

PREVAILED	Roll Call No. _____
FAILED	Ayes _____
WITHDRAWN	Noes _____
RULED OUT OF ORDER	

HOUSE MOTION _____

MR. SPEAKER:

I move that Engrossed Senate Bill 371 be amended to read as follows:

- 1 Page 2, between lines 13 and 14, begin a new paragraph and insert:
- 2 "SECTION 4. IC 16-18-2-101.5 IS ADDED TO THE INDIANA
- 3 CODE AS A **NEW** SECTION TO READ AS FOLLOWS
- 4 [EFFECTIVE JULY 1, 2013]: **Sec. 101.5. "Drug label", for purposes**
- 5 **of IC 16-42-25, has the meaning set forth in IC 16-42-25-1.**
- 6 SECTION 5. IC 16-18-2-116.5 IS ADDED TO THE INDIANA
- 7 CODE AS A **NEW** SECTION TO READ AS FOLLOWS
- 8 [EFFECTIVE JULY 1, 2013]: **Sec. 116.5. "Erectile dysfunction**
- 9 **drug", for purposes of IC 16-42-25, has the meaning set forth in**
- 10 **IC 16-42-25-2."**
- 11 Page 8, after line 19, begin a new paragraph and insert:
- 12 "SECTION 7. IC 16-42-25 IS ADDED TO THE INDIANA CODE
- 13 AS A **NEW** CHAPTER TO READ AS FOLLOWS [EFFECTIVE
- 14 JULY 1, 2013]:
- 15 **Chapter 25. Drugs: Use of Erectile Dysfunction Drugs**
- 16 **Sec. 1. As used in this chapter, "drug label" means the pamphlet**
- 17 **or document accompanying an erectile dysfunction drug that:**
- 18 **(1) outlines the protocol authorized by the federal Food and**
- 19 **Drug Administration;**
- 20 **(2) sets forth how the drug is to be used; and**
- 21 **(3) has been agreed upon by the drug manufacturer applying**
- 22 **for authorization of the drug by the Food and Drug**
- 23 **Administration.**

1 **Sec. 2. As used in this chapter, "erectile dysfunction drug"**
2 **means a medicine, drug, or substance prescribed or dispensed with**
3 **the intent of temporarily alleviating the symptoms of erectile**
4 **dysfunction with the expectation that a man will achieve or**
5 **maintain an erection long enough to engage in sexual intercourse.**
6 **The term includes the off-label use of any drug known to maintain**
7 **an erection if the drug is prescribed with the intent of temporarily**
8 **alleviating the symptoms of erectile dysfunction.**

9 **Sec. 3. (a) It is unlawful for an individual to knowingly give, sell,**
10 **dispense, administer, prescribe, or otherwise provide an erectile**
11 **dysfunction drug to a man for the purposes of temporarily**
12 **alleviating the symptoms of erectile dysfunction unless the**
13 **individual meets the following requirements:**

14 **(1) The individual is a physician licensed under IC 25-22.5.**

15 **(2) The individual satisfies the protocol outlined in the final**
16 **print drug label, as approved by the Food and Drug**
17 **Administration.**

18 **(b) Before giving, selling, dispensing, administering, prescribing,**
19 **or otherwise providing an erectile dysfunction drug to a man**
20 **showing symptoms of erectile dysfunction, a physician licensed**
21 **under IC 25-22.5 shall do the following:**

22 **(1) Examine in person the man showing symptoms of erectile**
23 **dysfunction.**

24 **(2) Conduct a penile doppler ultrasound examination of the**
25 **man's penis to determine whether an erectile dysfunction**
26 **drug will alleviate the man's erectile dysfunction symptoms.**

27 **(3) Provide the following information to the man diagnosed**
28 **with erectile dysfunction:**

29 **(A) A copy of the final printed drug label.**

30 **(B) The name and telephone number for the physician who**
31 **prescribed the erectile dysfunction medication and**
32 **information for follow-up care.**

33 **(c) A physician licensed under IC 25-22.5 who gives, sells,**
34 **dispenses, administers, prescribes, or otherwise provides an**
35 **erectile dysfunction drug to a man shall schedule a follow-up**
36 **appointment with the man at approximately fourteen (14) days**
37 **after prescribing the erectile dysfunction drug to:**

38 **(1) conduct a physical exam, including an electrocardiogram,**
39 **to ensure that the man is healthy enough for continued sexual**
40 **activity; and**

41 **(2) assess the degree to which the erectile dysfunction drug**
42 **has aided in temporarily relieving the symptoms of erectile**
43 **dysfunction.**

44 **(d) The physician described in subsection (c) shall make a**
45 **reasonable effort to ensure that the patient returns for the**
46 **follow-up appointment described in subsection (c), including**
47 **recording in the patient's medical records:**

- 1 **(1) the date and time of the follow-up appointment;**
 2 **(2) a brief description of the efforts the physician and the**
 3 **physician's staff took to ensure the patient's return; and**
 4 **(3) the name of the individual who performed the efforts.**
 5 **Sec. 4. (a) A person who intentionally, knowingly, or recklessly**
 6 **violates this chapter commits an unlawful activity related to an**
 7 **erectile dysfunction drug, a Class A misdemeanor.**
 8 **(b) In addition to the criminal penalty under subsection (a), a**
 9 **person who violates this chapter may be subject to disciplinary**
 10 **sanctions under IC 25-1-9 and civil liability for wrongful death and**
 11 **medical malpractice.**
 12 SECTION 8. IC 35-51-16-1, AS ADDED BY P.L.70-2011,
 13 SECTION 1, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE
 14 JULY 1, 2013]: Sec. 1. The following statutes define crimes in IC 16:
 15 IC 16-19-12-1 (Concerning the state department of health).
 16 IC 16-20-9-1 (Concerning local health departments).
 17 IC 16-21-2-2.5 (Concerning licensure of hospitals).
 18 IC 16-21-5-3 (Concerning licensure of hospitals).
 19 IC 16-21-6-12 (Concerning hospital financial disclosure law).
 20 IC 16-21-7-5 (Concerning hospitals).
 21 IC 16-25-5-8 (Concerning hospices).
 22 IC 16-25-6-1 (Concerning hospices).
 23 IC 16-27-1-15 (Concerning home health agencies).
 24 IC 16-27-2-3 (Concerning home health agencies).
 25 IC 16-27-4-23 (Concerning home health agencies).
 26 IC 16-28-7-5 (Concerning monitors).
 27 IC 16-28-9-3 (Concerning monitors).
 28 IC 16-28-9-4 (Concerning monitors).
 29 IC 16-28-9-5 (Concerning monitors).
 30 IC 16-30-5-1 (Concerning health planning).
 31 IC 16-31-3-16 (Concerning emergency medical services).
 32 IC 16-31-3-22 (Concerning emergency medical services).
 33 IC 16-31-10-2 (Concerning emergency medical services).
 34 IC 16-34-2-5 (Concerning abortion).
 35 IC 16-34-2-6 (Concerning abortion).
 36 IC 16-34-2-7 (Concerning abortion).
 37 IC 16-36-4-15 (Concerning medical consent).
 38 IC 16-36-4-16 (Concerning medical consent).
 39 IC 16-36-5-27 (Concerning medical consent).
 40 IC 16-36-5-28 (Concerning medical consent).
 41 IC 16-37-1-12 (Concerning vital statistics).
 42 IC 16-37-1-13 (Concerning vital statistics).
 43 IC 16-37-2-2.1 (Concerning vital statistics).
 44 IC 16-37-2-19 (Concerning vital statistics).
 45 IC 16-37-3-16 (Concerning vital statistics).
 46 IC 16-38-5-4 (Concerning health registries).

- 1 IC 16-39-7.1-3 (Concerning health records).
- 2 IC 16-39-7.1-6 (Concerning health records).
- 3 IC 16-41-1-3 (Concerning communicable diseases).
- 4 IC 16-41-2-9 (Concerning communicable diseases).
- 5 IC 16-41-3-3 (Concerning communicable diseases).
- 6 IC 16-41-4-3 (Concerning communicable diseases).
- 7 IC 16-41-5-3 (Concerning communicable diseases).
- 8 IC 16-41-6-3 (Concerning communicable diseases).
- 9 IC 16-41-7-5 (Concerning communicable diseases).
- 10 IC 16-41-8-1 (Concerning communicable diseases).
- 11 IC 16-41-8-3 (Concerning communicable diseases).
- 12 IC 16-41-8-5 (Concerning communicable diseases).
- 13 IC 16-41-9-1.5 (Concerning communicable diseases).
- 14 IC 16-41-10-5 (Concerning communicable diseases).
- 15 IC 16-41-10-7 (Concerning communicable diseases).
- 16 IC 16-41-12-13 (Concerning communicable diseases).
- 17 IC 16-41-12-14 (Concerning communicable diseases).
- 18 IC 16-41-12-15 (Concerning communicable diseases).
- 19 IC 16-41-13-3 (Concerning communicable diseases).
- 20 IC 16-41-13-4 (Concerning communicable diseases).
- 21 IC 16-41-13-6 (Concerning communicable diseases).
- 22 IC 16-41-14-13 (Concerning communicable diseases).
- 23 IC 16-41-14-15 (Concerning communicable diseases).
- 24 IC 16-41-14-16 (Concerning communicable diseases).
- 25 IC 16-41-14-17 (Concerning communicable diseases).
- 26 IC 16-41-14-20 (Concerning communicable diseases).
- 27 IC 16-41-15-18 (Concerning communicable diseases).
- 28 IC 16-41-16-11 (Concerning communicable diseases).
- 29 IC 16-41-18-6 (Concerning prevention and treatment programs).
- 30 IC 16-41-19-10 (Concerning prevention and treatment programs).
- 31 IC 16-41-20-13 (Concerning health, sanitation, and safety).
- 32 IC 16-41-21-18 (Concerning health, sanitation, and safety).
- 33 IC 16-41-21-19 (Concerning health, sanitation, and safety).
- 34 IC 16-41-22-21 (Concerning health, sanitation, and safety).
- 35 IC 16-41-22-22 (Concerning health, sanitation, and safety).
- 36 IC 16-41-23-4 (Concerning health, sanitation, and safety).
- 37 IC 16-41-24-11 (Concerning health, sanitation, and safety).
- 38 IC 16-41-25-2 (Concerning health, sanitation, and safety).
- 39 IC 16-41-27-34 (Concerning health, sanitation, and safety).
- 40 IC 16-41-29-5 (Concerning regulation of lodging facilities and
- 41 bedding materials).
- 42 IC 16-41-32-30 (Concerning regulation of lodging facilities and
- 43 bedding materials).
- 44 IC 16-41-33-9 (Concerning pest control).
- 45 IC 16-41-34-8 (Concerning pest control).
- 46 IC 16-41-35-40 (Concerning radiation).

- 1 IC 16-41-38-10 (Concerning radon gas).
2 IC 16-42-1-16 (Concerning Uniform Food, Drug, and Cosmetic
3 Act).
4 IC 16-42-1-34 (Concerning Uniform Food, Drug, and Cosmetic
5 Act).
6 IC 16-42-2-8 (Concerning Uniform Food, Drug, and Cosmetic
7 Act).
8 IC 16-42-2-9 (Concerning Uniform Food, Drug, and Cosmetic
9 Act).
10 IC 16-42-3-12 (Concerning Uniform Food, Drug, and Cosmetic
11 Act).
12 IC 16-42-4-5 (Concerning Uniform Food, Drug, and Cosmetic
13 Act).
14 IC 16-42-5-26 (Concerning sanitary requirements for food
15 establishments).
16 IC 16-42-5-27 (Concerning sanitary requirements for food
17 establishments).
18 IC 16-42-10-13 (Concerning food).
19 IC 16-42-18-7 (Concerning food).
20 IC 16-42-19-27 (Concerning the Indiana Legend Drug Act).
21 IC 16-42-21-4 (Concerning the Indiana Legend Drug Act).
22 **IC 16-42-25-4 (Concerning erectile dysfunction drugs).**
23 IC 16-44-1-1 (Concerning product labeling and inspection).
24 IC 16-44-2-22 (Concerning product labeling and inspection).
25 IC 16-46-6-12 (Concerning state health grants and programs).".
26 Renumber all SECTIONS consecutively.
(Reference is to ESB 371 as printed March 29, 2013.)

Representative VanDenburgh