

Senate Bill 488

By: Senators Bethel of the 54th, Loudermilk of the 52nd and Mullis of the 53rd

A BILL TO BE ENTITLED
AN ACT

1 To amend Article 5 of Chapter 4 of Title 26 of the Official Code of Georgia Annotated,
2 relating to prescription drugs, so as to provide that a reference product license holder shall
3 have immunity from liability from claims for loss arising from the use of a biosimilar
4 biological product; to provide for definitions; to provide for applicability; to provide for
5 related matters; to repeal conflicting laws; and for other purposes.

6 BE IT ENACTED BY THE GENERAL ASSEMBLY OF GEORGIA:

7 **SECTION 1.**

8 Article 5 of Chapter 4 of Title 26 of the Official Code of Georgia Annotated, relating to
9 prescription drugs, is amended by adding new a Code section to read as follows:

10 "26-4-81.1.

11 (a) As used in this Code section, the terms 'biological product,' 'biosimilar,'
12 'interchangeable,' 'license,' and 'reference product' shall have the meanings that apply to
13 such terms under section 351 of the Public Health Service Act (42 U.S.C. 262).

14 (b) A reference product license holder and each entity marketing, selling, or distributing
15 the reference product shall be immune from liability under the laws of this state with
16 respect to all claims for loss caused by, arising out of, relating to, or resulting from the
17 administration to or the use by an individual of any biosimilar biological product, including
18 any such product that is interchangeable with the reference product. Such claims shall
19 include, but not be limited to, any claim for product liability including failure to warn,
20 design defect, or manufacturing defect and any type of breach of warranty including any
21 warranty for merchantability, fitness, or any implied or express warranty. This Code
22 section shall apply to claims for any type of loss, including:

23 (A) Death;

24 (B) Physical, mental, or emotional injury, illness, disability, or condition;

25 (C) Fear of physical, mental, or emotional injury, illness, disability, or condition,
26 including any need for medical monitoring; and

27 (D) Loss of or damage to property, including business interruption loss.

28 (c) This Code section shall not apply to a reference product license holder with respect to
29 a biosimilar biological product that is manufactured by such holder."

30

SECTION 2.

31 All laws and parts of laws in conflict with this Act are repealed.