IC 16-42-26

Chapter 26. Drugs: Investigational Drug, Biological Product, or Device

IC 16-42-26-1
Affect on clinical trial laws; availability
Sec. 1. (a) This chapter does not affect IC 5-10-8-15, IC 12-15-5-9.2, IC 27-8-25, or IC 27-13-7-20.2.
(b) This chapter does not require a manufacturer to make available any investigational drug, biological product, or device.
As added by P.L.2-2015, SEC.3.

IC 16-42-26-2
"Investigational drug, biological product, or device"
Sec. 2. As used in this chapter, "investigational drug, biological product, or device" means an investigational or experimental:
(1) drug;
(2) biological product; or
(3) medical device;
that has successfully completed Phase I of a federal Food and Drug Administration approved clinical trial, but has not been approved for general use by the federal Food and Drug Administration and remains under investigation in a clinical trial.
As added by P.L.2-2015, SEC.3.

IC 16-42-26-3
"Qualified patient"
Sec. 3. As used in this chapter, "qualified patient" means a patient who meets the requirements under IC 25-22.5-1-2.1(a).
As added by P.L.2-2015, SEC.3.

IC 16-42-26-4
Availability of investigational drug, biological product, or device
Sec. 4. (a) A manufacturer of an investigational drug, biological product, or device may make available the investigational drug, biological product, or device to a qualified patient.
(b) A manufacturer may do any of the following:
(1) Provide an investigational drug, biological product, or device to a qualified patient without receiving compensation.
(2) Require a qualified patient to pay the costs of or associated with the manufacture of the investigational drug, biological product, or device.
As added by P.L.2-2015, SEC.3.

IC 16-42-26-5
Causes of action
Sec. 5. This chapter does not create a cause of action against a manufacturer of an investigational drug, biological product, or device.

Indiana Code 2016
for any harm to a qualified patient resulting from use of an investigational drug, biological product, or device.

As added by P.L.2-2015, SEC.3.