HOUSE BILL No. 1125

DIGEST OF INTRODUCED BILL

Citations Affected: IC 24-5-26.5; IC 34-6-2; IC 34-12-3.5; IC 34-51-3-7.

Synopsis: Deceptive lead generation. Makes false, misleading, or deceptive advertisements for claims related to medical devices and legend drugs and certain other actions a deceptive act, and provides for enforcement mechanisms. Limits certain claims against a manufacturer or seller of legend drugs or medical devices. Limits awards of exemplary or punitive damages against a manufacturer or seller of legend drugs or medical devices.

Effective: May 15, 2021.

Lehman

January 7, 2021, read first time and referred to Committee on Judiciary.

Introduced

First Regular Session of the 122nd General Assembly (2021)

PRINTING CODE. Amendments: Whenever an existing statute (or a section of the Indiana Constitution) is being amended, the text of the existing provision will appear in this style type, additions will appear in **this style type**, and deletions will appear in ~~this style type.~~

Additions: Whenever a new statutory provision is being enacted (or a new constitutional provision adopted), the text of the new provision will appear in **this style type**. Also, the word **NEW** will appear in that style type in the introductory clause of each SECTION that adds a new provision to the Indiana Code or the Indiana Constitution.

Conflict reconciliation: Text in a statute in *this style type* or ~~*this style type*~~ reconciles conflicts between statutes enacted by the 2020 Regular Session of the General Assembly.

HOUSE BILL No. 1125

A BILL FOR AN ACT to amend the Indiana Code concerning civil procedure.

Be it enacted by the General Assembly of the State of Indiana:

SECTION 1. IC 24-5-26.5 IS ADDED TO THE INDIANA CODE AS A **NEW** CHAPTER TO READ AS FOLLOWS [EFFECTIVE MAY 15, 2021]:

Chapter 26.5. Deceptive Lead Generation

Sec. 1. As used in this chapter, "commercial communication" means any written or oral statement, illustration, or depiction, whether in English or another language, that is designed to create interest in procuring legal services, whether it appears on or in a label, package, package insert, radio, television, brochure, newspaper, magazine, pamphlet, leaflet, circular, mailer, book insert, free standing insert, letter, catalog, poster, chart, billboard, public transit card, point of purchase display, film slide, audio program transmitted over a telephone system, telemarketing script, on-hold script, upsell script, training materials provided to a telemarketing firm, program length commercial, the Internet, cellular network, or any other medium, as well as promotional materials, items, and Internet web sites.

Sec. 2. As used in this chapter, "consumer" refers to an individual who views a commercial communication for personal or familial purposes.

Sec. 3. As used in this chapter, "lead generation" refers to the use of commercial communication to initiate consumer interest or inquiry into legal services provided in Indiana or another jurisdiction to redress an alleged injury from a medical device or legend drug.

Sec. 4. As used in this chapter, "legend drug" has the meaning set forth in IC 16-18-2-199.

Sec. 5. As used in this chapter, "manufacturer" has the meaning set forth in IC 34-6-2-77(a).

Sec. 6. As used in this chapter, "medical device" has the meaning set forth in IC 34-6-2-79.5.

Sec. 7. As used in this chapter, "seller" has the meaning set forth in IC 34-6-2-136(a).

Sec. 8. (a) It is a deceptive act for a person to engage in lead generation that is false, deceptive, or misleading.

(b) Deceptive acts under this chapter may include the following:

(1) Advertisements or other commercial communications that:

(A) cause, or are likely to cause, consumers to fail to use or to discontinue the consumers' medications; or

(B) remove a medical device;

without appropriate medical advice from a person who is independent from the lead generator and any person to whom the consumer would be referred.

(2) Advertisements or other commercial communications that open with sensationalized warnings or alerts that may mislead consumers to believe the consumers are watching a government sanctioned medical alert or public service announcement.

(3) Advertisements or other commercial communications that:

(A) misrepresent the risks associated with a medical device or legend drug;

(B) leave consumers with the false impression that the risks of the medical device or legend drug exceed the benefits; or

(C) leave consumers with the false impression that the United States Food and Drug Administration has recalled a medical device or legend drug that is the subject of the advertisement or other commercial communication.

(c) A claim misrepresents a fact or is false if the claim is not substantiated by competent and reliable scientific evidence.

Sec. 9. It is a deceptive act for a person engaged in lead generation to fail to make the following written and oral disclosures to a consumer who responds to an advertisement or other commercial communication subject to this chapter:

(1) The basis used to select the group of participants to which the person engaged in lead generation could make a referral.

(2) The terms of any agreement related to:

(A) fees or other payments related to the referral; or

(B) the income generating potential or volume of referrals that exceed the payments permitted for a legal referral service under Rule 7.2 of the Indiana Rules of Professional Conduct.

(3) If the person engaged in lead generation has reason to know that the attorney or law firm to which a consumer is referred is likely to seek co-counsel or refer the consumer's claim to another attorney or another law firm handling other similar claims, that the attorney or law firm to whom the consumer is being referred may not be the lead attorney handling the strategy and negotiations for the consumer's claim.

(4) Whether the lead generator is an attorney licensed to practice law in Indiana or a law firm with attorneys licensed to practice law in Indiana.

(5) Any other disclosure required under the rules adopted by the attorney general under section 12 of this chapter that the attorney general determines is necessary to permit a consumer to make an informed consent to a referral.

Sec. 10. It is a deceptive act for a person engaged in lead generation to regulate a lawyer's professional judgment in rendering legal service.

Sec. 11. The provisions set forth in this chapter also apply to deceptive acts by a lawyer referral service that receives any benefit or consideration for the direct or indirect referral of prospective clients to lawyers or law firms, including the following:

(1) Matching or connecting a prospective client to a lawyer drawn from a specific group or panel of lawyers or who matches a prospective client with lawyers or law firms.

(2) A group or pooled advertising program, offering to refer, match, or otherwise connect prospective legal clients with lawyers or law firms, in which the advertisements for the

program use a common telephone number or Internet web site address and prospective clients are then matched or referred only to lawyers or law firms participating in the group or pooled advertising program.

(3) Publishing in any media a listing of lawyers or law firms together in one (1) place.

(4) Providing tips or leads for prospective clients to lawyers or law firms.

Sec. 12. The attorney general may adopt rules under IC 4-22-2, including emergency rules in the manner provided under IC 4-22-2-37.1, to carry out this chapter. An emergency rule adopted by the attorney general under this section expires on the earlier of the following dates:

(1) The expiration date in the emergency rule.

(2) The date the emergency rule is amended or repealed by a later rule adopted under IC 4-22-2-24 through IC 4-22-2-36 or under IC 4-22-2-37.1.

Sec. 13. The attorney general may, regardless of whether a complaint has been filed under section 14 of this chapter, bring an action to enjoin a deceptive act under this chapter. In the action, the court may do any combination of the following:

(1) Issue an injunction.

(2) Order the person engaged in lead generation to reimburse the money unlawfully received from the aggrieved consumers to be held in escrow for distribution to aggrieved consumers, void or limit the application of contracts or clauses resulting from deceptive acts, and order restitution to be paid to aggrieved consumers.

(3) For a knowing or intentional violation against a consumer who is at least sixty (60) years of age, increase the amount of restitution ordered under subdivision (2) in any amount up to three (3) times the amount of damages incurred.

(4) Provide for the appointment of a receiver.

Sec. 14. (a) If the attorney general does not file an action under section 13 of this chapter, a manufacturer or seller of medical devices or legend drugs or a consumer may bring an action to enjoin a person engaged in lead generation from violating this chapter.

(b) A complaint under this section must be filed not later than ninety (90) days after the person engaging in lead generation commits a deceptive act under this chapter.

Sec. 15. A court with jurisdiction over an action under section

13 or 14 of this chapter may order the violator to pay court costs and reasonable investigation and litigation fees incurred by the attorney general, a manufacturer or seller of medical devices or legend drugs, or a consumer who prevails in the action.

SECTION 2. IC 34-6-2-73.4 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE MAY 15, 2021]: **Sec. 73.4. "Legend drug" has the meaning set forth in IC 16-18-2-199.**

SECTION 3. IC 34-6-2-77 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE MAY 15, 2021]: Sec. 77. **(a) "Manufacturer", for purposes of IC 34-12-3.5 and IC 34-51-3-7, means either of the following:**

(1) A person that is engaged in a business to produce, create, make, or construct any product or component of a product, and that:

(A) designs, manufactures, or formulates; or

(B) engages another person to design, manufacture, or formulate;

a medical device or component or part of a medical device.

(2) A person that, by compounding, cultivating, harvesting, or mixing, or by another process produces or prepares, legend drugs. The term includes a person that:

(A) prepares legend drugs in dosage forms by mixing, compounding, encapsulating, or entableting, or by another process; or

(B) packages or repackages legend drugs.

The term does not include pharmacists or practitioners (as defined in IC 16-18-2-288(a)).

~~(a)~~ **(b)** "Manufacturer", for purposes of IC 34-20, means a person or an entity who designs, assembles, fabricates, produces, constructs, or otherwise prepares a product or a component part of a product before the sale of the product to a user or consumer. "Manufacturer" includes a seller who:

(1) has actual knowledge of a defect in a product;

(2) creates and furnishes a manufacturer with specifications relevant to the alleged defect for producing the product or who otherwise exercises some significant control over all or a portion of the manufacturing process;

(3) alters or modifies the product in any significant manner after the product comes into the seller's possession and before it is sold to the ultimate user or consumer;

(4) is owned in whole or significant part by the manufacturer; or

(5) owns in whole or significant part the manufacturer.

~~(b)~~ **(c)** A seller who discloses the name of the actual manufacturer of a product is not a manufacturer under this section merely because the seller places or has placed a private label on a product.

SECTION 4. IC 34-6-2-79.5 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE MAY 15, 2021]: **Sec. 79.5. "Medical device" refers to an instrument, an apparatus, an implement, a machine, a contrivance, an implant, an in vitro reagent, or other similar or related article, including a component part or accessory:**

(1) that is recognized in the official National Formulary or the United States Pharmacopoeia, or any supplement to them;

(2) that is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in a human being or an animal; or

(3) that:

(A) is intended to affect the structure or any function of the body of a human being or an animal;

(B) does not achieve its primary intended purpose through chemical action within or on the body of a human being or an animal; and

(C) is not dependent upon being metabolized for the achievement of its primary intended purpose.

SECTION 5. IC 34-6-2-103, AS AMENDED BY P.L.132-2015, SECTION 2, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE MAY 15, 2021]: Sec. 103. (a) "Person", for purposes of IC 34-14, has the meaning set forth in IC 34-14-1-13.

(b) "Person", for purposes of IC 34-11-2-11.5, **IC 34-12-3.5,** ~~and~~ IC 34-24-4, **and IC 34-51-3-7,** means:

(1) an individual;

(2) a governmental entity;

(3) a corporation;

(4) a firm;

(5) a trust;

(6) a partnership; or

(7) an incorporated or unincorporated association that exists under or is authorized by the laws of this state, another state, or a foreign country.

(c) "Person", for purposes of section 44.8 of this chapter and IC 34-30-29-1, means an adult or a minor.

(d) "Person", for purposes of IC 34-26-4, has the meaning set forth in IC 35-31.5-2-234.

(e) "Person", for purposes of IC 34-30-5, means any of the following:

(1) An individual.

(2) A corporation.

(3) A partnership.

(4) An unincorporated association.

(5) The state (as defined in IC 34-6-2-140).

(6) A political subdivision (as defined in IC 34-6-2-110).

(7) Any other entity recognized by law.

(f) "Person", for purposes of IC 34-30-6, means an individual, a corporation, a limited liability company, a partnership, an unincorporated association, or a governmental entity that:

(1) has qualifications or experience in:

(A) storing, transporting, or handling a hazardous substance or compressed gas;

(B) fighting fires;

(C) emergency rescue; or

(D) first aid care; or

(2) is otherwise qualified to provide assistance appropriate to remedy or contribute to the remedy of the emergency.

(g) "Person", for purposes of IC 34-30-18, includes:

(1) an individual;

(2) an incorporated or unincorporated organization or association;

(3) the state of Indiana;

(4) a political subdivision (as defined in IC 36-1-2-13);

(5) an agency of the state or a political subdivision; or

(6) a group of such persons acting in concert.

(h) "Person", for purposes of sections 42, 43, 69, and 95 of this chapter, means an individual, an incorporated or unincorporated organization or association, or a group of such persons acting in concert.

(i) "Person", for purposes of IC 34-30-10.5, means the following:

(1) A political subdivision (as defined in IC 36-1-2-13).

(2) A volunteer fire department (as defined in IC 36-8-12-2).

(3) An employee of an entity described in subdivision (1) or (2) who acts within the scope of the employee's responsibilities.

(4) A volunteer firefighter (as defined in IC 36-8-12-2) who is acting for a volunteer fire department.

(5) A corporation, a limited liability company, a partnership, an unincorporated association, or any other entity recognized by law.

(j) "Person", for purposes of IC 34-28-7, means:

(1) an individual;

(2) a governmental entity;
(3) a corporation;
(4) a firm;
(5) a trust;
(6) a partnership; or
(7) an incorporated or unincorporated association that exists under or is authorized by the laws of this state, another state, or a foreign country.

(k) "Person", for purposes of IC 34-31-9, has the meaning set forth in IC 34-31-9-8.

SECTION 6. IC 34-6-2-136 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE MAY 15, 2021]: Sec. 136. **(a) "Seller", for purposes of IC 34-12-3.5 and IC 34-51-3-7, means a person that, in the course of business conducted for that purpose, does either of the following:**

(1) Sells, distributes, rents, leases, prepares, blends, packages, labels, or otherwise is involved in placing a medical device or legend drug into the stream of commerce.

(2) Installs, repairs, refurbishes, reconditions, or maintains a medical device.

(b) "Seller", for purposes of IC 34-20, means a person engaged in the business of selling or leasing a product for resale, use, or consumption.

SECTION 7. IC 34-12-3.5 IS ADDED TO THE INDIANA CODE AS A **NEW** CHAPTER TO READ AS FOLLOWS [EFFECTIVE MAY 15, 2021]:

Chapter 3.5. Legal Actions Involving Medical Device and Legend Drug Manufacturers and Sellers

Sec. 1. This chapter applies to an action that would otherwise accrue for an injury occurring after May 14, 2021.

Sec. 2. Except as provided in section 3 of this chapter, a person may not bring or maintain an action against a medical device or legend drug manufacturer or seller for the recovery of damages resulting from, or injunctive relief, abatement, or nuisance relating to, the design, manufacture, marketing, or sale of a medical device or legend drug if any of the following apply:

(1) The medical device or legend drug alleged to have caused the harm was designed, manufactured, packaged, labeled, sold, or represented according to the terms of an approval, conditional approval, clearance, license, or similar determination of the United States Food and Drug Administration.

(2) The medical device or legend drug complied with all standards, rules, regulations, orders, or other actions of the United States Food and Drug Administration under statutory authority relevant and material to the event or risk allegedly causing the harm, and the medical device or legend drug complied at the time the medical device or legend drug left the control of the manufacturer or seller.

(3) The act or transaction forming the basis of the claim involves contract provisions, representations, or other practices authorized by, or in compliance with, the rules, regulations, standards, orders of, or a statute enforced by the United States Food and Drug Administration.

Sec. 3. This chapter may not be construed to prohibit a person from bringing an action against a manufacturer or seller if the claimant establishes that the manufacturer or seller, at any time before the activity or event that allegedly caused the harm, did any of the following:

(1) Sold the medical device or legend drug after the effective date of a final order of the United States Food and Drug Administration to:

(A) remove the medical device or legend drug from the market;

(B) withdraw its approval of the medical device or legend drug; or

(C) substantially alter its terms of approval of the medical device or legend drug in a manner that would have avoided the claimant's alleged injury.

(2) Intentionally and in violation of applicable regulations as determined by the final action of the United States Food and Drug Administration withheld from or misrepresented to the United States Food and Drug Administration information material to the approval or maintaining of approval of the medical device or legend drug, and the information is relevant to the harm that the claimant allegedly suffered.

(3) Made an illegal payment to an official or employee of the United States Food and Drug Administration for the purpose of securing or maintaining approval of the medical device or legend drug.

(4) After the medical device or legend drug was sold, was found by the United States Food and Drug Administration to have knowingly violated applicable regulations requiring reporting to the United States Food and Drug Administration

of risks of harm, and the unreported information was material and relevant to the harm that the claimant allegedly suffered.

For the purposes of subdivisions (1) and (4), a medical device or legend drug is sold when it is delivered or provided to the end user, even if payment for the medical device or legend drug is not made until after the delivery or provision of the medical device or legend drug.

Sec. 4. This chapter does not establish a cause of action to redress an injury that was sustained before May 15, 2021.

SECTION 8. IC 34-51-3-7 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE MAY 15, 2021]: **Sec. 7. (a) This section applies only to a cause of action that would otherwise accrue for an injury occurring after May 14, 2021.**

(b) A medical device or legend drug manufacturer or seller is not liable for exemplary or punitive damages if any of the following applies:

(1) The medical device or legend drug alleged to have caused the harm was designed, manufactured, packaged, labeled, sold, or represented according to the terms of an approval, conditional approval, clearance, license, or similar determination of the United States Food and Drug Administration.

(2) The medical device or legend drug complied with all standards, rules, regulations, orders, or other actions of the United States Food and Drug Administration under statutory authority relevant and material to the event or risk allegedly causing the harm, and the medical device or legend drug complied at the time the medical device or legend drug left the control of the manufacturer or seller.

(3) The act or transaction forming the basis of the claim involves contract provisions, representations, or other practices authorized by, or in compliance with, the rules, regulations, standards, orders of, or a statute enforced by, the United States Food and Drug Administration.

(c) This section does not apply if the claimant establishes that the manufacturer or seller, at any time before the activity or event that allegedly caused the harm, did any of the following:

(1) Sold the medical device or legend drug after the effective date of a final order of the United States Food and Drug Administration to:

(A) remove the medical device or legend drug from the market;

(B) withdraw its approval of the medical device or legend drug; or

(C) substantially alter its terms of approval of the medical device or legend drug in a manner that would have avoided the claimant's alleged injury.

(2) Intentionally and in violation of applicable regulations as determined by the final action of the United States Food and Drug Administration, withheld from or misrepresented to the United States Food and Drug Administration information material to the approval or maintaining of approval of the medical device or legend drug, and the information is relevant to the harm that the claimant allegedly suffered.

(3) Made an illegal payment to an official or employee of the United States Food and Drug Administration for the purpose of securing or maintaining approval of the medical device or legend drug.

(4) After the medical device or legend drug was sold, was found by the United States Food and Drug Administration to have knowingly violated applicable regulations requiring reporting to the United States Food and Drug Administration of risks of harm, and the unreported information was material and relevant to the harm that the claimant allegedly suffered.

For the purposes of subdivisions (1) and (4), a medical device or legend drug is sold when it is delivered or provided to the end user, even if payment for the medical device or legend drug is not made until after the delivery or provision of the medical device or legend drug.

(d) This section may not be construed to do any of the following:

(1) Expand the authority of any state agency or state agent to adopt or promulgate rules, standards, or regulations if the authority to do so did not previously exist.

(2) Reduce the scope or any limitation on liability based on compliance with the rules or regulations of the United States Food and Drug Administration applicable to a specific act, transaction, person, or industry.

(3) Affect the liability of a service provider based on rates filed with and reviewed or approved by the United States Food and Drug Administration.

(4) Establish a cause of action to redress an injury that was

sustained before May 15, 2021.

SECTION 9. **An emergency is declared for this act.**