HOUSE BILL NO. 797

INTRODUCED BY BENNETT, MENAHAN, AZZARA, SEIFERT, HEMSTAD, CONN, KEYSER, DEVLIN, SWITZER, WINSLOW, SIVERTSEN, GOULD, NILSON, PAVLOVICH

IN THE HOUSE

February 1	7, 1981	Introduced and referred to Committee on Human Services.
February 21	1, 1981	Committee recommend bill do pass as amended. Report adopted.
February 23	3, 1981	Bill printed and placed on members desks.
February 2	4, 1981	Second reading, do pass.
		On motion rules suspended and bill placed on third reading this day.
February 2	5, 1981	Third reading, passed. Ayes, 89; Noes, 7. Transmitted to Senate.

IN THE SENATE

March 3, 1981	Introduced and referred to Committee on Public Realth, Welfare, and Safety.
March 26, 1981	Committee recommend bill be not concurred in. Report adopted.

IN THE HOUSE

March 27, 1981 Returned from Senate not concurred in.

On motion the Senate request for return of HB 797 for further consideration be granted. Motion adopted.

Returned to Senate.

IN THE SENATE

March 27, 1981

On motion Senate reconsider its action taken on adverse committee report. Motion adopted.

On motion Senate requests return of House Bill No. 797 from House for further consideration.

March 28, 1981

Returned from House.

On motion placed on second reading.

March 30, 1981

Motion pass consideration.

March 31, 1981

Second reading, concurred in.

On motion rules suspended. Bill placed on calendar for third reading this day and allowed to be transmitted on 71st legislative day. Motion adopted.

Third reading, concurred in. Ayes, 33; Noes, 16.

IN THE HOUSE

April 1, 1981

Returned from Senate. Concurred in. Sent to enrolling.

Reported correctly enrolled.

25

1	HOUSE BILL NO. 797 Sefet
2	INTRODUCED BY Sensell Monahay Accident
3 🛪	Gental Com Bey to Never Switer Under
4	A BILL COM AN ACT ENTITLEDS "AN ACT TO AUTHORIZE THE SALE
5	BY PRESCRIPTION OF DIMETHYL SULFOXIDE (OMSO); AMENDING
6	SECTION 50-31-311, MCA."
7	
8	BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MONTANA:
9	Section 1. Section 50-31-311, MCA, is amended to read:
16	#50-31-311. New drug application required. (1) No
11	Except as provided in [sections 2 through 8]. no person
12	shall may sell, deliver, offer for sale, hold for sale, or
13	give away any new drug unless:
14	(a) an application with respect thereto has been
15	approved and said approval has not been withdrawn under
16	section 505 of the federal act; or
17	(b) when not subject to the federal act, such drug has
18	been tested and has been found to be safe for use and
19	effective in use under the conditions prescribed,
20	recommended, or suggested in the labeling thereof and, prior
21	to selling or offering for sale such drug, there has been
22	filed with the department an application setting forth:
23	(i) full reports of investigations which have been
24	made to show whether or not such drug is safe for use and
17 13 19 20 21 22 23	(b) when not subject to the federal act, such drug has been tested and has been found to be safe for use and effective in use under the conditions prescribed, recommended, or suggested in the labeling thereof and, prior to selling or offering for sale such drug, there has been filed with the department an application setting forth: (i) full reports of investigations which have been

whather such drug is effective in use;

(ii) a full list of the articles used as components of
such drug;
(iii) a full statement of the composition of such drug;
(iv) a full description of the methods used in• and the
facilities and controls used for, the manufacture,
processing, and packing of such drug;
(v) such samples of such drug and of the articles used
as components thereof as the department may require; and
(vi) specimens of the labeling proposed to be used for
such drug.
(2) An application provided for in subsection (1)(b)
shall become effective on the 180th day after the filing
thereof, except that, if the department finds, after due
notice to the applicant and giving him an opportunity for a
hearing, that the drug is not safe or not effective for use
under the conditions prescribed, recommended, or suggested
in the proposed labeling thereof, it shall, prior to the
effective date of the application, issue an order refusing
to permit the application to become effective.
(3) An order refusing to permit an application under
this section to become effective may be revoked by the
department."
NEW SECTION. Section 2. DMSO defined. As used in

[sections 2 through 8], "DMSO" means dimethyl sulfoxide.

NEW SECTION. Section 3. DMSD

1 2

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

INTRODUCED BILL HB 797

authorized.

manufacture, sale, possession, and distribution of DMSO are lawful within this state. However, distribution or sale of DMSO for human use must be by prescription in accordance with 50-31-307. A person who violates this section is subject to the penalties provided for in 50-31-506.

1

2

3

4

5

6

7

8

10

11

12

13

14

15

16

17 18

19

20

21

22

NEW SECTION. Section 4. Respital not to interfere. A hospital or health care facility may not interfere with the physician-patient relationship by restricting or forbidding the use of DMSD when requested by a patient and prescribed or administered by a physician.

NEM SECTION. Section 5. Health care facility nonliability. No hospital, health care facility, or employee thereof shall be held liable for the administration of DMSO to any person at the direction of a physician licensed in Montana.

NEW SECTION. Section 6. Physician not subject to disciplinary action. A physician may not be subjected to disciplinary action by the board of medical examiners for prescribing or administering DMSO to a patient under his care as an adjunct to recognized, customary, or accepted modes of therapy in the treatment of any malignancy, disease, illness, or physical condition.

23 <u>NEH SECTION</u> Section 7. DMSO not endorsed. [Sections 24 2 through 8] are not an endorsement of DMSO for the 25 treatment of any malignancy, disease, illness, or physical

l condition.

2 NEW SECTION. Section 6. DMSO optional. [Sections 2

3 through 8] do not require:

(1) a physician, pharmacist, pharmacy, manufacturer,

5 or distributor to manufacture, sell, or distribute 0%50; or

(2) a physician to prescribe DMSO for any patient.

-End-

Approved by Comm. On Human Services

1	HOUSE BILL NO. 797
2	INTRODUCED BY BENNETT, MENAHAN, AZZARA, SEIFERT,
3	HEMSTAD. CONN. KEYSER. DEVLIN. SWITZER.
4	WINSLOW+ SIVERTSEN+ GOULD+ NILSON+ PAVLOVICH
5	
6	A BILL FOR AN ACT ENTITLED: "AN ACT TO AUTHORIZE THE SALE
7	BY PRESCRIPTION OF DIMETHYL SULFOXIDE (DMSO); AMENDING
8	SECTION 50-31-311+ MCA+*
9	
10	BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MONTANA:
11	Section 1. Section 50-31-311, MCA, is amended to read:
12	#50-31-311. New drug application required. (1) No
13	Except as provided in [sections 2 through 8], no person
14	shall may sell, deliver, offer for sale, hold for sale, or
15	give away any new drug unless:
16	(a) an application with respect thereto has been
17	approved and said approval has not been withdrawn under
18	section 505 of the federal act; or
19	(b) when not subject to the federal act, such drug has
20	been tested and has been found to be safe for use and
21	effective in use under the conditions prescribed.
22	recommended, or suggested in the labeling thereof and, prior
23	to selling or offering for sale such drug, there has been
24	filed with the department an application setting forth:
25	(i) full reports of investigations which have been

made to show whether or not such drug is safe for use and
whether such drug is effective in use;
(ii) a full list of the articles used as components of
such drug;
(iii) a full statement of the composition of such drug;
(iv) a full description of the methods used in, and the
facilities and controls used for the manufacture.
processing, and packing of such drug;
(v) such samples of such drug and of the articles used
as components thereof as the department may require; and
(vi) specimens of the labeling proposed to be used for
such drug.
{2} An application provided for in subsection (1)(b)
shall become effective on the 180th day after the filing
thereof, except that, if the department finds, after due
notice to the applicant and giving him an opportunity for a
hearing, that the drug is not safe or not effective for use
under the conditions prescribed, recommended, or suggested
in the proposed labeling thereof, it shall, prior to the
effective date of the application, issue an order refusing
to permit the application to become effective.
(3) An order refusing to permit an application under

department."

this section to become effective may be revoked by the

[sections 2 through 8]. "DMSO" means dimethyl sulfoxide.

2

3

5

7

8

9

11

13

14

15

16 17

18

19

20 21

22

23

24

25

NEW SECTION. Section 3. DMSO authorized. The manufacture, sale, possession, and distribution of DMSO are lawful within this state. However, distribution or sale of DMSO for human use must be by prescription in accordance with 50-31-307. A person who violates this section is subject to the penalties provided for in 50-31-506.

NEW SECTION. Section 4. Hospital not to interfere. A hospital or health care facility may not interfere with the physician-patient relationship by restricting or forbidding the use of DMSO when requested by a patient and prescribed or administered by a physician.

NEW SECTION. Section 5. Health care facility nonliability. No hospital, health care facility. PHARMACY, or employee thereof shall be held liable for the administration of DMSO to any person at the direction of a physician licensed in Montana.

NEW SECTION. Section 6. Physician not subject to disciplinary action. A physician may not be subjected to disciplinary action by the board of medical examiners for prescribing or administering DMSD to a patient under his care as an adjunct to recognized, customary, or accepted modes of therapy in the treatment of any malignancy, disease, illness, or physical condition.

NEW SECTION: Section 7: DMSO not endorsed: [Sections

2 through 81 are not an endorsement of DMSO for the 1 2 treatment of any malignancy, disease, illness, or physical 3 condition. 4 NEW SECTION. Section 8. DMSO optional. [Sections 2 5 through 8] do not require: 6 (1) a physician, pharmacist, pharmacy, manufacturer, 7 or distributor to manufacture, sell, or distribute DMSO: or 8 (2) a physician to prescribe DMSO for any patient.

-End-

1	HOUSE BILL NO. 797
2	INTRODUCED BY BENNETT, MENAHAN, AZZARA, SEIFERT,
3	HEMSTAD. CONN. KEYSER, DEVLIN, SWITZER.
4	WINSLOW+ SIVERTSEN+ GOULD+ NILSON+ PAVLOVICH
5	
6	A BILL FOR AN ACT ENTITLED: "AN ACT TO AUTHORIZE THE SALE
7	BY PRESCRIPTION OF DIMETHYL SULFOXIDE (DMSO); AMENDING
8	SECTION 50-31-311, MCA."
9	
0	BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MONTANA:
1	Section 1. Section 50-31-311, MCA, is amended to read:
2	#50-31-311. New drug application required. (1) No
3	Except as provided in [sections 2 through 8], no person
4	shell may sell, deliver, offer for sale, hold for sale, or
5	give away any new drug unless:
.6	(a) an application with respect thereto has been
.7	approved and said approval has not been withdrawn under
18	section 505 of the federal act; or
19	(b) when not subject to the federal act, such drug has
20	been tested and has been found to be safe for use and
21	effective in use under the conditions prescribed
22	recommended, or suggested in the labeling thereof and, prior
23	to selling or offering for sale such drug, there has been
24	filed with the department an application setting forth:
3 6	til full generate of investigations which have been

made to show whether or not such drug is safe for use and whether such drug is effective in use;

- 3 (ii) a full list of the articles used as components of4 such drug;
- 5 (iii) a full statement of the composition of such drug;
- 6 (iv) a full description of the methods used in, and the 7 facilities and controls used for, the manufacture,
- 8 processing, and packing of such drug;
- 9 (v) such samples of such drug and of the articles used
 10 as components thereof as the department may require; and
- 11 (vi) specimens of the labeling proposed to be used for
 12 such drug.
- (2) An application provided for in subsection (1)(b) 13 shall become effective on the 180th day after the filing 14 thereof, except that, if the department finds, after due 15 16 notice to the applicant and giving him an opportunity for a 17 hearing, that the drug is not safe or not effective for use 18 under the conditions prescribed, recommended, or suggested 19 in the proposed labeling thereof, it shall, prior to the effective date of the application, issue an order refusing 20 21 to permit the application to become effective.
- 23 this section to become effective may be revoked by the department."
- 25 <u>NEW SECTION.</u> Section 2. DMSO defined. As used in

[sections 2 through 8], "DMSO" means dimethyl sulfoxide.

NEW SECTION. Section 3. DMSO authorized. The manufacture, sale, possession, and distribution of DMSO are lawful within this state. However, distribution or sale of DMSO for human use must be by prescription in accordance with 50-31-307. A person who violates this section is subject to the penalties provided for in 50-31-506.

NEW SECTION: Section 4. Hospital not to interfere. A hospital or health care facility may not interfere with the physician-patient relationship by restricting or forbidding the use of DMSO when requested by a patient and prescribed or administered by a physician.

NEW SECTION. Section 5. Health care facility nonliability. No hospital, health care facility, PHARMACY, or employee thereof shall be held liable for the administration of DMSO to any person at the direction of a physician licensed in Montana.

NEW SECTION. Section 6. Physician not subject to disciplinary action. A physician may not be subjected to disciplinary action by the board of medical examiners for prescribing or administering DMSO to a patient under his care as an adjunct to recognized, customary, or accepted modes of therapy in the treatment of any malignancy, disease, illness, or physical condition.

NEW SECTION. Section 7. DMSG not endorsed. [Sections

-End-

Control of the contro

ı	HOUSE BILL NO. 797
2	INTRODUCED BY BENNETT. MENAHAN. AZZARA. SEIFERT.
3	HEMSTAD, CONN, KEYSER, DEVLIN, SWITZER,
4	WINSLOW, SIVERTSEN, GOULD, NILSON, PAVLOVICH
5	
6	A BILL FOR AN ACT ENTITLED: "AN ACT TO AUTHORIZE THE SALE
7	BY PRESCRIPTION OF DIMETHYL SULFOXIDE (DMSO); AMENDING
8	SECTION 50-31-311, MCA."
9	
10	BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MONTANA:
11	Section 1. Section 50-31-311: MCA: is amended to read:
12	"50-31-311. New drug application required. (i) No
13	Except as provided in [sections 2 through 8], no person
14	shall may sell, deliver, offer for sale, hold for sale, or
15	give away any new drug unless:
16	(a) an application with respect thereto has been
17	approved and said approval has not been withdrawn under
18	section 505 of the federal act; or
19	(b) when not subject to the federal act, such drug has
20	been tested and has been found to be safe for use and
21	effective in use under the conditions prescribed,
22	recommended, or suggested in the labeling thereof and, prior
23	to selling or offering for sale such drug, there has been
24	filed with the department an application setting forth:
25	(i) full reports of investigations which have been

1	made to show whether or not such drug is safe for use and
2	whether such drug is effective in use;
3	(ii) a full list of the articles used as components of
4	such drug;
5	(iii) a full statement of the composition of such drug;
6	(iv) a full description of the methods used in, and the
7	facilities and controls used for the manufacture,
8	processing, and packing of such drug;
9	(v) such samples of such drug and of the articles used
10	as components thereof as the department may require; and
11	(vi) specimens of the labeling proposed to be used for
12	such drug.
13	(2) An application provided for in subsection (1)(b)
14	shall become effective on the 180th day after the filing
15	thereof, except that, if the department finds, after due
16	notice to the applicant and giving him an opportunity for a
17	hearing, that the drug is not safe or not effective for use
18	under the conditions prescribed, recommended, or suggested
19	in the proposed labeling thereof, it shall, prior to the
20	effective date of the application, issue an order refusing
21	to permit the application to become effective.
22	(3) An order refusing to permit an application under
23	this section to become effective may be revoked by the

	(11) a full list of the articles used as components of
5	such drug;
	(iii) a full statement of the composition of such drug;
	(iv) a full description of the methods used in, and the
f	acilities and controls used for the manufacture.
þ	rocessing, and packing of such drug;
	(v) such samples of such drug and of the articles used
ć	is components thereof as the department may require; and
	(vi) specimens of the labeling proposed to be used for
5	such drug.
	(2) An application provided for in subsection (1)(b)
s	hall become effective on the 180th day after the filing
t	hereof, except that, if the department finds, after due
r	notice to the applicant and giving him an opportunity for a
t	nearing, that the drug is not safe or not effective for use
·	under the conditions prescribed, recommended, or suggested
i	in the proposed labeling thereof, it shall, prior to the
•	effective date of the application, issue an order refusing
1	o permit the application to become effective.
	(3) An order refusing to permit an application under
t	this section to become effective may be revoked by the
d	department.*
	NEW SECTION. Section 2. DMSO defined. As used in

-2-

HB 0797/02

HB 0797/02

tari kanaksala masa mata kanaksala mata kanaksa

[sections 2 through 8], "DMSO" means dimethyl sulfoxide.

2

3

7

8

9

10

11

12

13

14

15

17

18

19

20

22

24

NEW SECTION. Section 3. DMSO authorized. The manufacture. sale, possession, and distribution of DMSO are lawful within this state. However, distribution or sale of DMSO for human use must be by prescription in accordance with 50-31-307. A person who violates this section is subject to the penalties provided for in 50-31-506.

NEW SECTION. Section 4. Hospital not to interfere. A hospital or health care facility may not interfere with the physician-patient relationship by restricting or forbidding the use of DMSO when requested by a patient and prescribed or administered by a physician.

NEW SECTION. Section 5. Health care facility nonliability. No hospital. health care facility. PHARMACY; or employee thereof shall be held liable for the administration of DMSO to any person at the direction of a physician licensed in Montana.

NEW SECTION. Section 6. Physician not subject to disciplinary action. A physician may not be subjected to disciplinary action by the board of medical examiners for prescribing or administering DMSO to a patient under his care as an adjunct to recognized, customary, or accepted modes of therapy in the treatment of any malignancy, disease, illness, or physical condition.

25 <u>NEW SECTION</u>. Section 7. DMSD not endorsed. [Sections

(2) a physician to prescribe DMSO for any patient. -End-

an indonesia, rationale con the Summan de Contrator and Addition to the Contrator and the contrator of the contrator and Contr