By: Middleton

S.B. No. 822

	A BILL TO BE ENTITLED
1	AN ACT
2	relating to the prohibited manufacture, processing, possession,
3	distribution, offer for sale, and sale of cell-cultured protein.
4	BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF TEXAS:
5	SECTION 1. Section 431.002, Health and Safety Code, is
6	amended by adding Subdivision (5-a) to read as follows:
7	(5-a) "Cell-cultured protein" means a food product
8	derived from harvesting animal cells and artificially replicating
9	those cells in a growth medium to produce tissue.
10	SECTION 2. Section 431.021, Health and Safety Code, is
11	amended to read as follows:
12	Sec. 431.021. PROHIBITED ACTS. The following acts and the
13	causing of the following acts within this state are unlawful and
14	prohibited:
15	(a) the introduction or delivery for introduction into
16	commerce of any food, drug, device, or cosmetic that is adulterated
17	or misbranded;
18	(b) the adulteration or misbranding of any food, drug,
19	device, or cosmetic in commerce;
20	(c) the receipt in commerce of any food, drug, device, or
21	cosmetic that is adulterated or misbranded, and the delivery or
22	proffered delivery thereof for pay or otherwise;
23	(d) the distribution in commerce of a consumer commodity, if
24	such commodity is contained in a package, or if there is affixed to

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1 that commodity a label that does not conform to the provisions of 2 this chapter and of rules adopted under the authority of this 3 chapter; provided, however, that this prohibition shall not apply 4 to persons engaged in business as wholesale or retail distributors 5 of consumer commodities except to the extent that such persons:

6 (1) are engaged in the packaging or labeling of such 7 commodities; or

8 (2) prescribe or specify by any means the manner in 9 which such commodities are packaged or labeled;

10 (e) the introduction or delivery for introduction into 11 commerce of any article in violation of Section 431.084, 431.114, 12 or 431.115;

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(f) the dissemination of any false advertisement;

(g) the refusal to permit entry or inspection, or to permit the taking of a sample or to permit access to or copying of any record as authorized by Sections 431.042-431.044; or the failure to establish or maintain any record or make any report required under Section 512(j), (1), or (m) of the federal Act, or the refusal to permit access to or verification or copying of any such required record;

(h) the manufacture within this state of any food, drug,
device, or cosmetic that is adulterated or misbranded;

(i) the giving of a guaranty or undertaking referred to in Section 431.059, which guaranty or undertaking is false, except by a person who relied on a guaranty or undertaking to the same effect signed by, and containing the name and address of the person residing in this state from whom the person received in good faith

1 the food, drug, device, or cosmetic; or the giving of a guaranty or 2 undertaking referred to in Section 431.059, which guaranty or 3 undertaking is false;

4 (j) the use, removal, or disposal of a detained or embargoed
5 article in violation of Section 431.048;

6 (k) the alteration, mutilation, destruction, obliteration, 7 or removal of the whole or any part of the labeling of, or the doing 8 of any other act with respect to a food, drug, device, or cosmetic, 9 if such act is done while such article is held for sale after 10 shipment in commerce and results in such article being adulterated 11 or misbranded;

(1)(1) forging, counterfeiting, simulating, or falsely representing, or without proper authority using any mark, stamp, tag, label, or other identification device authorized or required by rules adopted under this chapter or the regulations promulgated under the provisions of the federal Act;

17 (2) making, selling, disposing of, or keeping in possession, control, or custody, or concealing any punch, die, 18 19 plate, stone, or other thing designed to print, imprint, or reproduce the trademark, trade name, or other identifying mark, 20 imprint, or device of another or any likeness of any of the 21 foregoing on any drug or container or labeling thereof so as to 22 23 render such drug a counterfeit drug;

(3) the doing of any act that causes a drug to be a
counterfeit drug, or the sale or dispensing, or the holding for sale
or dispensing, of a counterfeit drug;

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(m) the using by any person to the person's own advantage,

1 or revealing, other than to the department, to a health authority,
2 or to the courts when relevant in any judicial proceeding under this
3 chapter, of any information acquired under the authority of this
4 chapter concerning any method or process that as a trade secret is
5 entitled to protection;

(n) the using, on the labeling of any drug or device or in 6 7 advertising relating to such drug or any device, of any 8 representation or suggestion that approval of an application with respect to such drug or device is in effect under Section 431.114 or 9 10 Section 505, 515, or 520(g) of the federal Act, as the case may be, or that such drug or device complies with the provisions of such 11 12 sections;

(o) the using, in labeling, advertising or other sales promotion of any reference to any report or analysis furnished in compliance with Sections 431.042-431.044 or Section 704 of the federal Act;

17 (p) in the case of a prescription drug distributed or offered for sale in this state, the failure of the manufacturer, 18 19 packer, or distributor of the drug to maintain for transmittal, or to transmit, to any practitioner licensed by applicable law to 20 administer such drug who makes written request for information as 21 to such drug, true and correct copies of all printed matter that is 22 23 required to be included in any package in which that drug is 24 distributed or sold, or such other printed matter as is approved under the federal Act. Nothing in this subsection shall be 25 26 construed to exempt any person from any labeling requirement imposed by or under other provisions of this chapter; 27

1 (q)(1) placing or causing to be placed on any drug or device
2 or container of any drug or device, with intent to defraud, the
3 trade name or other identifying mark, or imprint of another or any
4 likeness of any of the foregoing;

5 (2) selling, dispensing, disposing of or causing to be sold, dispensed, or disposed of, or concealing or keeping in 6 possession, control, or custody, with intent to sell, dispense, or 7 8 dispose of, any drug, device, or any container of any drug or device, with knowledge that the trade name or other identifying 9 10 mark or imprint of another or any likeness of any of the foregoing has been placed thereon in a manner prohibited by Subdivision (1); 11 12 or

(3) making, selling, disposing of, causing to be made, 13 sold, or disposed of, keeping in possession, control, or custody, 14 15 or concealing with intent to defraud any punch, die, plate, stone, or other thing designed to print, imprint, or reproduce the 16 17 trademark, trade name, or other identifying mark, imprint, or device of another or any likeness of any of the foregoing on any 18 19 drug or container or labeling of any drug or container so as to render such drug a counterfeit drug; 20

(r) dispensing or causing to be dispensed a different drug in place of the drug ordered or prescribed without the express permission in each case of the person ordering or prescribing;

(s) the failure to register in accordance with Section 510 of the federal Act, the failure to provide any information required by Section 510(j) or (k) of the federal Act, or the failure to provide a notice required by Section 510(j)(2) of the federal Act;

1 (t)(1) the failure or refusal to:

2 (A) comply with any requirement prescribed under
3 Section 518 or 520(g) of the federal Act; or

4 (B) furnish any notification or other material or
5 information required by or under Section 519 or 520(g) of the
6 federal Act;

7 (2) with respect to any device, the submission of any
8 report that is required by or under this chapter that is false or
9 misleading in any material respect;

10 (u) the movement of a device in violation of an order under 11 Section 304(g) of the federal Act or the removal or alteration of 12 any mark or label required by the order to identify the device as 13 detained;

(v) the failure to provide the notice required by Section 412(b) or 412(c), the failure to make the reports required by Section 412(d)(1)(B), or the failure to meet the requirements prescribed under Section 412(d)(2) of the federal Act;

(w) except as provided under Subchapter M of this chapter and Section 562.1085, Occupations Code, the acceptance by a person of an unused prescription or drug, in whole or in part, for the purpose of resale, after the prescription or drug has been originally dispensed, or sold;

(x) engaging in the wholesale distribution of drugs or operating as a distributor or manufacturer of devices in this state without obtaining a license issued by the department under Subchapter I, L, or N, as applicable;

27 (y) engaging in the manufacture of food in this state or

operating as a warehouse operator in this state without having a license as required by Section 431.222 or operating as a food wholesaler in this state without having a license under Section 431.222 or being registered under Section 431.2211, as appropriate; (z) unless approved by the United States Food and Drug

6 Administration pursuant to the federal Act, the sale, delivery, 7 holding, or offering for sale of a self-testing kit designed to 8 indicate whether a person has a human immunodeficiency virus 9 infection, acquired immune deficiency syndrome, or a related 10 disorder or condition;

(aa) making a false statement or false representation in an application for a license or in a statement, report, or other instrument to be filed with or requested by the department under this chapter;

(bb) failing to comply with a requirement or request to provide information or failing to submit an application, statement, report, or other instrument required by the department;

18 (cc) performing, causing the performance of, or aiding and
19 abetting the performance of an act described by Subsection (x);

20 (dd) purchasing or otherwise receiving a prescription drug 21 from a pharmacy in violation of Section 431.411(a);

(ee) selling, distributing, or transferring a prescription drug to a person who is not authorized under state or federal law to receive the prescription drug in violation of Section 431.411(b);

25 (ff) failing to deliver prescription drugs to specified 26 premises as required by Section 431.411(c);

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(gg) failing to maintain or provide pedigrees as required by

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1 Section 431.412 or 431.413;
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2 (hh) failing to obtain, pass, or authenticate a pedigree as
3 required by Section 431.412 or 431.413;

4 (ii) the introduction or delivery for introduction into5 commerce of a drug or prescription device at a flea market;

(jj) the receipt of a prescription drug that is adulterated,
misbranded, stolen, obtained by fraud or deceit, counterfeit, or
suspected of being counterfeit, and the delivery or proffered
delivery of such a drug for payment or otherwise; [or]

10 (kk) the alteration, mutilation, destruction, 11 obliteration, or removal of all or any part of the labeling of a 12 prescription drug or the commission of any other act with respect to 13 a prescription drug that results in the prescription drug being 14 misbranded; or

15(11) the manufacture, processing, possession,16distribution, offer for sale, or sale of cell-cultured protein.

SECTION 3. Section 431.081, Health and Safety Code, is amended to read as follows:

Sec. 431.081. ADULTERATED FOOD. A food shall be deemed to be adulterated:

21 (a) if:

(1) it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance the food shall not be considered adulterated under this subdivision if the quantity of the substance in the food does not ordinarily render it injurious to health; (2) it:

1 (A) bears or contains any added poisonous or 2 added deleterious substance, other than one that is a pesticide 3 chemical in or on a raw agricultural commodity, a food additive, a 4 color additive, or a new animal drug which is unsafe within the 5 meaning of Section 431.161;

6 (B) is a raw agricultural commodity and it bears 7 or contains a pesticide chemical which is unsafe within the meaning 8 of Section 431.161(a);

9 (C) is, or it bears or contains, any food 10 additive which is unsafe within the meaning of Section 431.161(a); provided, that where a pesticide chemical has been used in or on a 11 12 raw agricultural commodity in conformity with an exemption granted or a tolerance prescribed under Section 431.161(a), and such raw 13 agricultural commodity has been subjected to processing such as 14 15 canning, cooking, freezing, dehydrating, or milling, the residue of such pesticide chemical remaining in or on such processed food 16 17 shall, notwithstanding the provisions of Section 431.161 and Section 409 of the federal Act, not be deemed unsafe if such residue 18 19 in or on the raw agricultural commodity has been removed to the good manufacturing practice, 20 extent possible in and the concentration of such residue in the processed food, when ready to 21 eat, is not greater than the tolerance prescribed for the raw 22 23 agricultural commodity; or

(D) is, or it bears or contains, a new animal
drug, or a conversion product of a new animal drug, that is unsafe
under Section 512 of the federal Act;

27 (3) it consists in whole or in part of a diseased,

1 contaminated, filthy, putrid, or decomposed substance, or if it is 2 otherwise unfit for foods;

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3 (4) it has been produced, prepared, packed or held 4 under unsanitary conditions whereby it may have become contaminated 5 with filth, or whereby it may have been rendered diseased, 6 unwholesome, or injurious to health;

7 (5) it is, in whole or in part, the product of a 8 diseased animal, an animal which has died otherwise than by 9 slaughter, or an animal that has been fed upon the uncooked offal 10 from a slaughterhouse;

(6) its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; [or]

14 (7) it has been intentionally subjected to radiation, 15 unless the use of the radiation was in conformity with a regulation 16 or exemption in effect in accordance with Section 409 of the federal 17 Act; or

18 (8) it contains, in whole or in part, cell-cultured 19 protein;

20 (b) if:

21 (1) any valuable constituent has been in whole or in 22 part omitted or abstracted therefrom;

(2) any substance has been substituted wholly or in
24 part therefor;

25 (3) damage or inferiority has been concealed in any 26 manner;

27 (4) any substance has been added thereto or mixed or

1 packed therewith so as to increase its bulk or weight, or reduce its 2 quality or strength or make it appear better or of greater value 3 than it is;

4 (5) it contains saccharin, dulcin, glucin, or other
5 sugar substitutes except in dietary foods, and when so used shall be
6 declared; or

7 (6) it be fresh meat and it contains any chemical
8 substance containing sulphites, sulphur dioxide, or any other
9 chemical preservative which is not approved by the United States
10 Department of Agriculture, the Animal and Plant Health Inspection
11 Service (A.P.H.I.S.) or by department rules;

12 (c) if it is, or it bears or contains, a color additive that
13 is unsafe under Section 431.161(a); or

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(d) if it is confectionery and:

15 (1) has any nonnutritive object partially or 16 completely imbedded in it; provided, that this subdivision does not 17 apply if, in accordance with department rules, the object is of 18 practical, functional value to the confectionery product and would 19 not render the product injurious or hazardous to health;

(2) (2) bears or contains any alcohol, other than alcohol not in excess of five percent by volume. Any confectionery that bears or contains any alcohol in excess of one-half of one percent by volume derived solely from the use of flavoring extracts and less than five percent by volume:

(A) may not be sold to persons under the legal age
 necessary to consume an alcoholic beverage in this state;

27 (B) must be labeled with a conspicuous, readily

1 legible statement that reads, "Sale of this product to a person 2 under the legal age necessary to consume an alcoholic beverage is 3 prohibited";

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4 (C) may not be sold in a form containing liquid 5 alcohol such that it is capable of use for beverage purposes as that 6 term is used in the Alcoholic Beverage Code;

may not be sold through a vending machine;

8 (E) must be labeled with a conspicuous, readily 9 legible statement that the product contains not more than five 10 percent alcohol by volume; and

(D)

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(F) may not be sold in a business establishment which derives less than 50 percent of its gross sales from the sale of confectioneries; or

14 (3) bears or contains any nonnutritive substance; 15 provided, that this subdivision does not apply to a nonnutritive substance that is in or on the confectionery by reason of its use 16 17 for a practical, functional purpose in the manufacture, packaging, or storage of the confectionery if the use of the substance does not 18 19 promote deception of the consumer or otherwise result in adulteration or misbranding in violation of this chapter; and 20 provided further, that the executive commissioner may, for the 21 purpose of avoiding or resolving uncertainty as to the application 22 23 of this subdivision, adopt rules allowing or prohibiting the use of 24 particular nonnutritive substances.

25 SECTION 4. Subchapter D, Chapter 433, Health and Safety 26 Code, is amended by adding Section 433.057 to read as follows:

27 Sec. 433.057. PROHIBITION ON CELL-CULTURED PROTEIN. (a)

In this section, "cell-cultured protein" has the meaning assigned by Section 431.002.

3 (b) A person may not manufacture, process, possess,
4 distribute, offer for sale, or sell cell-cultured protein.

5 (c) To the extent another state law conflicts with this 6 section, this section controls.

7 SECTION 5. As soon as practicable after the effective date 8 of this Act, the executive commissioner of the Health and Human 9 Services Commission shall adopt any rules necessary to implement 10 the changes in law made by this Act.

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SECTION 6. This Act takes effect September 1, 2025.