

**Testimony of Allan Coukell, BSc (Pharmacy)**  
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**Submitted to the Michigan State Legislature**  
**House Health Policy Committee**  
**22 May 2024**

Chair Rogers and members of the House Health Policy Committee,

Thank you for the opportunity to submit testimony related to HB 4890 and HB 5519, both of which Civica supports.

**About Civica**

Civica Inc. (Civica, Civica Rx) is a non-stock, non-profit pharmaceutical company that is developing quality, affordable insulin for the benefit of the 8 million Americans with diabetes who depend on this life-saving drug.

Civica was founded by health systems and philanthropies to address the problem of drug shortages in hospitals. Subsequently, we expanded the mission to lowering drug costs for consumers at the pharmacy counter.

**Civica Insulin**

Civica will manufacture the three insulins that account for most daily use in the United States – insulin glargine, lispro and aspart. These correspond to Lantus, Humalog and Novolog, respectively, and we expect Civica insulins to be interchangeable with those products.<sup>1</sup> We will

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<sup>1</sup> In FDA parlance, “biosimilar” is the term for the “generic” version of a biologic drug, such as insulin. Interchangeable means a biosimilar that can be substituted for the brand product without requiring a specific new prescription.

manufacture both in vials and prefilled pens and will be manufactured in our new, state-of-the-art U.S. manufacturing facility.

We are funding the cost of developing these insulins and bringing them to market through philanthropic contributions, including from leading diabetes organizations, and through a partnership with the State of California.

Civica's goal is to ensure that quality insulin is affordable to anyone who needs it, and we plan to set a recommended maximum price to the consumer of *no more*<sup>2</sup> than \$30 per vial of insulin and no more than \$55 for a box of five pen cartridges, a significant discount compared to prices charged to uninsured individuals today.

Our intent with this pricing strategy is both to offer low-priced insulin directly to consumers and to create marketplace competition that will lead other insulin manufacturers to lower their prices. (Indeed, our announced pricing is one of multiple factors that has already contributed to recent price reductions by the brand name insulin manufacturers.)<sup>3</sup> Crucially, we also aim to eliminate the pattern of high list prices and non-transparent rebates that are common in the drug supply chain, and which serve to harm consumers – especially the uninsured and anyone who must pay out of pocket based on list price at any point during the calendar year.

We know too well the stories of people forced to ration insulin because of cost, leading to devastating health consequences and painful tradeoffs between insulin and other household expenses, such as rent or food. These hardships affect the uninsured and the insured alike.

### **Michigan legislation**

Civica would welcome the opportunity to partner with the state of Michigan to ensure insulin affordability, including the potential to build an insulin manufacturing facility in the state.

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<sup>2</sup> Some pharmacies may charge less.

<sup>3</sup> Dafney, L. "Falling Insulin Prices—What Just Happened?" N Engl J Med 2023; 388:1636-1639 DOI: 10.1056/NEJMp2303279. <https://www.nejm.org/doi/pdf/10.1056/NEJMp2303279>

While vials and pre-filled pens of Civica insulin will be manufactured in our recently completed state-of-the-art U.S. aseptic fill-finish manufacturing facility, and we are prepared to provide the State of Michigan and its residents with product shipped from this facility, the drug substance – that is, the “raw” insulin that goes into the vials and pens – will be manufactured under contract for Civica by a partner company located outside the United States. We would like to bring that part of the manufacturing process back to the U.S., and if Civica were the private sector contractor selected under Chapter 8F, we would be able to do so.

We have assessed currently available and potential insulin manufacturing (i.e. biopharmaceutical microbial fermentation) capacity in the US and have determined that there is a need for more.

Such a manufacturing facility in Michigan would create 150 to 200 good paying jobs. It would supply insulin drug substance, not only for the people of Michigan, but for the entire nation. It would help to ensure the availability, quality, and affordability of insulin for the long term.

The legislation requires the insulin manufacturer to sell insulin to pharmacies without providing PBM rebates, which is consistent with our approach to insulin pricing and affordability.

In addition, the legislation also allows the state to purchase “Michigan-branded” insulin, and we welcome the potential opportunity to partner to help the state achieve that goal, similar to how other states are approaching a public-private partnership for insulin development.

Thank you for your important work on insulin affordability. I welcome any questions.

Sincerely,

Allan Coukell, BSc(Pharmacy)  
Senior Vice President for Public Policy, Civica Inc.  
President, Civica Foundation.

