and Human Services Committee, thank you for this opportunity to offer proponent testimony for HB 190, commonly referred to as the "Cure Bill." The Cure Bill creates a multi-state compact that will offer future taxpayer savings as an incentive to any entity that develops a cure for a disease that would result in actual savings to state budgets.

The method and scale of the incentive created by the bill is unlike anything ever done in history. The tens of billions of dollars offered for most major diseases will change the landscape of research and development and lead to a dramatic improvement in how we live. Unlike nearly every other effort to date, the Cure Bill accomplishes this without any upfront appropriation or risk to taxpayers.

Need for the Cure Bill

Why do we need to incentivize the development of cures? The current problem is not a lack of money, but rather that it much more profitable, and safer, for pharmaceutical and biotechnology companies to develop incrementally better treatments instead of cures. The monetary incentive in our current system is so one-sided that true cures for major diseases are almost never funded for human clinical trials.

Pharmaceutical research falls under two broad umbrellas: "basic science research" and "applied science research." Basic science research starts with laboratory discoveries of new promising molecules by hundreds or thousands of experiments done in test tubes and progresses through various stages until it ends with testing in laboratory animals. Year after year, researchers dazzle us with exciting new breakthrough cures in animals in everything from cancer to blindness. However, for all the great basic science research done, and all the hope offered from multiple cures in animals, it means nothing unless human clinical trials are done that result in Federal Drug Administration (FDA) approval. Nearly all of the research for new products directly funded by the government through the National Institute of Health (a third of all funding annually) and all of the research funded through charities (six or seven percent annually) is restricted to basic science research.

In order to create a new product for human use, applied science research in human clinical trials is necessary to gain FDA approval. Non-governmental, for-profit pharmaceutical and biotechnology companies conduct nearly all human clinical trials for new products.

When pharmaceutical and biotechnology companies choose a promising molecule from the field of basic science research (completed animal studies) in which to invest millions of dollars for human clinical trials, they nearly always choose treatments for diseases instead of cures. As for-profit companies, three economic factors overwhelmingly incentivize the choice of treatments over cures.

First, developing new products is expensive and many products fail during clinical trials. Improved treatments, for example, with a slightly better efficacy, side-effect profile, or more convenient dosing, are often incremental advances built on already existing products. We see many diseases treated by three to eight very similar products.[1] This incremental approach is less likely to fail than trying to develop an entirely new product like a cure. Because of the expense in bringing new products to market, many companies choose the safer bet of an improved treatment over an entirely new cure.

Second, treatments are normally needed over a long period of time, sometimes indefinitely, and therefore generate substantially more revenue than a cure that you are only required to take for short period of time and will potentially never need again. From a business perspective, treatments ensure repeat customers, while cures, if widely available, can cause a customer not to need any product because the disease is gone and potentially eradicated worldwide. For example, a cure for HIV, if widely available and accessible, could largely eradicate the disease and eliminate the need for a patient to take multiple drugs throughout the rest their life. This results in likely problems in pricing. A treatment that someone needs to take daily for years can be priced at, say, $10 a pill, while a cure that someone takes once or over a short number of weeks would have to be priced at many multiples of that price to generate the same revenue. Many insurance companies and government payers refuse to cover products with huge price tags and fear bad publicity and public backlash even if they are willing to pay that huge price tag.

Finally, and perhaps most importantly, the development of a cure of a major disease would render the existing treatments for that disease, including any pending treatments in the pipeline, obsolete overnight. Any company that has any stake in an existing treatment that

[1] For example, proton pump inhibitors to treat acid reflux (Protonix, Nexium, Prevacid, Prolosec, Dexilant, Aciphex), non-sedating antihistamines to treat allergies (Claritin, Zyrtec, Allegra, Xyzal, Clarinex) and selective serotonin reuptake inhibitors (SSRIs) to treat depression (Prozac, Zoloft, Paxil, Celexa, Lexapro, Luvox).

is generating the company revenue would have to subtract the loss to the company from the now, no-longer-needed treatment from any potential gain from a cure.[2]

Accordingly, we need to create a new financial incentive for private companies to choose to research cures. Specifically, private companies must stand to make as much, or likely more, revenue for a cure than they do for a treatment. This bill does that – all without any upfront appropriation or ever spending any new taxpayer money.

How the Compact Works

The multi-state compact would become operational after six states enact the legislation before you. Ohio passed the bill into law in July of 2019. Once five more states join, the compact would become active and representatives of each of the founding states would meet to draft rules and choose at least ten major diseases to initially target for a cure. However, there is no limit on the number of diseases, subtypes of diseases, or milestones the Compact can add to the list. Once the initial diseases are chosen by the founding members, then the Compact, for each disease, would work with a bank that will eventually provide the up-front award when a cure is found. Each award, if claimed by an inventor of a cure, becomes a loan that is repaid only when and if the compacting states see actual savings in their budgets. States will only be required to pay real savings. If a cure does not work as projected or unforeseen side effects diminish the savings achieved, then only the savings actually realized, if any, are transferred. Accordingly, the risk lies entirely with the bank that a cure will result in the projected savings, never with the taxpayer.

The Compact would work with each bank to develop the cure criteria, or what an inventor would need to prove to claim the incentive award. After the cure criteria are developed, the actuaries from the Compact and the banks will calculate the projected dynamic five-year cost savings that the compacting states would realize after each disease were cured and the cure became widely available. Those savings would then be published as the incentive award, along with the cure criteria. At that point, any individual, organization, or company will be eligible to earn the award offered after providing a proven cure that meets the criteria, including being fully approved by the FDA if that is required.

To project net impact to state budgets, the actuaries would take into account state expenses such as state share of Medicaid (not federal), local and state employee plans, corrections, and other direct and indirect savings for each of the diseases over a five-year period. If a cure is found, the cure criteria met, and the award claimed, the bank with which the

[2] As an industry, one need only remember the long list of products mentioned in the previous footnote to envision how many products for a given disease, and much revenue, would be lost if a cure were developed instead of an additional treatment.

Compact has worked for that disease pays the award. Each year after a cure is widely available, state budgets will be analyzed, along with claims data and other actual expense data to ensure accuracy, and, if savings are achieved, the states would be required to transfer those savings (up to the projected amount) to the Compact the following year. Again, compacting states' only responsibility it to transfer actual savings that result in their budgets because of a future cure, so this bill can never cost taxpayers additional money.

In order to claim the incentive, the inventor must transfer the patent and other intellectual property necessary for the Compact to contract with a contract manufacturer to mass produce, distribute, license, and assume any liability for, the cure, and sell it to the Compacting states at cost. Other states, the federal government, and foreign governments that did not enter the Compact before a cure was discovered can still purchase the cure; however, they must pay a royalty on each dose of cure equal to their five-year savings divided by the number of projected doses needed. The royalty money is not part of the calculated award, which is only the five-year savings of the compacting states. This extra revenue pays the bank interest (which is why banks are interested in participating). The remainder, which will be the bulk of the revenue, will largely be rebated back to the compacting states to offset award payments. Thus, it is worthwhile for states to enter the compact before a cure is found because it is very likely that states in the Compact will not need to share any savings because royalty payments will be more than Compacting states' savings. Given there is no risk to taxpayers or upfront appropriation—there is nothing to lose and everything to gain for states to join the Compact.

Many prior government officials have advocated for finding cures, but all government spending, mostly allocated through the National Institute of Health, funds only basic science research for new products, which does not progress beyond animal studies. Accordingly, only by incentivizing the private sector by providing a financial reward on a scale that meets or exceeds the existing financial incentive to research treatments can cures for major diseases ever be found.

Thank you for your time and consideration of the Cure Bill. Again, I am most grateful to Rep. Thurston for his leadership on this issue and to this committee for considering the bill. If you have any questions, please do not hesitate to contact me on my cell phone at (937) 902-9737.