Ohio Legislative Service Commission

Bill Analysis

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H.B. 290

131st General Assembly
(As Introduced)

Reps. Sprague and Anielski, Blessing, Dever, Grossman, Hackett, Henne, Rezabek, Romanchuk, Thompson

BILL SUMMARY

- Permits use of an investigational drug, product, or device that is still in clinical trials, and has not been approved for general use by the United States Food and Drug Administration to treat an eligible patient suffering from a terminal illness.
- Provides qualified immunity to a physician who recommends or treats an eligible patient with an investigational drug, product, or device as authorized by the bill.
- Authorizes, but does not require, the manufacturer to provide an investigational drug, product, or device to an eligible patient or the patient's treating physician.
- Provides qualified immunity to a manufacturer or terminal distributor of dangerous drugs that provides or distributes an investigational drug, product, or device as authorized by the bill.
- Provides that a terminal distributor is not subject to any action related to its license or any monetary penalty for distributing an investigational drug, product, or device as authorized by the bill.
- Authorizes health insurers to exclude coverage, other than for preexisting conditions and previously commenced benefits, for investigational drug, product, or device recipients for a period of up to six months and to exclude coverage for the cost of the drug, product, or device.

CONTENT AND OPERATION

Drugs, products, and devices that have not completed clinical trials

The bill permits an eligible patient who is suffering from a terminal illness to be treated with an investigational drug, product, or device. It defines "investigational drug, product, or device" as a drug, biological product, or medical device that has successfully completed the first phase of clinical trials required by the United States Food and Drug Administration (FDA) and remains under clinical trial but has not been approved for general use by the FDA. This does not include a schedule I controlled substance (a drug for which there is no legal use).[1]

Generally, clinical trials consist of three phases. Phase 1 trials use a small number (between 20 and 80) of healthy volunteers to try to determine dosing, document how a drug is metabolized and excreted, and identify acute side effects.

Phase 2 trials include more participants (about 100-300) who have the disease or condition that the product could treat. In Phase 2 trials, researchers seek to gather additional safety data and preliminary evidence of the drug's beneficial effects. If the Phase 2 trials indicate that the drug may be effective, and the risks are considered acceptable, the drug moves to Phase 3.

In Phase 3 trials, the drug is studied in a larger number of people with the disease (approximately 1,000-3,000). This phase further tests the product's effectiveness, monitors side effects and may compare the product's effects to a standard treatment, if one is already available.[2]

Eligibility for treatment with an investigational drug, product, or device

Terminal illness

The bill provides that to be eligible for treatment with an investigational drug, product, or device, a patient must have a terminal illness that satisfies all of the following:

(1) **Permanent** – The condition is caused by a disease, illness, or injury from which the patient is unlikely to recover if left untreated;

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[1] R.C. 4731.96(A)(2); R.C. 3719.41, not in the bill.

[2] U.S. Department of Health and Human Services, U.S. Food and Drug Administration, *Inside Clinical Trials: Testing Medical Products in People*, available at: http://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm143531.htm (last visited Oct. 9, 2015).

(2) **No approved treatment** – The condition is irreversible and incurable through a method of treatment approved by the FDA;

(3) **Limited life expectancy** – It appears that the condition is likely to cause death within 12 months as determined in accordance with reasonable medical standards and a reasonable degree of medical certainty.[3]

Eligible patient

In addition to having a terminal illness, for an individual to be an eligible patient the following additional conditions must be met:

(1) **Treatment options and risks considered** – The treating physician has determined that the individual has considered all approved treatment options and determined that there is no satisfactory or comparable approved treatment and that the risk from the investigational drug, product, or device is no greater than the probable risk from not treating the terminal illness;

(2) **Physician recommendation** – The treating physician recommends use of the investigational drug, product, or device and agrees to either administer or personally furnish it or has issued a prescription to the individual;

(3) **Physician documentation** – The treating physician documents in the individual's medical record that all of the preceding conditions have been met.[4]

Treating physician

The bill authorizes only a treating physician to treat an eligible patient with an investigational drug, product, or device. "Treating physician" is defined as the physician or physicians primarily responsible for providing medical care and treating an eligible patient's terminal illness. The bill specifies that "treating physician" does not include the patient's primary care physician, unless no other physician is primarily responsible for treating the terminal illness.[5]

Informed consent

To treat an eligible patient, the bill requires the treating physician to secure the patient's informed consent in a signed statement. If the patient is a minor or lacks the

[3] R.C. 4731.96(A)(5).

[4] R.C. 4731.96(B).

[5] R.C. 4731.96(A)(6).

capacity to consent, the informed consent must be obtained from a parent, guardian, or other person legally responsible for the patient.

The treating physician must include all of the following in the statement:

(1) An explanation of the approved treatment options for the patient's terminal illness;

(2) The specific proposed investigational drug, product, or device;

(3) The potentially best and worst outcomes of using the investigational drug, product, or device with a realistic description of the most likely outcome, including the possibility that new, unanticipated, different, or worse symptoms might result and death may be hastened;

(4) An explanation that the investigational drug, product, or device manufacturer may hold the patient liable for all expenses that arise from the patient's use of the investigational drug, product, or device.[6]

The individual giving consent must sign the document in the conscious presence of a competent witness. The witness must also sign the document and attest that the individual giving consent appeared to (1) concur with the treating physician in believing that approved treatment options would be unlikely to prolong the patient's life, (2) understand the risks involved, and (3) willingly desire to use the investigational drug, product, or device to treat the terminal illness.[7]

Qualified immunity for physicians

The bill provides that, except for actions constituting willful or wanton misconduct, a physician who recommends or treats an eligible patient with an investigational drug, product, or device in accordance with the bill is not liable for, or subject to, damages in a civil action, prosecution in a criminal action, or professional disciplinary action for an act or omission related to treatment with an investigational drug, product, or device.[8]

The bill also exempts a physician acting under the bill from current law that authorizes the State Medical Board to take disciplinary action for selling, giving away, personally furnishing, prescribing, or administering drugs for other than legal and

[6] R.C. 4731.96(C)(2)(a).

[7] R.C. 4731.96(C)(2)(b) and (c).

[8] R.C. 4731.96(D).

legitimate therapeutic purposes, or for violation of federal or state law regulating the possession, distribution, or use of any drug.[9]

Drug labeling

Current law generally requires a health professional who personally furnishes drugs to a patient to ensure that the drugs are labeled and packaged in accordance with state and federal drug laws and any applicable rules and regulations. The bill creates an exception to this requirement when an investigational drug, product, or device is provided in accordance with the bill.[10]

Alternative medical treatments

The bill provides that treatment with an investigational drug, product, or device does not constitute "alternative medical treatment" under existing law that permits a physician to use alternative medical treatment that is complementary to or different from conventional medical care.[11]

Manufacturer provision of investigational drugs, products, and devices

Subject to numerous exceptions, current law prohibits selling dangerous drugs at retail, possessing dangerous drugs for sale at retail, and possessing dangerous drugs. The bill creates an exception for a manufacturer of dangerous drugs that provides an investigational drug, product, or device to an eligible patient or the patient's treating physician to be used for treatment as authorized by the bill.[12]

The bill also explicitly authorizes, but specifies that it does not require,[13] the manufacturer of a dangerous drug to provide an investigational drug, product, or device to an eligible patient or the patient's treating physician. The investigational drug, product, or device may be provided directly to the patient or physician or provided through a terminal distributor of dangerous drugs. Terminal distributors of dangerous drugs are licensed under current law and include pharmacies, hospitals, nursing homes, and other entities that sell or provide dangerous drugs directly to patients.

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[9] R.C. 4731.22(B)(3).

[10] R.C. 4729.291.

[11] R.C. 4731.227.

[12] R.C. 4729.51(C)(4).

[13] R.C. 4729.88(D).

A manufacturer may provide the investigational drug, product, or device for free or charge for the costs associated with manufacturing and providing it. A manufacturer may require the patient to participate in data collection regarding use of the drug, product, or device.[14]

Qualified immunity for manufacturers and terminal distributors

The bill provides that a manufacturer or terminal distributor that provides or distributes an investigational drug, product, or device as authorized by the bill is not liable for or subject to damages in a civil action or prosecution in a criminal proceeding for actions or omissions related to providing or distributing the drug, product, or device.[15] Additionally, a terminal distributor is not subject to any action related to its terminal distributor license or any monetary penalty for actions or omissions related to distributing the drug, product, or device.[16] These immunity provisions do not apply for actions or omissions constituting willful or wanton misconduct.[17]

Charges not covered

The bill provides that its provisions authorizing a treating physician to treat an eligible patient with an investigational drug, product, or device do not require any insurer, government health care program, or other provider of health care coverage to provide coverage for charges incurred from the use of any investigational drug, product, or device.[18]

Insurance coverage exclusion

The bill authorizes a health insurer to exclude coverage in relation to an investigational drug, product, or device provided under the bill for either or both of (1) the cost of the drug, product, or device or (2) its recipient. Exclusion of coverage of the recipient begins on the date the drug, product, or device is first dispensed to the recipient. It is not to last more than six months or to include preexisting conditions or benefits that commenced prior to the start date of the exclusion.

These provisions apply to the following that are delivered, issued for delivery, or renewed on or after January 1, 2016: an individual or group health policy, contract, or

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[14] R.C. 4729.88(B).

[15] R.C. 4729.88(C)(1).

[16] R.C. 4729.88(C)(2) and 4729.57(A)(4).

[17] R.C. 4729.88(C).

[18] R.C. 4731.96(E).

agreement issued by a health insuring corporation; an individual or group policy of sickness and accident insurance; and a multiple employer welfare arrangement that operates a group self-insurance program. It also applies to a public employee benefit plan established or modified on or after January 1, 2016.[19]

The bill provides that if an investigational drug, product, or device recipient dies while being treated with the drug, product, or device, the recipient's estate, devisees, and heirs are not liable for any outstanding costs related to treating the recipient or the recipient's lack of health insurance coverage.[20]

State interference prohibited

The bill prohibits an official, employee, or agent of the state from preventing or attempt to prevent an eligible patient or treating physician from accessing an investigational drug, product, or device in accordance with the bill.[21]

COMMENT

Federal law provides that no person may introduce or deliver for introduction into interstate commerce any new drug that is not approved by the FDA;[22] however, there is a procedure under which the FDA on a case-by-case basis may permit drugs that are still in clinical trial to be provided to patients.[23] The bill attempts to create a broad exception to the federal law for Ohio patients with terminal conditions. In general, when state and federal law conflict, federal law will displace, or preempt, state law.[24]

HISTORY

ACTION	DATE
Introduced	07-16-15

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[19] R.C. 1739.05(B), 1751.671(B), and 3923.851(B); Section 3.

[20] R.C. 1751.671(C), and 3923.851(C).

[21] R.C. 4729.89.

[22] 21 United States Code 355(a).

[23] 21 Code of Federal Regulations 312.300.

[24] U.S. Constitution Article VI, section 2 (Supremacy Clause).