

\_\_\_\_\_ moved to amend as follows:

In line 37, delete "both" and insert "all"

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In line 44, delete "and"

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In line 45, after "administration" insert ", and any other reports  
or studies that are peer-reviewed, evidence-based, available to the public  
in a medical or scientific journal or from an accredited college or  
university, not self-published by its one or more researchers or authors,  
and with all research and data used in the reports or studies identified  
and available for review.

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(c) With respect to the insurance claims, patient reports,  
food and drug administration data, and other reports or studies  
described in division (C) (1) (b) of this section, any data or  
research related to such information and any interpretation of  
that data or research that the director considers shall be peer-  
reviewed, evidence-based, available to the public in a medical  
or scientific journal or from an accredited college or  
university, not self-published by its one or more researchers or  
authors, and with all research and data used in the reports or

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studies identified and available for review. 18

(d) The director shall make known to the public any data, 19  
reports, research, or studies used when satisfying the 20  
requirements of division (C) (1) of this section, including by 21  
making the information available on the internet web site 22  
maintained by the department of health" 23

In line 51, after "health." insert "Each drug displayed on the list, 24  
or on any update of the list, shall be displayed alongside links to the 25  
data, interpretations, reports, research, and studies described in 26  
division (C) (1) of this section for that drug." 27

The motion was \_\_\_\_\_ agreed to.

## SYNOPSIS 28

**Severe adverse effects determination - data quality** 29  
**standards** 30

### **R.C. 3715.39** 31

Establishes standards for the data used by the Director in 32  
determining if a prescription drug causes severe adverse effects 33  
in greater than five per cent of the drug's users, including 34  
that the data be peer-reviewed, evidence-based, available to the 35  
public in a medical or scientific journal or from an accredited 36  
college or university, not self-published by its one or more 37  
researchers or authors, and with all research and data used in 38  
the reports or studies identified and available for review. 39

Also requires links to the foregoing data for a drug 40  
determined to cause severe adverse effects at the bill's 41

threshold and listed on the Department of Health's website to be	42
displayed on the website alongside the listed drug.	43