Ohio Legislative Service Commission

Bill Analysis

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Sub. H.B. 290

131st General Assembly
(As Passed by the House)

Reps. Sprague and Anielski, Blessing, Dever, Grossman, Hackett, Henne, Rezabek, Romanchuk, Thompson, Huffman, Antonio, Barnes, Bishoff, Brown, Butler, T. Johnson, Kuhns, LaTourette, Sykes, Antani, Arndt, Baker, Boccieri, Boose, Boyd, Burkley, Clyde, Dovilla, Fedor, Ginter, Green, Hagan, Hall, Hambley, G. Johnson, Lepore-Hagan, Maag, Manning, McClain, M. O'Brien, S. O'Brien, Patterson, Perales, Ramos, Reineke, Roegner, Ruhl, Ryan, Schuring, Sheehy, Young

BILL SUMMARY

- Permits the 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 condition.
- 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.
- Restricts the possession, purchase, distribution, and sale of investigational drugs and products by wholesale distributors of dangerous drugs and licensed terminal distributors of dangerous drugs.
- Provides that the bill does not require a health care insurer, the Medicaid program or any other government health care program, or any other entity that offers health care benefits, to provide coverage for the costs incurred from the use of an investigational 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 condition 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 condition

The bill provides that to be eligible for treatment with an investigational drug, product, or device, a patient must have a terminal condition, as determined by the individual's treating physician and by one other physician who has examined the individual.[3] "Terminal condition" is defined as the following conditions, if irreversible, incurable, and untreatable through a method of treatment approved by the FDA:

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[1] R.C. 4731.96(A)(1); 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 April 13, 2016).

[3] R.C. 4731.96(B)(1)(a).

(1) A progressive form of cancer;

(2) A progressive neurological disorder;

(3) A progressive musculoskeletal disorder;

(4) A condition that, based on reasonable medical standards and a reasonable degree of medical certainty, appears likely to cause death within a period of time that is relatively short but does not exceed 12 months.[4]

Eligible patient

In addition to having a terminal condition, 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 condition;

(2) **Physician recommendation** – The treating physician recommends use of the investigational drug, product, or device, attests that it represents the individual's best chance at survival, 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.[5]

Access to clinical trials

The bill contains an exception to prohibit certain otherwise eligible patients from being eligible under the bill. An individual who meets the requirements specified above is not an eligible patient if a clinical trial using the investigational drug, product, or device is actively being conducted within the individual's county of residence or an adjoining county, unless the individual applied for participation but was denied access to that clinical trial.[6]

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

[5] R.C. 4731.96(B)(1).

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

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 primarily responsible for providing medical care and treating an eligible patient's terminal condition. 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 condition. A patient may have more than one treating physician.[7]

The bill defines "physician" as an individual authorized by Ohio law to practice medicine and surgery or osteopathic medicine and surgery.[8]

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 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 condition;

(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.[9]

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

[7] R.C. 4731.96(A)(7).

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

[9] R.C. 4731.96(C)(1) and (2)(a).

life, (2) understand the risks involved, and (3) willingly desire to use the investigational drug, product, or device to treat the terminal condition.[10]

The bill provides that the eligible patient, or the patient's parent, guardian, or other person legally responsible for the patient, may revoke consent to treatment with an investigational drug, product, or device at any time and in any manner that communicates the revocation.[11]

Qualified immunity for physicians

The bill provides that, except for actions constituting willful or wanton misconduct, a treating 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.[12]

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 legitimate therapeutic purposes, or for violation of federal or state law regulating the possession, distribution, or use of any drug.[13]

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.[14]

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

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

[11] R.C. 4731.96(C)(3).

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

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

[14] R.C. 4729.291.

physician to use alternative medical treatment that is complementary to or different from conventional medical care.[15]

Restrictions on the possession, purchase, distribution, and sale of investigational drugs and products

The bill applies to investigational drugs and products current law that restricts the possession, purchase, distribution, and sale of dangerous drugs. Effectively, this means that a person must be licensed by the state to possess, purchase, distribute, or sell investigational drugs or products, unless the person meets one of the exceptions in existing law applicable to the possession, purchase, distribution, and sale of dangerous drugs.

Subject to numerous exceptions, current law prohibits a person other than a registered wholesale distributor of dangerous drugs from possessing for sale, selling, distributing, or delivering, at wholesale, dangerous drugs. The bill extends that prohibition to investigational drugs and products.[16] Current law also restricts a wholesale distributor of dangerous drugs' ability to possess for sale, or sell, at wholesale, dangerous drugs. The bill extends that restriction to investigational drugs or products.[17]

Regarding terminal distributors of dangerous drugs, which are licensed under current law and include pharmacies, hospitals, nursing homes, and other entities that sell or provide dangerous drugs directly to patients, current law generally prohibits them from purchasing dangerous drugs for the purpose of resale from any person other than a registered wholesale distributor. The bill extends that prohibition to investigational drugs and products.[18] Current law also generally prohibits terminal distributors from selling or distributing dangerous drugs at retail or possessing or controlling them other than for the distributor's personal consumption. The bill extends that prohibition to investigational drugs and products.[19]

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[15] R.C. 4731.227.

[16] R.C. 4729.51(A)(1).

[17] R.C. 4729.51(B)(1).

[18] R.C. 4729.51(D).

[19] R.C. 4729.51(E).

Manufacturer provision of investigational drugs, products, and devices

The bill authorizes, but specifies that it does not require,[20] 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. A manufacturer may provide the investigational drug, product, or device with or without 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.[21]

Qualified immunity for manufacturers and terminal distributors

The bill provides that, except for willful or wanton misconduct, 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.[22]

Charges not covered by insurance or estate

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 health care insurer, the Medicaid program or any other government health care program, or any other entity that offers health care benefits to provide coverage for costs incurred from the use of any investigational drug, product, or device.[23]

However, the bill provides that if an eligible patient dies while being treated with the drug, product, or device and there are any outstanding costs related to treating the patient, the patient's estate, devisees, and heirs cannot be held liable by any person or government entity for those costs.[24]

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

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

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

[23] R.C. 4731.96(G).

[24] R.C. 4731.96(F).

State interference prohibited

The bill prohibits an official, employee, or agent of the state from preventing or attempting to prevent, solely because an investigational drug, product, or device has not been approved for general use by the FDA, an eligible patient or treating physician from accessing an investigational drug, product, or device in accordance with the bill.[25]

Assisted suicide not authorized

The bill provides that it does not condone, authorize, or approve of assisted suicide, or any action that is considered mercy killing or euthanasia.[26]

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;[27] 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.[28] 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.[29]

HISTORY

ACTION	DATE
Introduced	07-16-15
Reported, H. Health & Aging	01-26-16
Passed House (96-1)	02-23-16

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

[26] R.C. 4731.96(H).

[27] 21 United States Code 355(a).

[28] 21 Code of Federal Regulations 312.300.

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