SENATE MOTION

MADAM PRESIDENT:

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

Page 2, line 6, after "7.5." insert "**(a)**".

Page 2, between lines 7 and 8, begin a new paragraph and insert:

"**(b) "Adverse event", for purposes of IC 16-42-25, has the meaning set forth in IC 16-42-25-1.**".

Page 2, line 10, after "101.5" insert "**(a)**".

Page 2, between lines 11 and 12, begin a new paragraph and insert:

"**(b) "Drug label", for purposes of IC 16-42-25, has the meaning set forth in IC 16-42-25-2.**

SECTION 3. IC 16-18-2-116.5 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2013]: **Sec. 116.5. "Erectile dysfunction drug", for purposes of IC 16-42-25, has the meaning set forth in IC 16-42-25-3.**".

Page 4, between lines 24 and 25, begin a new paragraph and insert:

"SECTION 7. IC 16-42-25 IS ADDED TO THE INDIANA CODE AS A **NEW** CHAPTER TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2013]:

Chapter 25. Drugs: Use of Erectile Dysfunction Drugs

Sec. 1. As used in this chapter, "adverse event" means an undesirable experience associated with the use of an erectile dysfunction drug. The term includes the following incidents:

(1) Death.

(2) A life threatening occurrence.

(3) Hospitalization.

(4) Priapism.

(5) Disability or permanent damage.

(6) Medical intervention necessary to prevent permanent impairment or damage.

Sec. 2. As used in this chapter, "drug label" means the pamphlet or document accompanying an erectile dysfunction drug

that:

(1) outlines the protocol authorized by the federal Food and Drug Administration;

(2) sets forth how the drug is to be used; and

(3) has been agreed upon by the drug manufacturer applying for authorization of the drug by the Food and Drug Administration.

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

Sec. 4. (a) It is unlawful for an individual to knowingly give, sell, dispense, administer, prescribe, or otherwise provide an erectile dysfunction drug to a man for the purposes of temporarily alleviating the symptoms of erectile dysfunction unless the individual meets the following requirements:

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

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

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

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

(2) Conduct a prostate examination or oversee a prostate examination by an individual who is licensed or certified in Indiana and whose scope of practice includes the conducting of a prostate examination.

(3) Document the following information on the patient's medical records:

(A) The size of the patient's prostate.

(B) Whether the patient is showing symptoms of benign prostate problems.

(C) Whether a benign prostate problem could be contributing to the patient's erectile dysfunction.

(4) Provide the following information to the man diagnosed with erectile dysfunction:

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

(B) The name and telephone number for the physician who prescribed the erectile dysfunction medication and information for follow-up care in the event of an adverse event described in section 2 of this chapter.

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

after prescribing the erectile dysfunction drug to:

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

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

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

(1) the date and time of the follow-up appointment;

(2) a brief description of the efforts the physician and the physician's staff took to ensure the patient's return; and

(3) the name of the individual who performed the efforts.

Sec. 5. (a) A physician licensed under IC 25-22.5 who gives, sells, dispenses, administers, prescribes, or otherwise provides an erectile dysfunction drug to a man showing the symptoms of erectile dysfunction and who is aware of a subsequent adverse event from the erectile dysfunction drug shall report the adverse event not later than three (3) days following the physician's knowledge of the adverse event to the medical licensing board of Indiana.

(b) The medical licensing board of Indiana shall do the following:

(1) Compile and retain the reports received under subsection (a).

(2) Make the reports available as public records and open to inspection. However, the medical licensing board of Indiana shall ensure that personally identifiable information contained in the reports concerning a patient are redacted before the reports are made available to the public under this section.

Sec. 6. (a) A person who intentionally, knowingly, or recklessly violates this chapter commits an unlawful activity related to an erectile dysfunction drug, a Class A misdemeanor.

(b) In addition to the criminal penalty under subsection (a), a person who violates this chapter may be subject to disciplinary sanctions under IC 25-1-9 and civil liability for wrongful death and medical malpractice.".

Page 7, between lines 1 and 2, begin a new line block indented and insert:

"**IC 16-42-25-6 (Concerning erectile dysfunction drugs).**".

Renumber all SECTIONS consecutively.

(Reference is to SB 371 as printed February 22, 2013.)

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Senator LANANE