Approved	2-10-86	*
pp.o.ca	Date	

MINUTES OF THE HOUSE COMMITTEE ON FEDERAL & STATE AFFAIRS

The meeting was called to order by _____REPRESENTATIVE ROBERT H. MILLER

Chairperson at

<u>1:30</u> a.m./p.m. on ____ February 6

____, 19_86n room __526S____ of the Capitol.

All members were present except:

Rep. Peterson

Committee staff present:

Lynda Hutfles, Secretary Russ Mills, Research

Conferees appearing before the committee:

Pat Goodison, Right to Life Robert Runnels, Kansas Catholic Conference Representative John Sutter Austin Vincent, Kansas Association of Evangelicals Ed Kern, Greater Kansas City Doctor's for Life Bill Gilfillan, Kansans for Life Jerry Slaughter, Kansas Medical Society Barbara Sabol, Department of Health & Environment Belva Ott, Planned Parenthood of Kansas Leslie Anbari, Unitarian Universalist Service Anne Moriarity, National Organization of Women Darlene Stearns, Religious Coalition for Abortion Rights Theresa Shively, National Abortion Rights Action League Adelle Hughey, Comprehensive Health Associates Representative Kathryn Sughrue Steve Page, Department of Health & Environment George Puckett, Kansas Restaurant Association Judy Schrock, Kansas Nurses Association

The meeting was called to order by Chairman Miller.

Representative Sughrue made a motion, seconded by Representative Sallee, to approve the minutes of the February 5 meeting. The motion carried.

HB2052 - Reports concerning termination of pregnancies required.

The Chairman announced that time would be limited to thirty minutes for the proponents and thirty minutes for the opponents.

Pat Goodison, Right to Life, gave testimony in support of the bill expressing her belief that the intent of this bill is to merely update the statute in keeping with the present practice of abortion. Complete and accurage records are important in order for women to be completely informed. There is a need in Kansas to recognize the necessity of complete abortion reporting including those performed outside the hospital setting, such as clinics and individual doctor's offices. See attachment A.

Robert Runnels, Kansas Catholic Conference, gave testimony in support of HB2052 because it strengthens the information base regarding those persons and places that are involved in the abortion trade. See attachment B.

Representative John Sutter, sponsor of the bill, explained the bill which requires every medical facility, including hospitals, ambulatory surgical centers, clinics and various physicians who provide this service to keep records of abortions and to submit an annual report to the Secretary of Health & Environment. See attachment C.

Austin Vincent, Kansas Association of Evangelicals, distributed a position paper on the "Sanctity of Human Life". See attachment \underline{D} .

Unless specifically noted, the individual remarks recorded herein have not been transcribed verbatim. Individual remarks as reported herein have not been submitted to the individuals appearing before the committee for editing or corrections.

Page _1_ of ____

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CONTINUATION SHEET

MINUTES OF THE	HOUSE COMMIT	TEE ONFEDERAL	& STATE	AFFAIRS	
room <u>526S</u> . Statehou	se, at <u>1:30</u> a.m./p	.m. onFebrua	ary 6		19 86

Ed Kern, Greater Kansas City Doctors for Life, read a statement in support of the bill which Dr. Kathy Chartrand was to have submitted. Dr. Chartrand was unable to attend the meeting.

Bill Gilfillan, Vice-President of Kansans for Life, gave testimony in support of HB2052. See attachment E.

Jerry Slaughter, Kansas Medical Society, told the committee the society had no position on abortion per se, but did support the bill. They did have concern for the confidentiality of the records.

Barbara Sabol, Secretary of Health & Environment, gave the committee some background information and told the committee that she felt expansion of the reporting system did not promote a valid public health purpose. This legislation appears to be a regulatory burden and may contribute to the cost of health care. See attachment F.

Belva Ott, Planned Parenthood of Kansas, gave testimony in opposition to HB2052. Mrs. Ott said that abortion providers are currently reporting pregnancy terminations voluntarily. With the passage of this bill, compliance is still voluntary as no penalty exists for non-compliance. There will be an increased and unnecessary expenditure for the state and the bill is potentially unconstitutional. There also exists an opportunity for harassment and intimidation of individual abortion providers who do comply. See attachment G.

Leslie Anbari, Unitarian Universalist Service, gave testimony in opposition to the bill stating that many clinics and medical care facilities have suffered harassment because of reporting of abortions. They are also concerned with the violations that might occur of confidentiality.

Anne Moriarity, Kansas NOW, gave testimony in opposition to the bill, expressing their feeling that the real intent of the bill is to erect one of several planned hurdles in the path of women who attempt to exercise thier fundamental rights. See attachment H.

Darlene Stearns, Religious Coalition for Abortion Rights in Kansas, gave testimony in opposition to the bill. She explained that their concern is the harassment of physicians and staff required to report abortions by this bill by those people opposing abortion. See attachment I

Theresa Shively, Kansas NARAL, distributed her statement in which she stated it is fiscally irresponsible to use tax dollars to require reporting of abortions which has no benefit to the public at large or the state. Termination of pregnancy poses no health risk to the general public and is reported voluntarily without the extra burden of state dollars and state time to monitor and regulate compliance. See attachment J.

Adelle Hughey, Comprehensive Health Associates, gave testimony in opposition to the bill. She said that anti-choice people will not believe what is reported. Their facility is already harassed, including staff and they are picketed on Sunday afternoons. In answer to a statement concerning payment of pregnancy terminations (cash only) she stated that they do accept checks, insurance forms, etc. See attached form K.

Hearings on HB2052 were concluded.

 ${\underline{\tt HB2681}}$ - food treated with sulfites

Representative Sughrue, sponsor of the bill, explained the bill which requires food service establishments to provide notice to customers of the use of sulfiting agents. The bill was copies after California law. See attachment L.

CONTINUATION SHEET

MINUTES OF THE	HOUSE COMMITTEE ON	FS&A	
room 526S Stateh	nouse, at 1:30 a.m./p.m. on	February 6	10 8

Steve Page, Department of Health & Environment, explained the department's support of the bill and gave background information on the use of sulfites in foods in Kansas. See attachment M.

George Puckett, Kansas Restaurant Association, told the committee that the FDA has proposed a rule that will ban the use of sulfites from foodservice establishments for use as a fruit and vegetable freshener. The final rule is expected by June 1, 1986. The KRS's position continues to be one of recommending that sulfite agents not be applied in any way at the retail level. See attachment N.

Judy Schrock, Kansas Nurses Association, gave testimony in support of the bill and would support the complete elimination of sulfites from use in restaurants as they are currently used on fresh foods and vegetables. See attachment O.

Hearings were concluded on HB2681.

The Chairman explained to the committee the necessity of having two senate bills next week, departing from the normal policy of hearing house bills first.

The meeting was adjourned.



LEGISLATIVE TESTIMONY

Crosby Place Mall 717 S. Kansas Ave.

Topeka, Ks. 66603

(913) 233-8601

HOUSE FEDERAL AND STATE AFFAIRS COMMITTEE

EBRUARY 6, 1986

Pight To Life of Kansas. We appreciate the opportunity to appear in support of House hill 2052 which addresses a long standing concern of our organization.

This bill had full hearings and was passed out of public health and welfare last year. It was rereferred to your committee at the request of the sponsor to keep it alive near the end of the session. House Bill 2052 amends YSA 65 425. The intent is merely to update the statute in keeping with the present practice of abortion. At the time that abortion was legalized in Yansas the legislature recognized the necessity of complete reporting of abertion, but since abortion was legal only in hospitals the law was drafted to reflect that fact. Since the 1973 supreme court decision more and more abortions have been performed outside the hospital setting till the present time when most abortions are done in clinics and individual doctors offices.

The importance of keeping "vital statistics" is self evident and long since recognized as a necessary duty of government. The statewide registration of births and death or mortality records was established as a statutory duty of the Kansas Board of Health in 1885. In 1913 and 1951 respectively registration of marriages and divorces was added to the "vital events" kept by the "ealth Departments Pureau of Vital Statistics.

ATT_{ACHMENT} A
H. F+SA
2/6/86

We can take pride in much of the work done by the Bureau of Vital Statistics.

Their annual summary report gives us some idea of the voluminous records kept on morbidity and mortality of Yansas citizens, birth related events, marriages and divorces, and maternal and child health issues. Attached to my testimony is a copy of the latest monthly printout of abortion statistics. You will note that abortions are included by the Health Department and correctly so in the section entitled Birth Related Mortality.

Abortion cannot be equated with a tonsilectomy or any other medical procedure. Abortion takes the life of a living human preborn infant. It is a mortality, that is, a death statisite.

Statutorily, the decision of what information to require concerning reported abortion is left to the discretion of the Health Department. House Pill 2052 retains that provision. Historically, I believe there has been no change in the type of information required since 1970 except possibly that of repeat abortion. I believe this was not kept for the first year or two. When it was first included in 1971 or 1972 the number of women undergoing a second or third or fourth abortion was around one or two percent. That percentage has risen steadily to around thirty percent at the present time. This is one of the best kept secrets of the pro-choice movement.

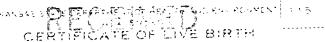
Regardless, complete and accurate records are important in order for women to be completely informed. USA Today reported this week the chaos being created over the withdrawal of one more major company from the production of the TUD or Intrauterine Pevice, and one other major drug company has gone bankrupt. The entire TUD fiasco is but one example of how some in the health care industry have put profit and self interest above the welfare of the patients they serve.

We believe the Health Department is keeping good information within the limitations they have been placed and we see no reason to charge them with any other duties. We do not believe most complications are being reported. One reason is that in most cases the abortionist is only aware of the immediate complications that occur while the patient is still within the facility. The public health and welfare committee struck a provision in the orginal bill to require follow up reporting and while we feel that was reasonable and necessary, we think the bill as it stands now is a good bill and makes basic ordinary common sence. You are not being asked to make a policy decision as to whether or not we should keep abortion statistics...only whether or not we should have accurate and complete statistics.

It makes no sense for the State of Yansas to spend money on intricate records as we are now and not have those records as complete and accurate as possible. Having no statistics could be more meaningful than inaccurate statistics because you could make some honest guesses and they would be just that and presented as such. One important fact that the committee should be aware if is that the Mational Center for Pisease Control uses the Health Pepartment statistics with no qualification or reservation and thus our national abortion statistics are flawed.

Last year the committee expressed a concern over confidentiality and amended the bill in lines 43 and 45 to provide that the "names and addresses of medical care facilities and persons required to report in this section shall be confidential and may not be disclosed by the secretary."

I urge the committee to report HB 2052 favorable for passage.



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STATE OF KANEGE

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THE KANGAS STATE DEPARTMENT OF MEALTH AND ENVIRON. Eurosia of Vital Statistics

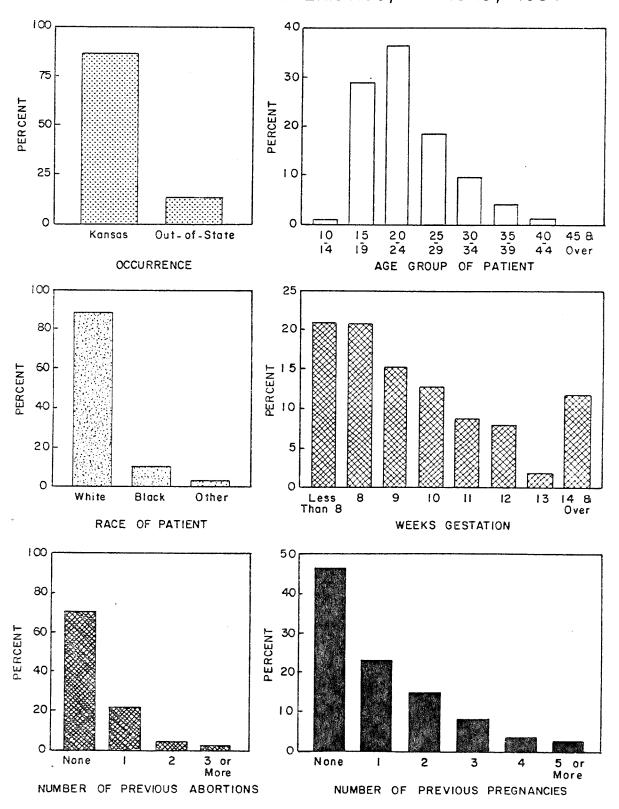
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REPORTED INDUCED ABORTIONS BY SELECTED CHARACTERISTICS, KANSAS, 1984



Residence data.

Figure 9

BIRTH-RELATED MORTALITY

This section examines mortality as it relates to pregnancy, childbirth, and infancy. For discussion purposes it is presented in five subdivisions: (1) induced abortions; (2) fetal deaths (stillbirths); (3) perinatal period III mortality; (4) infant deaths; and (5) maternal deaths.

INDUCED ABORTIONS

The Kansas liberalized abortion law was enacted in July, 1970, and from that time through 1984, 162,340 abortions were reported in Kansas. There were 9,754 abortions reported in Kansas in 1984.

The number of abortions reported in Kansas from 1971 to 1984 is shown below. The decline in the number of abortions reported in Kansas in 1974 and 1975 is attributable to the reduction in the number of out-of-state residents having abortions performed in Kansas since the 1973 United States Supreme Court ruling which legalized abortion in all states. The number of abortions reported in Kansas in 1984 represented a 0.9 percent decrease from the 1983 total of 9,844.

Number of Abortions Reported in Kansas by Year

<u>Year</u>	Number
1984	9,754
1983	9,844
1982	11,107
1981	12,137
1980	13,381
1979	13,901
1978	10,904
1977	10,898
1976	11,597
1975	10,860
1974	10,871
1973	12,612
1972	12,248
1971	9,472

Summary statistics are available only for those 8,008 abortions reported by hospitals and clinics participating in our abortion reporting system during 1984, regardless of where the abortion occurred.

In 1984, 4,614 abortions or 63.2 percent of the 7,303 that occurred in the State, were performed for Kansas residents. Of the 2,689 nonresidents who had abortions in Kansas, 93.9 percent (2,526) were Missouri residents. Residents from other states included those from Oklahoma (62), Nebraska (34), Iowa (20), Illinois (11) and Arkansas (9). Twenty-seven patients represented other states.

Kansas Residence Summary:

The following analysis refers to the 5,319 abortions reported for Kansas residents, regardless of where the abortion occurred.

Occurrence: In 1984, the Kansas Department of Health and Environment received statistics on 705 abortions performed in other states for Kansas residents. Of those 705 abortions, 613 (87.0 percent) occurred in Missouri, 68 (9.6 percent) occurred in Oklahoma, and 19 (2.7 percent) occurred in Nebraska.

Age of Patient: Most reported abortions were performed in the 15-19 and 20-24 age groups as shown in Figure 9. Enumerated below is the number of abortions by age group of patient, percent distribution and age-specific abortion ratios (number of abortions reported per thousand live births for a given age group.) Induced abortions by county of residence and age group of patient in 1984 are given in Appendix Table 30.

Abortions: Distribution by Age Group of Patient and Age-Specific Ratios

Age Group	Number	Percent	Ratio**
Total	5,319 49 1,549 1,924 976 522 225 62 2	100.0 0.9 29.2 36.3 18.4 9.8 4.2 1.2 0.0	333.1 139.4 74.4 80.3 141.5 279.3

^{**}Age-specific abortion ratios are expressed as the number of abortions per 1,000 live births for a given age group.

Race: Most of the abortion patients, 88.5 percent (4,672), in 1984 were white. Black patients represented 9.3 percent (490), and other races constituted 2.2 percent (114). Race was not stated in 43 cases.

Marital Status of Patient: Of the 5,319 abortion patients residing in Kansas in 1984, 4,192 or 79.3 percent, were not married; 1,091 or 20.7 percent were married and 36 patients did not report their marital status.

Number of Previous Abortions: In 1984, 3,788 or 71.6 percent, of the patients had no previous abortions. Almost twenty-two (21.8) percent, or 1,154, had one previous abortion, 4.6 percent (245) had two previous abortions, and 2.0 percent (106) had three or more previous abortions. In 26 cases the number of previous abortions was not stated.

Number of Previous Pregnancies: Forty-six (46.5) percent (2,469) of the patients reported no previous pregnancies, and 22.9 percent (1,213) reported one previous pregnancy. Fifteen (15.2) percent (808) had two previous pregnancies, 15.4 percent (816) reported three or more previous pregnancies, and 13 patients did not report the number of previous pregnancies.

Method of Abortion: Ninety-seven (97.2) percent (5,169) of the abortions were performed by suction curettage. Sharp curettage was utilized in 51 cases, and intra-uterine saline instillation was performed in 7 cases. In 89 cases, other methods were used, and 3 cases did not report the method of abortion.

Weeks Gestation: Most abortions (88.3 percent) were performed within the first three months of pregnancy, or prior to the fourteenth week of gestation. Only 615, or 11.7 percent, were performed later than the thirteenth week after conception, while 77 cases did not state weeks gestation.

Table 30 Reported Induced Abortions by Age Group of Patient By County of Residence Kansas, 1984

		Age Group of Patient								
County of					G 0				45 &	
Residence	Total	10-14	15-19	20-24	25-29	30-34	35-39	40-44	Over	N.S.
Kansas	5,319	49	1,549	1,924	976	522	225	62	2	10
Allen	30 7	-	13 2	7 4	3 1	4 -	2	1 -	- -	_
Anderson	32	_	13	13	3	3	-	-	-	-
Barber	8	-	4	1	2	- 5	2	_	1	-
Barton	42	-	13	11	11	י ל	2	_		
Bourbon	21	-	7	7	3	2	1	1 -	-	_
Brown	6 46	- 2	1 14	3 19	9		2	_	_	-
Butler	40	_	1	1	_	1	_	-	-	-
Chase	7	-	2	3	-	1	1	-	-	-
	20	1	8	11	4	6	_	_	-	-
Cherokee	30 2		_	-	_	2	-	-	-	-
Clark	2	_	1	1	_	-	-	-	-	_
Clay	2	_	1	1	-	-	-	_	_	_
Cloud	9	-	3	3	3	-	-	_	-	_
Coffey	13	_	3	7	2	1	-	-	-	-
Comanche	2	-	2	_	-	-	- 1	2	_	_
Cowley	44	-	13	19	8	1 3	5	2	_	_
Crawford	87	1	28	38	12	3	-	_	_	_
Decatur	2	-	2	_	_	_				
Dickinson	8	_	3	2	2	-	-	-	-	1
Doniphan	15	-	8	4	2	-	10	1 4	_	1
Douglas	351	1	89	156	64	26	10	_	_	_
Edwards	5 2	_	2	1	<u> </u>		_	_	-	-
Elk	2	_		'						-
Ellis	85	-	26	41	10	7	1 1		_	_
Ellsworth	3	-	1 10	1 13	8	14	2	1	_	-
Finney	38 42	- 1	15	9	6	10	1	-	-	-
Ford	48	_	17	15	9	6	-	1	-	-
	26	2	9	12	9	2	2	_	_	-
Geary	36	_	-	-	1	_	_	-	-	-
GoveGraham	3	_	1	-	1	1	-	-	-	-,
Grant	4	-	1	1	1	_	1	-	_	_
Gray	3	_	-	2	1	_	_	-	_	
Greeley	_	-	_	_	_	-	-	-	-	-
Greenwood	3	-	2	-	1	-	-	-		_
Hamilton	1	-	-	1		-	_		_	1
Harper	7	-	2	3	1 3	-		-	_	
Harvey	30	-	13	"4)					
Haskell	4	-	1	1	1	-	1	-	-	_
Hodgeman	-	-	-	-	-	- 1	3	1		_
Jackson	20	' -	8	7 8	4	1 2	3 -		_	
Jefferson	26		12	-	-	_	_	-	-	-
Jewell							-	4 11	1	1
Johnson	1,155	8	328	393	212	133	65	14	_ '	
Kearny	1	-	-	1	- 2	_	_		_	_
Kingman	7	-	1 1	3	3 -	_		_	_	-
Kiowa	1 45	1	21	13	5	2	2	1	-	-
Labette								_	_	_
Lane	3	-	2 26	36	21	<u> </u>	4	1	_	_
Leavenworth	92	_		-		1	-	-	-	-
Lincoln	9	 -	5	_	-	1	2	1	-	-

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Table 30 (cont.)
Reported Induced Abortions by Age Group of Patient
By County of Residence
Kansas, 1984

		Age Group of Patient								
County of Residence	Total	10-14	15–19	20-24	25-29	30-34	35-39	40-44	45 & Over	N.S.
Lyon	128	3	40	54	16	13	1 1	1 -	-	-
Marion	5	-	1 4	3 2	-	_	. <u>'</u>	_	_	_
Marshall	6 28	_	9	10	3	4	2	_	_	_
McPherson Meade	4	-	3 .	1	-	-	-	-	-	-
Miami	30	_	13	9	5	2	1	-	-	-
Mitchell	5	-	1	2	-	2	-	-	_	_
Montgomery	37	1	18	11	4	2	1	_	_	
Morris	2	-	1	- 1	_	-	_	_	_	_
Morton	2	-	1	1	_	_	_			
Nemaha	11	-	5 3	4	- 3	_ 1	- 3	2	-	_
Neosho	17 4	_	3 4		_		-	-	_	-
Ness	4	_	2	1	1		-	-	-	-
Osage	27	1	10	5	5	5	1	-	-	-
Osborne	5	_	2	1	_	1	-	1	_	_
Ottawa	3	-	1	1	-	-	1	-	-	-
Pawnee	5	-	-	2	2	-	-	1	-	-
Phillips	4	- ·	3	1	-	_	_] [_	_
Pottawatomie	26	-	12	6	6	1	1	_	_	
Pratt	8	-	-	2	2	1	3	-	-	-
Rawlins	1	-	1		-	_	3		_	_
Reno	90	-	29	30	19	9 -	_	1		_
Republic	3 8	_	1 3	1 4	1	_	_	_	-	_
Rice										_
Riley	225	1	54	108	38	14	8	2 -		_
Rooks	5	-	2	1	2 -	_	_	_	_	_
Rush	12	_	1 5	3	1	2	-	_	_	1
Russell	69	1	25	19	8	6	5	3	-	2
Jaime							_	_	_	_
Scott	2	-	- 015	202	1 165	82	37	10	_	2
Sedgwick	824 42	10	215	303	14	3	2	1	-	1
Seward	578	11	157	205	106	72	22	5	-	-
Sheridan	1	'-	1	-	-	-	-	-	_	-
Sherman	_	_	_	_	_	_	-	-	-	-
Smith	6	-	2	2	2	-	-	-	-	_
Stafford	6	-	5	-	-	-	-	1 -	_	_
Stanton	6	-	1	2	1	- 1	2 -	_	_	-
Stevens	4	-	3	_	_	1	_		,	
Sumner	18	_	9	3	3	1	1	1 _	-	
Thomas	8	-	5	2	1	_	_	_	-	_
Trego	1	-	1	1 5	3	1	1	_	-	-
Wabaunsee	12	1 _	_	-	-	-	-	-	-	-
							_	1	_	_
Washington	6	-	3 -	1 1	1 _	_		-	-	-
Wichita	1 14	_	4	5	4		1	-	-	-
Wilson	5		1	1 1	3	_	-	-	_	-
Wyandotte	542	2	130	199	124	68	16	3	-	-
1	1		7	8	14	_	1	-	-	-

SELECTED INDUCED ABURTION STATISTICS FOR DECEMBER AND CUMULATIVE TOTALS FOR THE YEAR

NANSAS 1985

			KANSAS. 1	985		and the second of the second o		
The second secon		JANUARY	- Control of the Cont	,	JANUARY			JANUARY -
		ECEMBER	DECEM	BER DI	ECEMBER	DECEM	IBER	DECEMBER
DECEM	105	5,414	PRIMARY INDICATION			NUMBER OF OTHER TERMINATIONS		
			FOR ABORTION				100	4,999
RESIDENCE	1.0.0	. 1.51.	MENTAL HEALTH	5	3,762	NONE • • • • • • • • • • • • • • • • • • •	102 3	328
IN STATE	100	454ور	SUCIO-ECONOMIC	94	1,483	ONE	-	56
OUT OF STATE	5	1,960	RAPE	1	2	TWO		14
UNKNOWN	-	-	INCEST	-	-	THREE		. 14
		and the same of the table and the same of	FELONIOUS		AND DESCRIPTION OF THE PARTY OF	FOUR	-	6
AGE GROUP OF			INTERCOURSE	3	44	FIVE OR MORE	-	0
PATIENT				ĭ	20	UNKNOWN-NS		9
			PHYSICAL HEALTH		13	and distributed to discovery. And the same of the manufacture, supplied to the fact of the		
UNDER 11	-	-	FETAL DEFECT	_		PREVIOUS INDUCED ABORTIONS		
11 YEARS	-	-	EMERGENCY EXISTED	,	90			
12 YEARS		-	OTHER OR NS		71/	NONE	71	3,725
13 YEARS	-	9				ONE	25	1,238
14 YEARS	1	57	METHOD OF ABORTION			TWQ	7	319
15 YEARS	6	138				THREE OR MORE	2	155
16 YEARS	5	262	SUCTION CURETTAGE	105	5+382	UNKNOWN-NS	-	10
17 YEARS	์จ	354	SHARP CURETTAGE	-	3	Olivido Mid-1423 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4		
18 YEARS	7	411	INTRA-UTERINE			NUMBER OF LIVING CHILDREN		
19 YEARS	<u></u>	434	SALINE		-	MONBER OF FIATING CHIEFFA		
20-24 YEARS	38	1.837	INSTILL ATION	-	5	NONE	62	3,344
20=24 TEARS++++	18	1.040	INTRA-UTERINE			NONE	16	1,007
25-29 YEARS	9	528	PROSTA-GLANDIN			ONE	50	756
30-34 YEARS	4	254	INSTILLATION	•	8	TWO	. 6	201
35-39 YEARS	**	75	HYSTEROTOMY	-	-	THREE		60
40-44 YEARS			HYSTERECTOMY		3	FOUR	,	39
45 AND OVER	-	10	OTHER	٠	10	FIVE OR MORE	1	7
UNKNOWN-NS	1	10	UNKNOWN OR NS	-	3	UNKNOWN-NS		
RACE OF PATIENT			NUMBER OF DAYS IN			NUMBER OF PREVIOUS		
_	0.4	7 / 0	HOSPITAL			PREGNANCIES		
WHITE	96	4,748	TIOUT TIPE				4.0	2.387
BLACK	4		LESS THAN 1 DAY	104	5,367	NONE	49	
0THER	5	118	1 DAY	-	10	ONE	50	1.239
UNKNOWN-NS	-	29	The state of the s	1·	14	TWO	16	883
			2 DAYS	:	8	THREE	7	•
MARITAL STATUS				-	15	FOUR	12	
OF PATIENT			NOT STATED			FIVE	-	94
The continues of the co						SIX	-	34
YFS	27	1.092				SEVEN OR MORE	1	43
NO	76	4.295				UNKNOWN-NS	-	7
UNKNOWN-NS		27				511	•	

SELECTED INDUCED ABORTION STATISTICS FOR DECEMBER AND CUMULATIVE TOTALS FOR THE YEAR

KANSAS, 1985

		JANUARY			JANUARY			JANUARY
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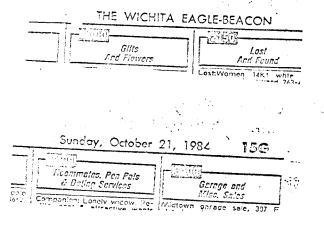
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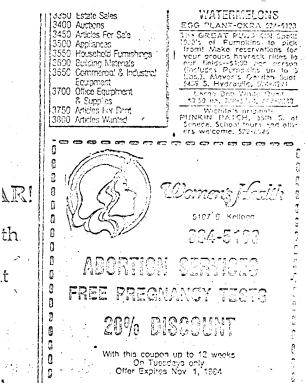
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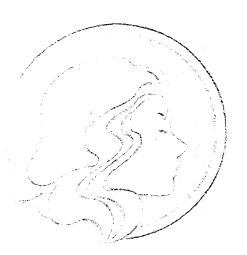
THE ADVERTISEMENTS BELOW ARE FROM THE WICHITA EAGLE BEACON

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AND THE WICHITA YELLOW PAGES.







Care Services P.A.

Abortion Services

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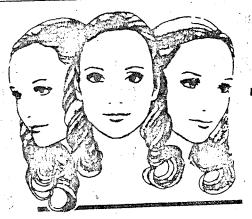
THE CLINICS LISTED ON THESE TWO PAGES ARE NOT CURRENTLY CLASSIFIED AS MEDICAL CARE FACILITIES WITHIN THE MEANING OF "MEDICAL CARE FACILITY" ON LINE 25 OF HOUSE BILL 2052. THEY DO NOT REPORT ABORTIONS. LINES #31through 36 IN HOUSE BILL 2052 ARE REQUIRED TO MANDATE REPORTING OF THESE ABORTION CLINICS, AND OTHER ABORTION PRACTICES IN DOCTOR'S OFFICES.

FROM KANSAS CITY AREA YELLOW PAGES

9 9 9

CENTRAL FAMILY MEDICINE
SENSITIVE CARE FOR WOMEN & MEN
ABORTIONS
OB-GYN • FAMILY MEDICINE
1003 Central Av------321-3343

FROM WICHITA AREA YELLOW PAGES



MEMBER
NATIONAL ABORTION
FEDERATION

NICHTA WOMEN'S CENTER'S FREE PREGNANGY TESTS BIRTH CONTROL INFORMATION OB-GYN SPECIALISTS LOW COST OUTPATIENT ABORTION PROCEDURES

265-4349

700 N. MARKET - WICHITA, KS 67214

WICHITA FAMILY PLANNING

LOW COST OUTPATIENT

ABORTION PROCEDURES

COUNSELING & FREE PREGNANCY TESTING BIRTH CONTROL INFORMATION



- HEALTH SERVICES ARE PROVIDED THROUGH A PROFESSIONAL ASSOCIATION WITH PHYSICIANS
- O NAF MEMBER
- CONTRACEPTIVE INFORMATION SERVICES

264-0611

518 E Pine

ABORTION CLINIC OF WICHITA

Statement of Doctors for Life

Doctors for Life Support HB2052

It is our belief that accurate abortion statistics provide an important source of information to women considering abortion as well as physicians.

We further believe that the reporting of information currently required of licensed hospitals by the Kansas DHE would impose no invasion of privacy undue government interference or other hardship on private physicians.

On behalf of the Doctors for Life I urge the Committee to act favorably on HB2052.

Creater Kansas City Doctors for Life
Kathy Chartrand, D.O., President

directors of facilities licensed pursuant to the provisions of this act shall have the right to select the professional staff members of such facilities and to select and employ interns, nurses and other personnel, and no rules and regulations or standards of the licensing agency shall be valid which, if enforced, would interfere in such selection or employment. In formulating rules and regulations, the agency shall give due consideration to the size of the medical care facility, the type of service it is intended to render, the scope of such service and the financial resources in and the needs of the community which such facility serves.

History: K.S.A. 65-431; L. 1973, ch. 248, § 5; L. 1976, ch. 266, § 2; July 1.

Law Review and Bar Journal References: Mentioned in "Medical Record Guide," 71 J.K.M.S.

450, 453 (1970).

Discussed in note on "Hospitals' Role and Responsibility in Health Care Delivery," Alan Rupe, Robert D. Steiger, 14 W.L.J. 580, 593, 595 (1975).

65-432. Time for compliance with rules, regulations and standards. Any medical care facility which is in operation at the time of promulgation of any applicable rules or regulations or minimum standards under this act shall be given a reasonable time, under the particular circumstances not to exceed two years from the date of such promulgation, within which to comply with such rules and regulations and minimum standards.

History: K.S.A. 65-432; L. 1973, ch. 248, § 6; July 1.

65-434.

History: K.S.A. 65-134; L. 1973, ch. 248, § 7; L. 1974, ch. 348, § 25; L. 1974, ch. 352, § 84; L. 1975, ch. 416, § 5; Repealed, L. 1976, ch. 266, § 4; July 1.

History: K.S.A. 65-435; Repealed, L. 1976, ch. 266, § 4; July 1.

65-436. Information confidential; exceptions, (a) Except as provided in subsection (b), information received by the licensing agency through filed reports, inspections, or as otherwise authorized under this act, shall not be disclosed publicly in such manner as to identify individuals or medical care facilities.

(b) Notwithstanding the provisions of subsection (a) to the contrary, the following

information may be disclosed publicly in such a manner as to identify individuals or medical care facilities: (1) Information received by the licensing agency through filed reports, inspections or as otherwise authorized under this act, in a proceeding involving the question of licensure; and (2) information obtained from filed reports which is relevant to the development of a health systems plan under K.S.A. 1979 Supp. 65-4722, a state health plan under K.S.A. 1979 Supp. 65-4704 and 65-4709, a state medical facilities plan under K.S.A. 1979 Supp. 65-418 and the issuance of a certificate of need under K.S.A. 1979 Supp. 65-4808.

History: K.S.A. 65-436; L. 1973, ch. 248, § 8; L. 1979, ch. 191, § 15; July 1.

65-438. Judicial review; notice of appeal; records of proceedings filed. Any applicant or licensee aggrieved by the decision of the licensing agency may appeal, within thirty (30) days after the mailing or serving of notice of the decision as provided in K.S.A. 1976 Supp. 65-430 and any amendments thereto to the district court of the county in which the medical care facility is located or is to be located. The district court shall have the jurisdiction to affirm, modify, vacate or reverse the decision appealed. Notice of said appeal shall be filed in the office of the clerk of the district court, and a copy served upon the licensing agency within five (5) days thereafter. Upon the filing of the appeal, the licensing agency shall file, within twenty (20) days, with the clerk of the district court all records of the licensing agency in the case, including the evidence taken at the proceedings. Either the applicant, licensee, licensing agent or the state may apply for such further review as is provided by law in civil cases for appeals to the supreme court. Pending a final disposition of the matter, the status quo of the applicant or licensee shall be preserved except as the court otherwise orders.

History: K.S.A. 65-438; L. 1973, ch. 248, § 9; L. 1976, ch. 266, § 3; July 1.

Law Review and Bar Journal References:

Cited in "Administrative Law: The Kansas Commission on Civil Rights—True De Novo Review Arrives," Samuel D. Ogelby, 16 W.L.J. 161, 163 (1976).

65-439. Penalties. Any person establishing, conducting, managing, or operating any medical care facility without a license under this law shall be guilty of a misdemean not m first o for ea a cont be co His

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Attach B

TESTIMONY - H.B. 2052

HOUSE FEDERAL AND STATE AFFAIRS COMMITTEE Thursday, February 6, 1986 - 1:30 p.m.

KANSAS CATHOLIC CONFERENCE BY: Robert Runnels, Jr., Executive Director

Chairman, members of the House Federal and State

Affairs Committee, my name is Bob Runnels, I am Executive

Director of the Kansas Catholic Conference and speak under

the authority of the Roman Catholic Bishops of Kansas.

We support H.B. 2052 because it strenghtens our information base regarding those persons and places that are involved in the abortion trade.

Public opinion polls have recorded dramatic gains for the pro-life message. Opposition to legalized abortion has risen to its highest level in a decade. The most recent poll, commissioned by the New York Times and CBS News in November 1985, indicates that a majority of Americans see abortion as murder, and almost two-thirds would support legislation to protect the unborn in all or nearly all circumstances.

Better more complete information is a good first step towards helping us to evaluate the extent of abortions being done in Kansas.

We strongly urge your support of this legislation and ask that you favorably report it to the House for passage.

HB 2052 FEDERAL AND STATE AFFAIRS COMMITTEE FEBRUARY 6, 1986 REP. JOHN F. SUTTER

MR. CHAIRMAN AND MEMBERS OF THE COMMITTEE:

KSA 66-445, ADOPTED IN 1969, REQUIRES EVERY HOSPITAL

TO KEEP WRITTEN RECORDS IN PREGNANCIES CAREFULLY TERMINATED

(ABORTIONS) AND TO SUBMIT AN ANNUAL REPORT TO THE SECRETARY

OF HEALTH ON A FORM PRESCRIBED BY THE SECRETARY.

HB 2052 REQUIRES EVERY MEDICAL FACILITY, WHICH INCLUDES HOSPITALS, AMBULATORY SURGICAL CENTERS, CLINICS AND VARIOUS PHYSICIANS WHO PROVIDE THIS SERVICE TO KEEP RECORDS OF ABORTIONS AND TO SUBMIT AN ANNUAL REPORT TO THE SECRETARY OF HEALTH.

THE 24 SPONSORS OF HB 2052 ONLY WANT KSA 66-445 BROUGHT UP TO DATE AND TO HAVE THESE VARIOUS MEDICAL FACILITIES COMPLY WITH THE INTENT OF THE LAW ON REPORTING ABORTION.

I ENCOURAGE THIS COMMITTEE TO SERIOUSLY CONSIDER HB 2052 AND TO PASS IT OUT FAVORABLY WITHOUT AMENDMENTS.

Kansas Association of Evangelicals

BOARD OF DIRECTORS

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Rev. John C. Harrell Free Methodist Church 3450 S.E. Indiana Ave. Topeka, KS 6660S

<u>Vice-President</u>:

Rev. James Hossler Missionary Church 1500 Avenue "C" Dodge City, KS 57801

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Rev. Gaylen Minner United Methodist Church 116 S.W. 14th. St. Newton, KS 57114

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Wichita, KS 67211

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Mennonite Brethren Church
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Rev. Bruce Smith Christian Church Wichita, Kansas

Rev. James Spurgeon
Bethany United Presbyterian
Wichita, Kansas

Rev. John Van Valin Free Methodist Church McPherson, Kansas

Mr. Austin Kent Vincent Attorney Topeka, Kansas

NAE FIELD REPRESENTATIVE: Dr. Gordon Bacon P.C. Box 28 wheaton, IL 80187 THE KANSAS ASSOCIATION OF EVANGELICALS
Position Paper: "The Sanctity of Human Life" 1-15-85

The unborn child is a human life with a body personally fashioned by God (Job 10:8-12). Each custom-made body has it's unique design fashioned at the moment of conception, when as yet there were no members or substance (Psalm 139:13-16). This body has biological life from God through his or her parents (Gen. 2:2; Acts 17:26). God speaking in the Scriptures makes no effort to distinguish between pre-natal and post-natal life. In the New Testament, both are clearly in view with the use of one greek word. At Luke 1:41-44, the child in view is clearly unborn. In the words of Elizabeth,"...the baby in my womb leaped for joy." At Luke 18:15 the same word is used of the children who were brought to Jesus that He might touch them. Clearly these are already born. Therefore, human life begins at conception-each one specially.

Also identified as beginning with conception is the uniquely human attribute of response to God. Just as John the Baptist could leap for joy at Jesus' presence within the womb of Elizabeth, so David is aware that his sinful, disobedient nature was uniquely his even before birth (Psalm 51:5-8).

The unborn child is worthy of co-equal status with all the rest of mankind for one essential reason: Adam was made in the image of God (Gen. 1:26-27). By procreation this image was passed on to Adam's children (Gen. 5:3). This imago dei, of course, is spiritual, rather than physical. Bearing testimony to God's design, humans have similarities with God, and specifically, a capacity for fellowship with the Creator which distinguishes the human from all the rest of creation. Man has personality: mind, will, emotions and ego. God's character is perfect, man's is imperfect. Still, man is a moral being with conscience, heart and relationship to God, whether he honors God or not. Within that similarity lies the difference between man and animal - the image of God.

From the beginning, the destruction of the one form of life created in God's image did not sit well with our Heavenly Father (Gen. 9:6). We cannot, as a nation today, avoid God's judgment when our laws bring swift justice to those who dare harm our national bird, but ignore the carnage of abortion. As Christians in Kansas, we cannot rest content while it is perfectly legal in our state to murder a baby anytime before it departs naturally from the womb.

Rescue those being led away to death; hold back those staggering toward slaughter. If you say, 'but we knew nothing about this,' does not he who weighs the heart perceive it? Does not he who guards your life know it? Will he not repay each person according to what he has done?

Proverbs 24:11-12

Cooperating Together for the Faith of the Gospel

February 6, 1986

Throughout the history of Kansas, both as a territory and as a state, human life, pre-born as well as after-born was considered sacred under the law; and abortion was against the law. Then in 1969 Kansas adopted a permissive abortion law. Since then approximately 162,000 Kansans never enjoyed Kansas bread, feared a tornado or had the opportunity to pay taxes.

In 1973 the U.S. Supreme Court legalized abortion for any stated reason resulting in the loss of some 18 million American lives.

Fortunately, however, the wind is blowing another direction. Kansas, which has always been known for it's civil rights issue from John Brown to Brown vs. Board of Education in Topeka, is experiencing a grass roots prolife movement of increasing proportion. Dr. Bernard Nathanson's Silent Scream video horrified millions of us on television as we watched an abortion from a baby's perspective. President Reagan has personally spoken out in defense of the pre-born and appointed the first women justice to the nations highest court as a defender of the unborn American. With that appointment we are one step closer to reversing Roe v. Wade.

Quite frankly, the protection of the unborn is the civil rights movement of the 1980's. One year ago January, 110 people huddled on the sidewalk in front of Stormont Vail Hospital in -10° weather. They were protesting abortion in NE Kansas. Last October we had 172 protest. Then last month we had 742 NE Kansans march around that hospital in protest of abortion. Kansas is a vocal mouth of the right to life movement. One day I hope we will have a mural here of a modern day John Brown, a number of Kansans who worked legally and effectively to overturn an evil. But we need the help of the Kansas House. Right now mainly hospitals are required to report on abortions in Kansas. All fifty states this year are considering statutes to regulate abortions under the guideline of the U.S. Supreme Court.

Kansans for Life estimates that 40% of all abortions occuring in Kansas are performed on women who come here from out of state. Current statistics do not reveal this because abortion clinics in Wichita and Kansas City do not have to report their abortions. Because of this Kansas has a reputation as an abortion haven.

Therefore, Kansans for Life enthusiastically endorses this abortion reporting act, HB 2052. Kansans for Life with its 6,000 members in Wichita, 2,500 members in Kansas City, 1,500 here in NE Kansas and numerous chapters and affiliates in Salina and parts west, join all other Right to Life groups in wholeheartedly supporting this measure.

Bur Sufulam Kansans for Life Bill Gilfillan Vice President

ATTACHMENT E

H. FJSA 2/6/86



Rev. Harold O.J. Brown, Ph.D. Reformed Church Klosters, Switzerland

SPONSORS:

Rev. D. Stuart Briscoe Pastor, Elmbrook Church Waukesha, Wisconsin

Mrs. Grace Hancox Brown Reformed Church Klosters, Switzerland

Mrs. Melinda Delahoyde Raleigh, North Carolina

Rev. Paul B. Fowler, Ph.D. Professor of New Testament Columbia Graduate School Columbia, South Carolina

Mrs. Elisabeth Elliot Gren Missionary, Author, Lecturer Hamilton, Massachusetts

Carl Horn, Esq. Attorney, President North Carolina Policy Council Charlotte, North Carolina

Thomas T. Howard, Ph.D. Professor of English Gordon College Hamilton, Massachusetts

Edward M. Hughes, M.D. Trumbull, Connecticut

Jerry B. Jenkins Vice President of Publishing Moody Bible Institute Chicago, Illinois

Rev. George Knight III, Th.D. Professor of New Testament Covenant Theological Seminary St. Louis, Missouri

Rev. Harold Lindsell, Ph.D. Editor Emeritus, Christianity Today Laguna Hills, California

Rev. J. Robertson McQuilkin President, Columbia Bible College Columbia, South Carolina

Rev. Peter C. Moore Fellowship of Christians in Universities and Schools Greenwich, Connecticut

Mrs. Edith Schaeffer L'Abri Fellowship Rochester, Minnesota

Rev. H. Stanley Wood, D.Min. Pastor, Concord Liberty Presbyterian Church Philadelphia Presbytery



Christian Action Council

701 W. Broad St., Suite 405 Falls Church, VA 22046 (703) 237-2100

January 15, 1986

I REMEMBER THE NIGHT before my abortion telling my baby I loved it and I hoped its soul could come back to me some day through another child.

I got my abortion the next morning, April 21st. It's funny how in that two hour session beforehand they never told me my baby would hurt and maybe even scream while they sucked it out.

And they never told me how many times I would cry in the years to follow wanting to hold my baby!

Fellow Christians, we have got to stop this insane baby killing! I don't really see where it's any different from killing Jesus!

A young woman wrote these words in an exhortation to her church recently. It's a <u>timely</u> one for us all. Abortion mills continue to grind out the grisly remains of small human beings. Along with them go the dreams and hopes of the women who sought abortions.

Dr. Anne Catherine Speckhard, Ph.D. of the University of Minnesota recently published a study on the <u>long term</u> manifestations of stress from abortion (five to ten years). Although the women she studied came from diverse backgrounds, their reactions were amazingly similar.

81% reported preoccupation with the aborted child.

73% reported flashbacks of the abortion experience.

69% reported feelings of "craziness" after the abortion.

54% recalled <u>nightmares</u> related to the abortion.

35% had perceived <u>visitations</u> from the aborted child.

23% reported hallucinations related to the abortion.

Although 72% of the subjects said they held \underline{no} religious beliefs at the time of their abortion, $\underline{96\%}$ in retrospect regarded abortion as the taking of life or as murder.

As the young woman said, "this insane baby killing" <u>must</u> stop. <u>Each</u> of us has an important role to play.

KANSAS DEPARTMENT OF HEALTH AND ENVIRONMENT

TESTIMONY ON HOUSE BILL NO. 2052

PRESENTED TO: HOUSE COMMITTEE ON FEDERAL AND STATE AFFAIRS

FEBRUARY 6, 1986

This is the official position taken by the Kansas Department of Health and Environment on House Bill No. 2052:

BACKGROUND INFORMATION:

According to K.S.A. 65-445 enacted by the 1969 Legislature, all hospitals have been required to report annually to the Kansas Department of Health and Environment all pregnancies which are lawfully terminated on forms prescribed by the Secretary of the Kansas Department of Health and Environment. In addition to the required reporting by hospitals, other facilities have participated on a voluntary basis. Statistical data from these combined sources have been published each year in the Annual Summary of Vital Statistics since 1970. According to reports issued by the Communicable Disease Center, Atlanta, Georgia, the Kansas information is equivalent to reporting systems in other states of similar size. The national and state reporting systems are designed as a surveillance procedure with a sufficient statistical sample for monitoring purposes. It differs from other vital statistics reporting systems where each event must be recorded. Recent trends reflect yearly decreases in the number of terminations, 1979-1984, with no apparent change in the reporting system.

STRENGTHS:

The change from "hospital" to the term "medical care facility" would include "ambulatory surgical centers" and would be appropriate since 88% of terminations are performed during the first 3 months of pregnancy and hospitalization is not necessary.

WEAKNESSES:

Expansion of the reporting system does not promote a valid public health purpose. This legislation appears to be a regulatory burden and may contribute to the cost of health care.

DEPARTMENT'S POSITION:

There is no known public health reason to expand the reporting system.

ATTACHMENT F

H. F15A 2/4/8L



Planned Parenthood of Kansas, Inc.

2226 East Central • Wichita, Kansas 67214 • (316) 263-7575 122 East Twelfth • Hays, Kansas 67601 • (913) 628-2434

TO: Members of the House Committee on Federal and State Affairs

FROM: BELVA OTT, PUBLIC AFFAIRS DIRECTOR, PLANNED PARENTHOOD OF KANSAS

DATE: FEBRUARY 6, 1986

RE: House BILL 2052

HOUSE BILL 2052 SHOULD NOT BE PASSED.

ABORTION PROVIDERS CURRENTLY REPORT PREGNANCY TERMINATIONS VOLUNTARILY.

COMPLIANCE IS NOW VOLUNTARY. IF THIS BILL BECOMES LAW, COMPLIANCE IS

STILL VOLUNTARY AS NO PENALTY EXISTS FOR NON-COMPLIANCE. WHAT, THEREFORE,

WILL BE ACCOMPLISHED?

- 1. AN INCREASED AND UNNECESSARY EXPENDITURE FOR THE STATE OF KANSAS FOR RECORDS NO MORE OR NO LESS ACCURATE THAN WE HAVE TODAY.
- 2. It is a potentially unconstitutional law. Please note the cases cited in the prepared statement I gave you earlier.
- 3. THERE EXISTS AN OPPORTUNITY FOR HARRASSMENT AND INTIMIDATION OF INDIVIDUAL ABORTION PROVIDERS WHO DO COMPLY.

ALL OF US HERE TODAY MUST BE AWARE THAT SEC. SABOL WILL DO HER UTMOST TO INSURE THAT ALL NAMES ARE KEPT CONFIDENTIAL. I HAVE ABSOLUTELY NO DOUBT ABOUT THIS AND DO NOT QUESTION THE SECRETARY OF THE DEPARTMENT IN THE LEAST. However, we must be realistic. Mail comes in. It is opened, channeled to the pertinent department and given to the individual in charge of maintaining those confidential records. It is extremely unlikely, regardless of the intention of privacy, that the physicians names can be kept confidential. In fact, it appears that harrassment

AND INTIMIDATION ARE POSSIBLY THE ONLY REASON FOR THIS BILL. JOE SCHIEDLER HEADS THE NATIONAL RTL ORGANIZATION. HE HAS STATED THAT HE CAN NOT CONDEM THOSE WHO BOMB ABORTION CLINICS. HE HAS ORGANIZED ACTIVITIES FOR THE YEAR FOR MEMBERS OF HIS ORGANIZATION WHICH INCLUDE THE PICKETING OF ABORTIONIST HOMES THIS NEXT MONTH, IN MARCH! ONE WAY THEY WILL KNOW WHO TO PICKET WOULD BE FROM THE LISTS THAT WILL BE REQUIRED BY PHYSICIANS IN THIS DATA THIS BILL WILL REQUIRE TO BE SENT IN.

What is the compelling state interest in obtaining those names? I submit to you that the reason for this bill is to provide lists of physicians to be harrassed and intimidated into not performing abortions. This bill is simply not needed and is not going to benefit any individual citizen of the state in a positive manner.

THANK YOU FOR THE PRIVILEGE OF APPEARING BEFORE YOU TODAY. I WILL BE HAPPY TO STAND FOR QUESTIONS.

Joe Scheidler's Activities

- December 28 Feast of the Holy Innocents
 "will seek a Christmas truce in the killing of the innocent
 pre-born."
- January 22 Roe \underline{v} . Wade anniversary a national sit-in probably in Washington D.C.
- February 14 St. Valentine's Day
 "a national day of mourning"
- Sometime in March "homes of abortionists will be picketed. This reporter knows which day is planned, but the abortionists should not. Plans change anyhow."

 (The underlining is mine.)
- March 28 Good Friday
 "a different kind of event will take place in the same month."
- April 13 "Planned Parenthood will be called to account by the activist pro-lifers."
- PRO-LIFE ACTION NETWORK (PLAN) HOTLINE 1-800-851-CALL



TO: MEMBERS OF THE HOUSE COMMITTEE ON FEDERAL AND STATE AFFAIRS

FROM: ANNE MORIARTY - KANSAS NATIONAL ORGANIZATION FOR WOMEN

DATE: FEBRUARY 6, 1986

RE: H.B. 2052

MR. CHAIRMAN, MEMBERS OF THE COMMITTEE, THE NATIONAL ORGANIZATION FOR WOMEN OPPOSES HOUSE BILL 2052. WE QUESTION THE NEED FOR AND THE INTENT OF THIS BILL. SINCE IT APPEARS THAT THERE IS GOOD VOLUNTARY COMPLIANCE TO THE EXISTING STATUTE, WE WOULD ASK WHAT THE COMPELLING STATE INTEREST IS IN MANDATING FURTHER REPORTING OF THESE LEGAL PROCEDURES. WE KNOW OF NO OTHER SURGICAL PROCEDURES WHICH ARE REQUIRED TO BE REPORTED. FOR INSTANCE, IS IT REQUIRED THAT PHYSICIANS REPORT THE NUMBER OF VASECTOMIES PERFORMED IN THE STATE OF KANSAS IN MEDICAL CARE FACILITIES, OR IN LOCATIONS OTHER THAN MEDICAL FACILITIES, OR INDEED, AT ALL?

WE SUSPECT THAT THERE IS NO COMPELLING STATE INTEREST. WE
PRESUME THAT THE REAL INTENT OF THIS BILL IS TO ERECT ONE OF
SEVERAL PLANNED HURDLES IN THE PATH OF WOMEN WHO ATTEMPT TO EXERCISE
THEIR FUNDAMENTAL RIGHTS AS GUARANTEED THEM BY THE FOURTEENTH AMENDMENT OF THE CONSTITUTION OF THE UNITED STATES.

ATTACHMENT H
H. F45A
2/4/86

THERE IS A QUESTION AS TO THE CONSTITUTIONALITY OF THIS BILL.

A REPORTING BILL IN PENNSYLVANIA WAS RECENTLY STRUCK DOWN, AS IT

RESULTED IN THREATS AND HARRASSMENT TO PROVIDERS, WHICH WAS SHOWN

TO HAVE A CHILLING EFFECT ON THOSE PROVIDERS AND BY EXTENSION, TO

WOMEN WHO SOUGHT TO EXERCISE THEIR FREEDOM OF CHOICE. (SEE AMERI
CAN COLLEGE OF OBSTETRICIANS v. THORNBURGH. NO.82-4336 (ED. PA.,

JUNE 17, 1985.)

I AM AWARE THAT HB 2052 CALLS FOR NAMES AND ADDRESSES OF PROVIDERS TO BE KEPT CONFIDENTIAL. I SUBMIT TO YOU THAT THE CONCEPT

OF CONFIDENTIALITY IS ONE THING, AND THAT IN REALITY, IT MAY BE

DIFFICULT TO MAINTAIN, WHERE THERE ARE THOSE WHO ARE DETERMINED TO

OBTAIN THAT INFORMATION FOR THEIR OWN PURPOSES.

IN SUMMARY, THE NATIONAL ORGANIZATION FOR WOMEN OPPOSES HB 2052 ON THE GROUNDS THAT IT IS UNNECESSARY, THERE IS NO COMPELLING STATE INTEREST INVOLVED, THE EXPANSION OF THIS ACT COULD RESULT IN ATTEMPTS TO THREATEN AND INTIMIDATE HEALTH CARE PROVIDERS, AND THE BILL MAY BE UNCONSTITUTIONAL.

THANK YOU FOR THE OPPORTUNITY TO SPEAK BEFORE YOU TODAY. I WOULD BE HAPPY TO ANSWER ANY QUESTIONS YOU MIGHT HAVE.



Religious Coalition for Abortion Rights in Kansas 913-354-4823 1248 Bukanan Topeka KS. 66604

6 February 1986

HOUSE FEDERAL AND STATE AFFAIRS COMMITTEE

TESTIMONY IN OPPOSITION OF HOUSE BILL 2052

I am Darlene Stearns, State Co-ordinator for Religious Coalition For Abortion Rights in Kansas. I appear today in opposition to House Bill 2052.

Our concern is the very real possibility of harassment of physicians, and staff, required to report abortions by this bill by those people opposing abortion. Although abortion is a legal medical procedure, harassment of physicians, staff employed by those physicians, and patients of those physicians occurs daily across the country. Clinics have been bombed and burned. Mail bombs have been received at clinics. Picketers accost patients entering and leaving clinics. Even more disturbing is the ability of anti-abortion people to obtain, quite illegally, names of staff and patients from car license tag numbers. Hostile telephone calls follow.

We have respect for, and confidence in Secretary Sabol and the employees of Health and Environment but we all are aware of the ease by which records can be invaded, even those on supposedly secure computors. All it takes is one person sympathetic to those who would harks to obtain the necessary namus.

The State of Kansas correctly requires reporting of those diseases posing a threat to the population as a whole. Elective procedures done on an out-patient basis do not pose a threat to the population as a whole. They are not communicable diseases. The privacy of the patient-doctor relationship is paramount except in those cases where the state has an overriding interest. Since the state has not requested this bill we can see no reason for its passage.

Committee on Women's Concerns Synod of Mid-America Presbyterian Church(USA)

Kansas East Conference United Methodist Church'

Unitarian Universalist Service Committee of Kansas

Union of American Hebrew Congregations Mid-West Council

Kansas-Oklahoma Conference United Church of Christ

Young Women's Christian Association of Topeka

Darlene Greer Stearns State Co-ordinator

RCAR in Kansas

ATTACHMENT I H. EYSA

2/4/86

from 'Conceived in Liberty'

Interviewed as two of his "counselors" try to quietly dissuade patients from entering a clinic across the street, Joseph Scheidler of Chicago has, by all reports, left behind those types of small scale operations in his attempts to disrupt clinic activity. In spite of, or perhaps because of, his often outrageous remarks, Scheidler seems to have been chosen America's new premiere anti-choice spokesperson by the media. Below are portions of articles written by and about him.

* excerpt from NEWSWEEK magazine's January 14, 1985 abortion cover story:

As founder and executive director of the Chicago-based Pro-Life Action League, he is openly contemptuous of what he calls "wimps for life"-the well-intentioned souls who shy away from the street-level fight against abortions. Scheidler's techniques of picketing, protesting and harassing abortion clinics have gotten him arrested five times, and alienated even some of his allies in the pro-life cause.

But his real strength is in guerrilla tactics...his 415-page book, "CLOSED: 99 Ways to Shut Down the Abortion Industry," recommends picketing the homes of doctors who perform abortions and using private detectives to dig up embarassing information about them.

He takes the fellow-traveler position on abortion clinic bombings; he doesn't condone them, but sympathizes with the motives. "I've talked with some of the bombers after the fact," he says. "Generally they are very thoughtful people who feel very keenly that these clinics are death camps. Personally, I don't have to take a tranquilizer to get to sleep every time an abortion clinic blows up."

- * excerpt from USA Today story 'Abortion foe gives movement a facelift' Dec. 2, 1985:

 Whirling around the country with his pep talks, Scheidler has upset every clinic in his path. Since 1983, he has taught more than 160 workshops, inspiring activists to invade clinics and picket doctor's homes. "Once they did it, they wouldn't stop. When you save someone, that's when you get hooked. Direct action gets in your blood."
- * from USA Today October 10, 1985 editorial written by Scheidler:

 ...While legislation and education are still valid means of promoting the pro-life effort, more active forms of opposition to abortion have become popular and are attracting thousands. Newcomers to the movement now go directly into street action, bypassing more traditional programs. CLOSED: 99 Ways directs pro-lifers to conduct aggressive, effective protests against abortion and abortion-providers, with chapters on activities that upset those who are seeking civility in the abortion debate.
- * excerpt from TV Guide's November 9, 1985 'Abortion Bias' story:

 "The bombings added a new seriousness to the coverage of the abortion debate," says

 Scheidler. "Most social movements are taken with a grain of salt until there's violence."

 While Scheidler says he doesn't condone violence, "We ought to cash in on it."
- * Scheidler's total opposition to all contraceptives in evident in this November 11, 1985
 USA Today editorial:

Those who promote contraception want people to enjoy sex without the "burden" of children.
...a contraceptive mentality is an abortion mentality. Both are anti-life, because
they are anti-child. Perhaps that is the main evil of contraception: It attempts
to exclude the possibility of new life by perverting a natural function into a mere means
of recreation...

It is unjust to millions who believe in the natural law and nature's God for contraceptives to be advertised, promoted, and foisted on the public as though they are accepted by everyone. They are not.

Burial for the fetal remains discovered in California in 1982 was finally okayed in 1985. A 'memorial service' was held in May; the long sought after burial was, however, put on hold until Sunday, October 6th, not coincidently the day before the U.S. Supreme Court reconvened.

The following item appeared in USA Today on October 9, 1985

■LOS ANGELES: Marine Corps officials said Tuesday they were duped by anti-abortionists into providing a color guard for a weekend burial service for fetuses. Marines were told the service was for a Vietnam combat veteran.

RCAR IN KANSAS 1248 Buchanan **Topeka**, KS 66004 913 354-4823



FEBRUARY 6, 1986

TO: HOUSE FEDERAL AND STATE AFFAIRS COMMITTEE

FROM: THERESA SHIVELY, EXECUTIVE DIRECTOR/LOBBYIST

RE: HB 2052

KANSAS NARAL OPPOSES HB 2052. IT IS UNNECESSARY, POTENTIALLY UNCONSTITUTIONAL AND A POSSIBLE CATALYST TO INCREASED CLINIC VIOLENCE.

REPORTING TERMINATION OF PREGNANCY IS DONE WITH A HIGH RATE OF VOLUNTARY COMPLIANCE NOW AND THE STATE HAS NOTHING TO GAIN BY MAKING IT MANDATORY. IT IS FISCALLY IRRESPONSIBLE TO USE TAX DOLLARS TO REQUIRE REPORTING WHICH HAS NO BENEFIT TO THE PUBLIC AT LARGE OR TO THE STATE. TERMINATION OF PREGNANCY POSES NO HEALTH RISK TO THE GENERAL PUBLIC AND IS REPORTED VOLUNTARILY WITHOUT THE EXTRA BURDEN OF STATE DOLLARS AND STATE TIME TO MONITOR AND REGULATE COMPLIANCE.

A FEDERAL COURT RULED THAT COMPELLED DISCLOSURE WOULD IMPOSE AN INFRINGEMENT OF THE CONSTITUTIONAL RIGHT TO PRIVACY OF
PHYSICIANS AND PATIENTS. IT LEADS TO INCREASED RISK OF HARASSMENT AND VIOLENCE AT CLINICS, WHICH HAS MORE THAN DOUBLED IN
RECENT YEARS. (See attached page.) KANSAS NARAL DOES NOT DOUBT
THAT SECRETARY SABOL WILL DO HER UTMOST TO KEEP THE NAMES AND
ADDRESSES OF PROVIDERS CONFIDENTIAL. BUT WHY TAKE THE RISK?

SURELY THE STATE CAN USE THESE TAX DOLLARS AND THE STATE'S
TIME IN MORE USEFUL AND BENEFICIAL WAYS FOR THE GOOD OF THE STATE

AND ITS POPULATION. THANK YOU FOR ALLOWING ME TO APPEAR HERE TODAY.

Kansas 1195 SW Buchanan

Affiliate National Abortion Rights Action League

NARAL

1195 SW Buchanan Room 201 Topeka, KS 66604 913-235-3405

H. F+SF1 2/4/86

ATTACHMENT J



ANTI-ABORTION STATISTICS (statistics on reported incidents from the National Abortion Federation)

	all of 1983	1/1 to 12/29 1984
Picketed or harassed Hate mail or calls Invasions	61 9 16	157 16 31
Vandalism	19	31 21
Death threats Assaults, battery	3	7
Burglary Kidnappings, hostages	1	0
Attempted arson or bombing Arson	0	6
Bombing Bomb Threats TOTAL	$\frac{3}{9}$ $\overline{113}$	17 <u>36</u> 330

Informed, as he had been before, that the presence of demonstrators outside abortion clinics invariably makes the patients and staff inside so tense as to raise the rate of medical complications, Scheidler retorted, "Good."

Quote from Joe Scheidler, founder, Pro-Life Action League. Quoted by Linda Witt in "Man with a Mission." Sunday Magazine Suppl. to Chicago Tribune, August 11, 1985.



Please return white copy to:

Kansas Department of Health and Environment Topeka, Kansas 66620

TYPE OR PRINT IN PERMANENT INK

KANSAS DEPARTMENT OF HEALTH AND ENVIRONMENT

REPORT OF INDUCED TERMINATION OF PREGNANCY

STATE FILE NUMBER

FACILITY-NAME If not hospital or clinic, giv	e address)		CITY, TOWN OR LOC TERMINATION	ATION OF PREGNAN	CY COUNT	Y OF PREGNANCY TERMINATION
					10	
a. Patient identification	1 Na		AGE OF PATIENT	MARRIED? (Circle)	DATE OF I	PREGNANCY TERMINATION
	N INO.		2b.	1 YES 2 No	(Month, Da	
RESIDENCE-STATE	COUNTY		CITY, TOWN OR LOCA		1 0.	INSIDE CITY LIMITS
TESIDENCE-STATE	COOKIT		on town on 200			(Circle)
ła.	4b.		4c.			4d. —
RACE (Circle)	EDUCATI (Specify high comple	nest grade		PREVIOUS PREGNA	NCIES (Complete	each section)
			LIVE B	IRTHS	PREVIOUS INDU	
1 White 2 Black	i					
[Elementary or		Now living	Now dead		
	Secondary (0-12)	College (1-4 or 5+)	Number	Number	Number	Number
Other, Specify	!		7a. None	7b. None	7c. None	7d. None
Ba. LENGTH OF TIME IN	6. HOSPITAL OR	AMBULATO	DRY SURGICAL CENTE	ER: Hours	OR Days	Additional Control of the Control of
Bb. STATUS OF PATIEN	T: Inpatient	1 0	R Outpatient 2			
PRIMARY INDICATION	FOR ABORTION	ON: (Circle	only one)			
MENTAL HEALTH		1] (Please sp	ecify)		
SOCIOECONOMIC		2	1			
RAPE			_			
		_	_			
INCEST			_			
FELONIOUS INTER (pregnancy under 1	6 years of age)		J			
PHYSICAL HEALTH	4	6	(Please sp	ecify)		
						
FETAL DEFECT		7] (Please sp	ecify)		
EMERGENCY EXIS	STED	8		abortion to save life of	mother)	
		-	(Please sp	ecify)		
OTHER		9	(Please sp	ecify)		
Oa. Procedure that Terminated Pregnan (Circle only one)		F TERMINA	ATION PROCEDURES	10b. Additional Profession (Circle all that	nination, if any	11. Complications of Pregnancy Termination (Circle all that apply)
1	s	SUCTION CL	JRETTAGE		1	1 NONE
			RETTAGE		2	2 HEMORRHAGE
_			INE INSTILLATION		3	3 INFECTION
			GLANDIN INSTILLATIO	-	4	4 UTERINE PERFORATION
			OTOMY		5	5 CERVICAL LACERATION
			CTOMY	,		6 RETAINED PRODUCTS
			Specify)		7	7 OTHER (Specify)
		J.,,Ell (
2. Was Sterilization Per	formed at Time	of Abortion	ı: 1 YES 2	NO		
DATE LAST NORMAL ME	NSES BEGAN		SICIAN'S ESTIMATE	NAME OF AT	TENDING PHYSIC	CIAN (Type or Print)
Month, Day, Year)				TICO 15		
3. NAME OF PERSON COM		14.		EKS 15.		

ATTACHMENT K

Please return white copy to:

Kansas Department of Health and Environment Topeka, Kansas 66620

TYPE OR PRINT IN PERMANENT INK

KANSAS DEPARTMENT OF HEALTH AND ENVIRONMENT

REPORT OF INDUCED TERMINATION OF PREGNANCY

STATE FILE NUMBER

FACILITY-NAME (If not hospital or clinic, gi	ve address)	CITY, TOWN OR LOCATERMINATION	ATION OF PREGNAN	COUNT	NTY OF PREGNANCY TERMINATION			
1a.		1b.		1c.				
PATIENT IDENTIFICATIO	N No.				PREGNANCY	TERMINATION		
The second second			1 YES 2 N	(Month, Da	y, Year)			
2a.	Commence Services The Services	2b. 2c. 3.						
RESIDENCE-STATE	COUNTY	CITY, TOWN OR LOCA	TION			INSIDE CITY LIMITS (Circle)		
						1 YES 2 NO		
4a.	4b.	4c.	PREVIOUS PREGNA	NCIES (Complete	anah saatian)	40. —		
RACE (Circle)	EDUCATION (Specify highest grade completed)		PREVIOUS PREGINA	INCIES (Complete	each section)			
	!			PREVIOUS INDU	JCED	ALL OTHER		
The Land of the Land		LIVE BII	RTHS	ABORTIONS	S	TERMINATIONS		
1 White 2 Black								
3 American Indian	Elementary or Secondary College	Now living 1	Now dead		and the second			
4 Other, Specify	(0-12) (1-4 or 5+)		Number	Number		lumber		
	i i	7a. None	7b. None	7c. None	/	d. None		
5.	6.							
8a. LENGTH OF TIME IN 8b. STATUS OF PATIEN	T: Inpatient 1 0	R Outpatient 2	R: Hours	OR Days				
9. PRIMARY INDICATION	FOR ABORTION: (Circle	only one)		1 1				
MENTAL HEALTH	1] (Please spe	ecify)		1			
SOCIOECONOMIC	2							
	4							
FELONIOUS INTEI	RCOURSE 5 6 years of age)							
PHYSICAL HEALT	н] (Please spe	cify)					
FETAL DEFECT .] (Please spe	ecify)					
EMERGENCY EXIS	STED		bortion to save life of					
OTHER	9	(Please spe	cify)					
					7			
10a. Procedure that Terminated Pregnar (Circle only one)		TION PROCEDURES	10b. Additional Profor this Term (Circle all that			ations of Pregnancy tion I that apply)		
1	SUCTION CL	IRETTAGE		1	1 NONE			
2	SHARP CUF	RETTAGE		2	2 HEMO	PRHAGE		
3	INTRA-UTERINE SAL	INE INSTILLATION		3	3 INFEC	CTION		
4	INTRA-UTERINE PROSTAG	GLANDIN INSTILLATION	J[4	4 UTER	INE PERFORATION		
	5 ERVICAL LACERATION							
	6 HYSTERECTOMY 6 RETAINED PRODUCTS							
7	OTHER (S	Specify)		7	7 OTHE	R (Specify)		
12. Was Sterilization Per	formed at Time of Abortion	: 1 YES 2	NO					
DATE LAST NORMAL ME (Month, Day, Year)		SICIAN'S ESTIMATE	NAME OF AT	TENDING PHYSIC	CIAN (Type or	r Print)		
13.	14.	WEE	KS 15.					
	PLETING REPORT (Type or							
16.								

KATHRYN SUGHRUE
REPRESENTATIVE. 116TH DISTRICT
FORD COUNTY
1809 LA MESA DRIVE
DODGE CITY, KANSAS 67801



COMMITTEE ASSIGNMENTS

MEMBER FEDERAL AND STATE AFFAIRS
ENERGY AND NATURAL RESOURCES
GOVERNMENTAL ORGANIZATION

TOPEKA

HOUSE OF REPRESENTATIVES

February 6, 1986

Members of the Federal & State Affairs Committee

H.B. 2681 would require food service establishments to provide notice to customers of the use of sulfiting agents.

This notice could be done by either a display sign, labels or menu statements to inform customers of the use of sulfiting agents. The use of sulfites in food poses a severe health hazard to some asthmatics.

Sulfiting agents may be used as preservatives in any food. These agents delay or prevent undesirable changes in color, flavor or texture, such as browning or discoloration due to oxidation. Sulfites also enhance crispness.

Because sulfites keep fruits and vegetables looking fresh, their use has increased in the last few years with the increasing popularity of salad bars. They are used in other restaurant foods, especially seafoods and potatoes.

REACTIONS TO SULFITES

Dr. Golub, National Medical Society, says the "symptons associated with sulfite-triggered allergic reactions can include weakness, faint-ness, severe wheezing, chest tightness, shortness of breath and a blue discoloration of the skin caused by insufficient oxygen circulation in the blood, which is known as cyanosis. Other manifestations are hives,

H. F45A 2/4/86

ATTACHMENT L

headaches, gastro-intestinal distress, swelling of the tongue, difficulty swallowing and even loss of consciousness." In addition, the additives have been linked to at least four deaths of people who suffered allergic reactions.

EXTENT OF THE PROBLEM

A recent story on 60 minutes estimates that there are at least 500,000 Americans that are sensitive to the substance. There are 9 million asthmatics in America, only 5 to 10% react to sulfites.

However, the number of people who could have a reaction is not known, but the number may be even larger because this type of reaction is not easy to recognize, thus goes unreported. About 70% of the cases reported are victims that are asmatic.

F.D.A. INVOLVEMENT

FDA has notified the 50 states, which inspect and regulate restaurants and other retail food outlets, that these establishments should post signs or notify customers on the menus when sulfites are used. The National Restaurant Association has notified its members and believes most have abandoned use of sulfites.

FDA also is reviewing other uses of sulfites to determine if more explicit labeling or other actions are necessary.

While the labeling policy is being implemented, the FDA continues to recommend that sulfites-allergic individuals ask at restaurants whether salads and raw fruit are treated with sulfites.

The Food and Drug Administration is proposing to require a warning statement in the professional labeling of all prescription drugs containing sulfites. This warning will enable physicians to avoid prescribing drug products containing sulfites for patients who are sensitive to these chemicals.

WHAT ARE OTHER STATES DOING?

An article in the Council of State Government lists activity by F.D.A. and action by several states.

The F.D.A. has asked state officials who monitor restaurants and other retail food stores to post signs or labels menus to warn consumers if sulfite is used. Several states have taken action. California, Connecticut, Kentucky, Michigan, Missouri, New Hampshire, Oregon, Pennsylvania, and Vermont require labeling. Colorado and Wyoming require restaurants to post signs. Several counties in Arizona ban the use of sulfiting agents as does the city of Chicago. Legislation has been introduced in Indiana, Maryland, Montana, and Rhode Island.

H.B. 2681 is patterned after the California Law. Many Kansans will appreciate your favorable consideration of H.B. 2681.



#11. "RESTRICTION OF USE OF SULFITING AGENTS IN FOOD AND DRUGS"

(Submitted by District 18)

WHEREAS, professional nurses are strong proponents of promotional health care, including dietary and drug ingestion practices of people, and

WHEREAS, the elimination of the use of sulfiting agents in foods and drugs can help to prevent allergic reactions, as well as fear of reactions, in 400,000-500,000 susceptible Americans, therefore be at

RESOLVED, that KSNA make known via letter to the Food and Drug Administration, Center for Science in the Public Interest, and American Nurses' Association its members' support of the banning or restriction on the use of sulfiting agents as food and drug additives, and be it further

RESOLVED, that KSNA members be encouraged to disseminate health alerts regarding hazards of the use of sulfiting agents to peers, colleagues, and consumers at every opportunity.

Rationale:

The potential hazards of sulfiting agents to susceptible individuals has only recently been determined and publicized.

It is appropriate for professional nurses to support stricter regulation of such a food and drug additive when its use has been proven to cause allergic reactions from mild to severe degrees in a large segment of the human population.

Background:

A class of food and drug additives called sulfiting agents used to prevent discoloration and bacterial growth cause hypersensitivity reactions in possibly one-twentieth of 8.9 million asthmatic Americans as well as an untold number of nonasthmatics.

Beginning in 1976 physicians have published reports that, among asthma sufferers, the chemicals can cause reactions such as weakness, tightness in the chest, shortness of breath, hives, severe wheezing, and even loss of consciousness.

The highest consumption of these preservatives occurs in persons ingesting restaurant salads, vegetables, and avocado dips to which are added solutions of potassium metabisulfite. Although the chemicals have been added to foods and beverages for centuries, today their use appears to be mostly a matter of convenience since other preservatives can be used in fruit and vegetable juices, alcoholic beverages, and eliminated entirely from salad bar ingredients.

Some of the drugs used currently to treat asthma symptoms also contain sulfiting agents.

In July of 1982, the Food and Drug Administration proposed to classify the group of sulfiting agents "generally recognized as safe" until Center for Science in the Public Interest (a non-profit consumer group advocating improved national policies on health issues) petitioned the FDA to deny safe status to these additives, calling for a ban or severe restriction on their use in restaurant food, dried fruit, seafood, processed food, alcoholic beverages, and drugs, and the issuance of a public health alert advising asthmatics and others with lung problems of the hazard posed by sulfiting agents and of the foods and drugs to avoid.

Bibliography.

Center for Science in the Public Interest. Nutrition Action, November, 1982, 9(9), p. 3.

CSPI. Nutrition Action, January-February, 1983, 10(1), pp. 4-5.

CSPI. **Nutrition Action**, May, 1983, 10(4), p. 3.

Stevenson, D., and Simon. R. Journal of Allergy and Clinical Immunology, 1981, 68, p. 26.

KANSAS DEPARTMENT OF HEALTH AND ENVIRONMENT

TESTIMONY ON H.B. 2681

PRESENTED TO: Presented to House Committee on Federal and State Affairs February 6, 1986.

This is the official position taken by the Kansas Department of Health and Environment on H.B. 2681.

BACKGROUND INFORMATION:

Over the last $3\frac{1}{2}$ to 4 years there has been extensive publicity and controversy surrounding the widespread use of sulfiting agents in the food supply. The controversy stems from sulfites' potential for triggering moderate to severe reactions, including death, in certain sulfite sensitive individuals. Sulfites are not however considered hazardous to the general population.

Sulfiting agents are primarily used to reduce or prevent spoilage and discoloration during the preparation, storage, and distribution of many foods. They are used in many packaged potato products to preserve the vegetables white appearance. Lettuce will not wilt or brown as quickly if treated with sulfites, thus extending its shelf life. Other produce and some seafoods also will not discolor and will retain a fresh appearance as a result of treatment with sulfites. These preservatives are also used in a number of drugs as well as beer and wine.

Asthmatics are the primary population at risk. Some 10 million Americans suffer from asthma and it is estimated that up to one million asthmatics may have a particular sensitivity to sulfites.

Through 1985, the number of complaints alledging adverse reactions reported to the Food and Drug Administration has climbed to over 800 including reports of 20 deaths. Epidemiologic investigations indicate that eight of the deaths were "probably" associated with the consumption of sulfites while four others were considered as "possibly" due to sulfite consumption. Three other deaths are not believed to be related to sulfites. The five remaining deaths are still being investigated. In Kansas, we have had one report of a possible reaction related to sulfite consumption.

The primary symptoms reported by most consumers is difficulty breathing. Wheezing, vomiting, nausea, diarrhea, unconsciousness, abdominal pain, cramps and hives have also been reported. The term sulfiting compounds refers to several sulfur based substances including sulfur dioxide, sodium sulfite, sodium potassium bisulfite and sodium potassium metabisulfite.

Since November 1959 sulfites have been on the FDA list of substances regarded as "generally recognized as safe". Sulfites have always been prohibited by FDA in foods that are important sources of Thiamine such as enriched flour and bread. Sulfites cannot be used on meats because of possible consumer deception, i.e., giving it a false appearance of freshness.

On April 3, 1985, the FDA proposed a regulation that would require the food industry to declare the presence of sulfites on product labels. A second regulation proposed August 14, 1985 would revoke the "generally recognized as

safe" status of sulfites used on raw produce. This would ban the use of sulfites on fruits and vegetables that are intended to be eaten raw. The effect of this regulations would eliminate sulfites being used on salads and salad bars in restaurants and would apply to raw produce sold in grocery stores. FDA is expected to act on these proposals this year.

The Kansas Department of Health and Environment has proposed adoption of sanitation regulations applicable to retail food stores operating in Kansas. In 1978, the KDHE adopted sanitation regulations pertaining to food service establishments. Adoption of regulations in each of these areas has been modeled after recommended codes provided by the food and Drug Administration. Through these regulations, and based upon interpretations provided by FDA, the Department would currently have the authority to find operators of food establishments in violation of regulations if foods containing sulfites were provided without consumer notification.

In 1985, the KDHE participated with FDA Region VII States in a survey of businesses to determine the extent of sulfite use. In the survey 172 food establishments were surveyed. Nine percent of the surveyed establishments indicated voluntarily ceasing to use of sulfites, however, 9 percent of the survey sample had continued using sulfiting compounds. Zero percent of those surveyed and using sulfites had notices posted for consumer information. Three percent of the establishments surveyed indicated the use of substitutes for sulfiting compounds.

Passage of this bill would have no impact on food service establishment license fees.

STRENGTHS:

Passage of HB 2681 would emphasize the importance that food establishment operators notify consumers of the use of sulfites.

WEAKNESSES:

HB 2681 contains no provisions for staff resources to assume the added work load associated with active surveillance and possible regulatory actions. Passive surveillance (responding to complaints) would have no significant fiscal impact.

Local health departments contracting with the KDHE for food service establishment inspections would also realize some increase in inspection times for active surveillance.

DEPARTMENTS POSITION:

The KDHE is supportive of the policy set out in HB 2681.

FD/4

MY NAME IS GEORGE PUCKETT, AND I REPRESENT THE KANSAS RESTAURANT ASSOCIATION, A STATEWIDE GROUP OF FOODSERVICE MANAGERS AND OWNERS REPRESENTING THE FOODSERVICE INDUSTRY.

HOUSE BILL NO. 2681 WOULD REQUIRE FOODSERVICE ESTABLISHMENTS TO NOTIFY ITS CUSTOMERS OF THE USE OF SULFITES. THE PURPOSE OF MY TESTIMONY TODAY IS NEITHER TO SUPPORT NOR OPPOSE HB 2681, BUT TO PROVIDE INFORMATION THAT MAY PROVE IT TO BE AN UNNECESSARY BILL.

THE FOOD AND DRUG ADMINISTRATION PROPOSED A RULE THAT WILL BAN THE USE OF SULFITES FROM FOODSERVICE ESTABLISHMENTS FOR USE AS A FRUIT AND VEGETABLE FRESHENER, ON AUGUST 14TH, 1985. A COPY OF THIS RULE HAS BEEN DISTRIBUTED WITH MY TESTIMONY FOR YOUR REVIEW. KANSAS RESTAURANT ASSOCIATION, ALONG WITH THE NATIONAL RESTAURANT ASSOCIATION SUPPORTS THE POSITION THAT, IF SULFITES ARE DANGEROUS TO ANY CONSUMER, THEY SHOULD NOT BE USED IN THE PREPARATION OF FOOD. A SMALL PERCENTAGE OF ASTHMATICS ARE KNOWN TO HAVE SUFFERED SEVERE AND EVEN FATAL REACTIONS TO SULFITING AGENTS. THE ASSOCIATION IS OF THE OPINION THAT MERE WARNING SIGNS IN AN ESTABLISHMENT ARE NOT ENOUGH, AND BELIEVES THE AGENT SHOULD BE BANNED IN FOOD PREPARATION. KRA HAS ENCOURAGED THE VOLUNTARY ELIMINATION OF SULFITE USE BY ITS MEMBERS THROUGH PUBLICATION OF ARTICLES IN ITS MONTHLY MEMBER BULLETIN, AND THE KANSAS RESTAURANT MAGAZINE, SINCE THE ONSET OF THE SULFITE MATTER. WE ALSO PROVIDED A LIST OF ACCEPTABLE SUBSTITUTES FOR RESTAURANTS TO USE IN PLACE OF SULFITES, WHICH IS THE YELLOW SHEET PROVIDED FOR YOUR INFORMATION. THIS LIST WAS ACQUIRED THROUGH THE NRA IN ITS EFFORT TO ALSO ELIMINATE SULFITING AGENTS IN THE PREPARATION OF FRESH FRUITS AND VEGETABLES.

THE COMMENT PERIOD FOR THE FDA PROPOSED RULE ON SULFITES ENDED SEPTEMBER 13TH, ACCORDING TO CORRESPONDENCE I RECEIVED FROM THE NATIONAL RESTAURANT ASSOCIATION, YESTERDAY. THE FDA IS NOW REVIEWING THE COMMENTS, WITH A FINAL RULE EXPECTED BY JUNE 1ST, 1986, ACCORDING TO ADDITIONAL INFORMATION SUPPLIED FROM NRA IN WASHINGTON, D.C., YESTERDAY. THE KRA'S POSITION CONTINUES TO BE ONE OF RECOMMENDING THAT SULFITE AGENTS NOT BE APPLIED IN ANY WAY AT THE RETAIL LEVEL.

I HAVE ALSO ENCLOSED FOR YOUR REVIEW, A SERIES OF ARTICLES DEALING WITH SULFITES FROM THE NRA WASHINGTON WEEKLY, AND AN ARTICLE ON THE PROPOSED FDA RULE FROM THE 8/19/85 ISSUE OF FOOD CHEMICAL NEWS. IN OUR OPINION, HB 2681 IS PREMATURE, PENDING FINAL ACTION BY THE FDA.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 182

[Docket No. 81N-0314]

Sulfiting Agents; Proposal To Revoke GRAS Status for Use on Fruits and Vegetables Intended To Be Served or Sold Raw to Consumers

AGENCY: Food and Drug Administration. **ACTION:** Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is announcing that currently available information has raised significant questions about the safety of the use of sulfur dioxide, sodium sulfite, sodium and potassium bisulfite, and sodium and potassium metabisulfite (collectively known as fulfiting agents or sulfites) on fruits and vegetables intended to be served raw or sold raw to consumers. As a result of these questions, FDA believes that this use of sulfites can no longer be considered to be generally recognized as safe (GRAS). Therefore, FDA is proposing to amend the regulations on the sulfiting agents in 21 CFR Part 182 to except their use on fruits and vegetables intended to be served raw or sold raw to consumers or to be presented to consumers as fresh from the uses of these substances that are GRAS.

This proposed action is based upon FDA's review of new information on sulfiting agents received in response to a proposal to affirm the GRAS status of sulfiting agents published in the Federal Register of July 9, 1982 (47 FR 29956); the January 31, 1985, final report of the Federation of American Societies for Experimental Biology (FASEB) on the Reexamination of the GRAS Status of Sulfiting Agents; recently published reports in the medical literature; consumer complaints received by the agency; and other relevant information.

DATE: Comments by September 13, 1985.

ADDRESS: Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gerad L. McCowin, Center for Food Safety and Applied Nutrition (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-472-5676.

SUPPLEMENTARY INFORMATION:

I. Background/Regulatory History

Sulfiting agents have a long history of use as food ingredients. Since November 20, 1959 (24 FR 9368), these food ingredients have been listed as GRAS for use as chemical preservatives.

In 1976, during the course of the agency's review of the safety of GRAS Substances (Ref. 1), the Select Committee on GRAS Substances (the Select Committee) of FASEB issued a report on the health aspects of the use of sulfiting agents as food ingredients (Ref. 2). Subsequently, in the Federal Register of July 9, 1982 (47 FR 29956), FDA proposed to affirm, with specific use limitations, the GRAS status of certain sulfiting agents (Ref. 2).

sulfiting agents (Ref. 3).

The agency received numerous comments on the 1982 proposal. Some comments reported new uses of the sulfiting agents, significant recent expansion of some old uses, widespread use by the food-service industry, and many uses that were unlabeled. Other comments reported the possibility that a significant number of individuals may experience potentially severe allergictype responses upon consuming foods treated with sulfiting agents. The agency is using the term "allergic-type responses" to describe the various types of symptoms that individuals have suffered after eating sulfite-treated fresh fruits and vegetables that were served or sold raw. These responses in some ways resemble responses to an allergen. However, the scientific community is unsure at this time about the actual mechanism of response elicited by the sulfite ingredient.

The agency also received a citizen petition regarding the use of sulfiting agents in food and drugs. The petition echoed many of the concerns expressed in the comments and urged the agency to take certain regulatory actions to restrict the use of sulfites in food.

A number of the comments received, as well as portions of the citizen petition, are relevant to the specific action being proposed in this document. The agency's responses to these comments are included in this document.

The new information received in response to the 1982 proposal prompted the agency to ask FASEB to reexamine the GRAS status of the use of sulfiting agents. FASEB established an ad hoc Review Panel on the Reexamination of the GRAS Status of Sulfiting Agents (the Panel). On July 9, 1984 (49 FR 27994), FDA announced the formation of the Panel.

The Panel evaluated recent scientific publications and new information and data submitted to FDA in response to its

1982 proposal. The Panel supplemented this information with additional materials acquired independently, and conducted an open meeting on November 29, 1984, at which individuals and organizations presented their views on sulfite-related issues. On January 31, 1985, FASEB issued its final report (Ref. 4).

In that report, although the Panel concluded that for the majority of the population "there is no evidence * * to suspect a hazard," the Panel also concluded that for the fraction of the public that is sulfite sensitive, "there is evidence * * * that demonstrates or suggests reasonable grounds to suspect a hazard of unpredictable severity to such individuals when they are exposed to sulfiting agents in some foods at levels that are now current and in the manner now practiced" (Ref. 4, p. 60).

Upon evaluation of available information, FDA concurs with the conclusions of the Panel and is currently assessing the use of sulfiting agents on foods.

In the Federal Register of April 3, 1985 (50 FR 13306), FDA published a proposal to require that all packaged foods that contain 10 parts per million (ppm) or more of sulfur dioxide equivalents must be labeled to disclose the presence of a sulfiting agent. If the agency adopts that proposal, sulfite-sensitive individuals will be able to avoid packaged food products to which they might be sensitive.

The agency believes, however, that labeling is not likely to be an effective means of protecting sulfite-sensitive individuals from certain sulfited foods, including fruits and vegetables that are served raw or sold raw to consumers in food-service establishments. Ingestion of these types of foods has been associated with rare but potentially lifethreatening responses in asthmatic individuals.

Because of the acute health problems that have been associated with the use of sulfites on fresh fruits and vegetables sold in food-service establishments, FDA has decided to act immediately with regard to this use, before deciding whether to affirm the GRAS status of the other uses of sulfiting agents. In addition, because of these health problems, the agency is providing only 30 days for comments on this proposal instead of the customary 60 days.

In this document, FDA is announcing its preliminary conclusion that the use of sulfiting agents on fruits and vegetables intended to be served raw or sold raw to consumers is not GRAS. To reflect this preliminary conclusion, the agency is

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an un proposing to amend Part 182 (21 CFR Part 182).

If the agency confirms its preliminary conclusion, this use of sulfiting agents would constitute the use of an unapproved food additive. As a result, the use of sulfites on any fruit or vegetable that is intended to be served or sold raw would cause that fruit or vegetable to be adulterated and in violation of section 402(a)(2)(C) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 342(a)(2)(C)). The agency intends to address all other uses of sulfiting agents, including their use on potatoes and potato products, in the near future.

II. The use of Sulfiting Agents on Fruits and Vegetables

A. Purpose

Amany raw foods, when exposed to the air, rapidly discolor or otherwise lose their natural, fresh appearance. For example, lettuce wilts and browns around the edges; cut apples become brown: avocado pulp turns black. Sulfiting agents are one type of chemical preservative that serves effectively to prevent or to delay the process of browning and deterioration of raw fruits and vegetables by acting as an antioxidant. Sulfites are used by restaurants to help maintain the fresh appearance of certain fruits and vegetables in salad bars. They are also used by some suppliers of produce that is intended for salad bar use or of vegetables that are intended for cooking. Although a number of substances such as citric acid, ascorbic acid, or sodium erythorbate could be used to maintain the freshness of raw fruits and vegetables, the primary commercial products sold for this use contain the various sulfite salts as their principal active ingredients.

Label directions for these products advise users to dissolve a specific amount of the product in water, to dip the food to be treated in this solution for a stated period of time, and to drain the food before refrigerating or cooking.

B. FDA's Concerns

FDA is concerned about the use of sulfiting agents on fruits and vegetables intended to be served raw or sold raw to consumers because of serious responses in sulfifte-sensitive individuals have. been associated with this widespread use of sulfites on fresh fruits and vegetables and because such use is not commonly labeled so that sensitive individuals may avoid sulfite-treated foods. FDA's concerns extend to fruits and vegetables that may have undergone physical processing before

sale, such as guacomole made from mashed avocado, and to raw fruits and vegetables that, to the consumer, appear to be fresh but that may have been processed in some way (e.g., freezing). Restaurant consumers of raw fruits and vegetables that have the appearance of freshness do not generally expect such foods to contain preservatives, and these foods are rarely labeled. Similarly, raw fruits and vegetables sold in grocery stores are not usually labeled, and consumers do not associate them with the presence of preservatives such as sulfiting agents.

FDA is also aware of a number of recent trends and practices that raise concern because they contribute to the likelihood of greater exposure to sulfites in the American diets. More Americans are eating a greater proportion of their meals away from home. One trend of considerable importance in recent years has been the increase in the presence of salad bars in restaurants and other food-service establishments. Such salad bars usually offer the consumer a wide variety of fruits and vegetables from which to choose. The popularity of these salad bars may be attributed at least in part to consumers' increasing concern about physical well-being and their desire to replace certain "processed" foods in the diet with "natural" or "fresh" foods or to reduce caloric intake.

Data indicate that sulfiting agents continued to be used on some of the foods offered for sale at many salad bars. However, their use is rarely disclosed to the consumer. In addition, the levels at which sulfiting agents are used by restaurant and food-service establishment personnel vary widely, largely as a result of the differences in the degree of care employed by such personnel. Consequently, there is a wide variation in the sulfite content of treated products.

The practices and trends described above take on added significance in light of reports received since 1982 of adverse responses associated with food allegedly treated with sulfiting agents. At present, FDA has received over 500 consumer complaints where the individuals reported suffering a variety of adverse allergic-type responses after eating food to which they believed sulfiting agents had been added.

Information currently available indicates that allergic-type responses to sulfites are most likely to occur among persons who are asthmatic. Although prevalence estimates vary, among the estimated 10 million asthmatic patients in the U.S. population, as many as 1 in 10 (or 1 million persons) may be sulfite sensitive (Ref. 4). Although there is even less certainty about the degree to which

nonasthmatic persons may also be sulfite sensitive, nonasthmatics were nevertheless involved in several of the complaints reported to the agency.

C. FDA Actions

In 1983, FDA began to take steps to provide consumers with information that would help them avoid foods to which they could be sensitive because the foods were treated with sulfiting agents.

In March of that year, FDA issued an interpretation of its model food sanitation code. This interpretation was later revised in its September 1983 "Retail Food Protection Program Information Manual" (Ref. 5). The revised interpretation stated that "fresh fruits and fresh vegetables and other foods which are intended for sale in the raw state and which have received treatment with sulfiting agents at the retail establishment will be considered safe under the provisions of the model food sanitation code only if the consumers are informed that sulfiting agents have been added." By March 1985, however, 19 States had still not adopted this interpretation. Moreover, because of the great number of restaurants and other retail establishments, comprehensive enforcement is difficult to achieve.

FDA is aware that some recent information indicates that the use of sulfiting agents on salad bar items in food-service establishments, and the use of these agents by suppliers of fresh and ready-to-cook produce to such establishments, have declined in the last 2 years. For example, the National Restaurant Association, which advised its members in February 1983 to stop applying sulfites, found in a subsequent survey (reported in the June 1, 1983 letter from R. Neville to Sanford Miller) that less than 4 percent of its members were using sulfiting agents. In addition, the Produce Marketing Association reported in November 1984 that a recent survey showed that 5 percent of its members were using sulfiting agents, and that only 2 percent were using them on a regular basis (Ref. 4).

Even these relatively low percentages, however, represent a large number of retail establishments in absolute terms. Moreover, these surveys do not include the large number of retail food establishments that do not belong to the organizations conducting these surveys. Thus, the problem of sulfite-sensitive individuals unknowingly eating sulfite-treated foods still exists. This is evidenced by the fact that more than 40 percent of the consumer complaints that FDA has received have come to the

agency since the Produce Marketing Association survey was completed. Moreover, such reports have continued even in recent months.

D. Summary

In summary, FDA's concerns stem from the following facts:

1: Sulfite-sensitive asthmatics in the United States may number as many as 1 million persons.

2. Current lifestyle trends and foodprocessing practices point to significant exposure of individuals to sulfiting agents used on fresh fruits and fresh vegetables.

3. The potential for carelessness or misuse exists when sulfiting agents are applied to food by food-service establishment personnel.

4. Although industry data indicate a decline in the use of sulfiting agents by restaurants and produce marketers, a significant number may still be using them and FDA is still receiving reports from individuals of allergic-type responses allegedly associated with eating sulfite-treated foods.

5. Although FDA has proposed that all packaged foods that contain sulfites be so labeled, labeling in restaurants and grocery stores is not a practical alternative because labeling in those environments is not customarily used and because of the difficulty of enforcing such labeling at either the Federal or State level.

For these reasons, FDA believes that it is necessary to take action as soon as possible concerning the GRAS status of the use of sulfiting agents on fresh fruits and fresh vegetables.

III. Safety Evaluation

Consumer Complaints

Since 1982, FDA has received complaints from approximately 500 individual consumers who reported adverse responses, including 13 deaths, after eating food that the individuals either knew contained or suspected of containing sulfiting agents. Among the 500 reports of adverse responses, the largest segment (approximately 40 percent) specifically mention the occurrence of adverse responses after eating raw fruits or raw vegetables in restaurants, while 4 percent specifically mention fresh produce purchased in a grocery store. Thus, nearly half of all complaints received specifically mention fresh fruits or vegetables. By comparison, approximately 15 percent of the 500 complaints specifically mention the occurrence of adverse responses after drinking wine or beer, and 14 percent specifically mention processed, packaged food eaten at home. The

remaining complaints were less specific about the type of food and the place of purchase or consumption.

The spectrum of reported responses to raw fruits and vegetables that had been treated with sulfites is broad, ranging from mild discomfort to very severe and even life-threatening. Although some reports fall into more than one clinical category, approximately 40 percent of the complaints mentioning fresh fruits or vegetables mention gastrointestinal effects, including nausea and diarrhea; about 50 percent mention various forms of respiratory distress; 10 percent mention anaphylaxis, coma, or shock; and 15 percent mention that hospitalization was required or emergency room care was sought. The remaining comments either did not mention specific symptoms or mentioned symptoms other than those described above. In approximately 30 percent of these complaints, the consumers described the responses as allergic responses.

IV. The Panels Report

As noted above, early in 1984 FDA requested that FASEB reexamine the GRAS status of sulfiting agents. In response, FASEB established the Panel, which considered all relevant available information on the use of sulfiting agents. This information included recent scientific publications; information submitted to FDA in response to its 1982 proposal; data on the levels of sulfiting agents currently used in the processing of foods and on the levels of sulfiting agents found in various foods as consumed; new toxicological information on sulfiting agents; and data regarding the ability of sulfiting agents to cause allergic-type responses in sensitive individuals. The Panel also had access to the consumer complaints (numbering approximately 300) that FDA had received by that time. In addition, the Panel conducted an open meeting on November 29, 1984, at which individuals and representatives of organizations presented data, information, and views on a range of sulfite-related issues. The Panel made its final report available to FDA on January 31, 1985.

A. Exposure

The Panel estimated that the mean dietary intake of sulfiting agents, as measured in sulfur dioxide equivalents, is about 10 milligrams per capita per day (0.17) milligram per kilogram body weight per day). It also estimated that the 99th percentile intake probably does not exceed 180 milligrams sulfur dioxide equivalents per capita per day (3 milligrams per kilogram body weight per

day). The latter figure represents regular consumption of foods containing high levels of sulfites, such as wine, shrimp, "instant" potatoes, dried apricots, and "tossed salad" (Ref. 4).

B. Sulfite-Sensitivity Reactions

The Panel reviewed the evidence for the occurrence of adverse responses in certain individuals after ingesting foods containing sulfiting agents. This evidence included numerous published findings from clinical experiments involving the exposure of both asthmatic and nonasthmatic individuals to sulfiting agents. The Panel also reviewed hundreds of reports, submitted by consumers, physicians, and FDA field investigators, of adverse responses occurring after consumption of foods known to contain or suspected of containing sulfiting agents. A summary of the Panel's findings follows.

1. Types of Responses. The most frequently reported response following exposure to sulfites or sulfur dioxide has been bronchial hyperreactivity (bronchoconstriction and bronchospasm), although other responses such as shock, gastrointestinal disturbances, and urticaria/angioedema as well as flushing, hypotension, and tingling sensations have also been reported (Ref. 7).

2. Clinical Studies. Clinical investigators have attempted to document adverse responses to sulfites. Many of the studies were conducted on individuals or groups of individuals who previously reported an adverse response to a sulfite-containing food. To quantify adequately the presence and severity of adverse sulfite sensitivity responses, clinical investigators exposed individuals to measured quantities of sulfiting agents in which the amount of sulfiting agents was expressed as sulfur dioxide equivalents. The investigators then reported the extent of any adverse response in terms of a drop in what is often called the patients' "forced expiratory volume at 1 second" (FEV₁).

For example, in 1973, Kochen reported that a mildly asthmatic child experienced acute, transient asthmatic reactions following ingestion of freshly opened sulfite-containing foods (Ref. 8). Reports about this type of reaction were relatively rare until recently. However, challenge testing was not carried out to determine if sulfites were the causative agents in this case. Subsequently, Prenner and Stevens, in 1976, presented a case report of anaphylaxis occurring in a 50-year old nonasthmatic male who consumed a restaurant meal that included a green salad sprayed with a

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adn the cor pot product containing bisulfite (Ref. 9). Oral challenge with sodium bisulfite (10 milligrams total dose) resulted in erythema, itching, nausea, warmness, coughing, and bronchoconstriction for about 1 hour. Lung function measurements were not made nor was a placebo administered as a part of the challenge.

In 1977, Freedman interviewed 272 asthmatic patients and reported that 30 experienced exacerbations of asthma following ingestion of orange drinks made with sodium bisulfite (Ref. 10). Fourteen of the 30 patients allowed challenge tests with a single dose of sodium metabisulfite solution containing 25 milligrams sulfur dioxide equivalents in a weakly acidic solution (sulfur dioxide concentration 100 ppm). Within 2 to 25 minutes, 8 of the 14 patients challenged gave a positive response, defined as a drop of at least 12 percent in FEV₁.

In one case, Baker et al. reported bronchospasm in an asthmatic patient following ingestion of canned crabmeat salad with a vinegar dressing (Ref. 11). Oral challenge of this patient with sodium metabisulfite resulted in severe bronchospasm within 30 minutes. No reaction was observed after ingestion of the canned crabmeat alone when given as a clinical challenge. In a second patient whose asthma was provoked by wine, a single-blind oral challenge with a capsule containing 500 milligrams sodium metabisulfite caused a drop in peak flow rate from about 440 liters per minute before challenge to 100 liters per minute 30 minutes after challenge. Challenge with a placebo capsule did not produce a significant pulmonary change in the second patient.

In 1983, Schwartz reported the clinical presence of vague, general symptoms following oral challenge with metabisulfite in two patients who developed dizziness, weakness, nausea, chest tightness, tachycardia, and dyspnea associated with restaurant meals (Ref. 12). Pulmonary function studies during an oral metabisulfite challenge showed no changes.

Stevenson and Simon reported in 1981 on clinical investigations on four patients with histories of severe bronchoconstriction and anaphylaxis associated with consumption of restaurant meals (Ref. 13). Single-blind oral challenges were administered to these patients in the fasting state and while they were taking their usual medications. Placebo capsules were administered orally every 30 minutes on the first morning of testing, and capsules containing 1, 5, 10, 25, or 50 milligrams of potassium bisulfite were given sequentially ever 30 minutes on the

second day. FEV1 values were measured at 30-minute intervals on both days. All four patients reacted to bisulfite challenges, developing asthmatic symptoms 10 to 15 minutes after ingestion of a provocative dose (10, 25, or 50 milligrams). FEV1 decreased 34 to 49 percent at 30 to 90 minutes after are provocation. Systemic symptoms including flushing, tingling, and faintness occurred in all subjects. Subsequent oral challenge of six sulfitesensitive asthmatic patients with sulfite solutions produced responses equal to the responses observed after oral capsule challenge but at levels approximately one-half of the provocative capsule dose (Ref. 14). Fifteen additional asthmatic patients with a history of incrased asthmatic responses associated with consumption of food and beverages were serially challenged with capsules containing 5, 10, 25, and 50 milligrams sodium metabisulfite (Ref. 15). Only one of these patients had a significant response to the challenge. In that case, administration of 5 milligrams sodium metabisulfite produced a fall of 28 percent in FEV1 in 2 minutes.

Capsules containing 1.4, 14, 144, or 288 milligrams potassium metabisulfite were sequentially administered to 134 patients selected from a clinic population of 1,073 patients having asthma and related allergic symptoms (Ref. 16). Decreases in FEV₁ values of at least 15 percent were reported in 50 of the 134 patients challenged. Based upon these challenges, Buckley et al. (1985) estimated that 4.6 percent of asthmatic patients respond to sulfite challenge (Ref. 16).

In another clinical study, lettuce treated with sodium bisulfite was employed as an oral challenge to evaluate pulmonary function of five stable, previously documented sulfitesensitive asthmatic patients after consumption of food containing sulfiting agents (Refs. 17 and 18). Three-ounce portions of lettuce were dipped according to package instructions in a commercial vegetable freshener containing sodium bisulfite or in a similar commercial product that did not contain a sulfite salt. Approximately 10 milliliters of solution (80 to 90 milligrams bisulfite) adhered to the lettuce after draining. All five patients showed a significant decreased in FEV1 (mean decrease 44 percent, range 31 to 64 percent) after consuming the sulfitetreated lettuce. None reacted to the control lettuce. Four of the patients were described as having moderate asthmatic responses, while the fifth had a lifethreatening response requiring extensive emergency treatment (Ref. 18).

Not all clinical investigations reviewed by the Panel provided equally convincing and strong evidence for an association between exposure to sulfites and adverse responses. In one study performed by Sonin and Patterson in 1985, 12 patients with idiopathic anaphylaxis, 9 of whom had a history of reactions associated with restaurant meals, and 10 control subjects were challenged with increasing oral doses of sodium metabisulfite dissolved in lemonade (Ref. 19). A similar extent of mild nonspecific irritant and subjective symptoms were reported in both groups of patients. No anaphylactic responses occurred in the 12 patients with idiopathic anaphylaxis. No bronchospasm occurred, although pulmonary functions was abnormal in three of these patients.

Similarly, in a presentation made at the open meeting of the ad hoc Review Panel, Taylor reported that oral capsule challenge of 100 non-steriod-dependent asthmatic patients with potassium metabisulfite resulted in no cases of sulfite sensitivity that could be confirmed by double-blind challenge (Ref. 20). However, single-blind challenges of 69 steroid-dependent asthmatic patients resulted in a decrease in FEV1 of at least 20 percent in 14 cases. Double-blind challenges of five of these steroid-dependent patients resulted in significant decreases in FEV1 in only two cases.

In another study, FEV₁ values did not decline and no manifestations of sulfite sensitivity were reported following administration of bisulfite to five steriod-dependent asthmatic patients without histories of responses associated with restaurant meals (Ref. 13).

Experience with oral challenge testing of sulfites has led to differing opinions concerning the extent of sensitivity resposes to sulfiting agents. Based upon their clinical work with capsule and solution challenges of a group of asthmatic patients, Simon et al. (Ref. 21) and Simon (Ref. 18) estimate that 5 to 10 percent of the 10,000,000 asthmatic patients in the United States may be sensitive to orally ingested sulfiting agents. Buckley et al. suggest a prevalence of 4.6 percent for sulfite sensitivity based on capsule challenges of selected members of a clinic population having asthma and related unusual allergic symptoms (Ref. 16). A lower prevalence of sulfite sensitivity (1 to 2 percent of the overall asthmatic population) is estimated by Taylor (Ref. 20) whose clinical results with capsule challenge suggest that sulfite sensitivity is limited to steroid-dependent

asthmatic patients. Patterson and colleagues have yet to identify sulfite sensitivity among idiopathic anaphylactic patients selected from an extensive asthmatic population and consider that sulfite sensitivity may be a minor problem (Ref. 22). Although a number of individuals have been clinically tested for sulfite sensitivity by oral challenge, there is no compilation of data available on the distribution of asthmatic and nonasthmatic patients sensitive to sulfiting agents according to age, sex, race, genetic traits, ethnicity, and other variables.

3. Individual Case Reports. The Panel reviewed copies of all the consumer complaints that had been sent to FDA, which, at the time the Panel did its work, numbered about 300. These included reports by individual consumers who were both asthmatic and nonasthmatic. The Panel also reviewed some, more thorough, case reports submitted by physicians. Some of the consumer and physician reports included additional information from followup investigations conducted by FDA field personnel. The Panel concluded that these reports indicate an association between adverse responses and the ingestion of meals that include foods containing sulfiting agents.

C. The Panel's Conclusions and Recommendations

The Panel concluded, in part, that the available information contains sufficient evidence to demonstrate a hazard of unpredictable severity to sulfitesensitive individuals when they are exposed to sulfiting agents in some foods at levels that are now being used.

The Fanel concluded that the reported associations are sufficiently numerous, and the responses sufficiently severe, to deserve serious attention. It found that, in some cases, sulfite-sensitive individuals have had life-threatening responses following exposure to sulfite-treated foods and recommended that practical means be found to protect these individuals from the potential hazards of sulfites.

The Panel specifically noted that fresh fruits and vegetables dispensed in food-service establishments or sold in grocery stores are among the foods that have been shown to elicit adverse responses.

The Panel concluded "that additional labeling requirements alone would not assure protection."

It further concludes:

This is particularly likely when sulfitetreated fresh fruits and vegetables and precut potatoes are dispensed in food service establishments or sold in grocery stores, and consumers, service and store personnel are not adequately aware that sulfite agents are present.

Information provided to the Pancl indicates that the use of sulfites on fresh produce in food service establishments is being discouraged by the National Restaurant Association and the Produce Marketing Association, and that use has decreased over the past two years. Such voluntary curtailment of sulfite use on such products is an important step in reducing opportunities for unsuspecting sulfite-sensitive individuals to be exposed, and discontinuance of these uses should be encouraged by appropriate use of the regulatory process.

IV. Discussion

A. This Proposal

In this proposal, FDA is announcing that based on the data and information that have become available to it since publication of its July 9, 1982, proposal on sulfiting agents; on the conclusions that the Panel reached in its 1985 reexamination of the GRAS status of sulfites; on its evaluation of the Panel report; and on other available data, it believes that there is no longer a basis to find that the use of sulfiting agents as a preservative on fruits or vegetables intended to be served or sold raw to consumers is CRAS.

Under 21 U.S.C. 321(s), for the use of a substance to be GRAS, there must be a consensus among qualified experts that that use has been shown to be safe. Given the recent evidence of severe acute responses reported in some individuals who have eaten sulfited fruits and vegetables and the other information discussed in this document, FDA believes that a consensus that this use of sulfites is safe does not currently exist. As a result, the agency is proposing to amend Part 182 to exclude this use from those that are GRAS under the regulations on the sulfiting agents.

FDA is basing this action on a number of factors:

1. There are people within the U.S. population, whose number may be as high as 1 million, according to some estimates, who are sulfite sensitive and suffer allergic-type responses of unpredictable severity upon ingesting foods treated with sulfiting agents.

2. The use of sulfiting agents by restaurants and other food-service establishments on fruits and vegetables presented to the consumer for sale as fresh (e.g., salad bars) is cited in the largest fraction (nearly half) of the consumer complaints of adverse responses received by FDA.

3. Although sensitive individuals can possibly avoid sulfite-treated foods that are packaged and labeled, the use of signs has not proven to be effective in protecting sensitive persons in such situations as restaurant salad bars,

when sulfiting agents are used on fruits and vegetables intended to be served or sold raw to consumers or presented to consumers as fresh. Adverse responses alleged to be associated with these uses have continued despite some States' efforts to require signs. Moreover, the Panel has stated that it believes that the use of signs will not be an effective means of protecting sensitive individuals. Furthermore, FDA believes. as stated earlier, that labeling in restaurants and grocery stores is not a practical alternative because labeling in those environments is not customarily used and because of the difficulty of enforcing such labeling at either the Federal or State level.

4. In addition, the levels of sulfiting agents on raw fruits and vegetables are likely to vary widely and will depend upon the care exercised by food-service personnel in following use instructions for their application. Thus, a significant potential exists for abuse or misuse of these chemical preservatives.

5. Because many restaurants now operate salad bars without using sulfites, it appears that substituting alternative preservatives or implementing revised operating procedures (e.g., refilling salad bar items more frequently) is a feasible course of action.

FDA believes that there is a pressing need for it to act with regard to the use of sulfites on raw fruits and vegetables. The response of certain individuals to sulfite-treated foods is often unpredictable, and the allergic-type responses can be extremely severe, even fatal. Consequently, the agency must act quickly to diminish the likelihood of additional severe adverse responses in unsuspecting consumers.

Therefore, the agency is allowing only 30 days for interested persons to comment on this proposal. Although 21 CFR 170.38(b)(2) states that 60 days will normally be given for comment on a proposal to find that the use of a substance is not GRAS, the procedures in § 170.38 are subject to Part 10 (21 CFR Part 10). (See 21 CFR 170.38(b)(1).) Under § 10.40(b)(2), the agency may shorten a comment period for good cause. As stated above, the agency believes that its concerns about the protection of the public health provide good cause for shortening the comment period in this instance.

FDA's concerns about the potential hazards from the use of sulfiting agents on fruits or vegetables intended to be served or sold raw extends to those fruits and vegetables that may not actually be fresh but that are presented to the consumer as fresh (e.g., thawed

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FD: made suppl frozen fruits and vegetables). Therefore, the proposed amendments to Part 182 reflect this concern.

B. Exclusions

The use of sulfiting agents on grapes is not included in this proposal. Sulfiting agents are used on grapes as a fungicide rather than as a preservative. Therefore, this use is subject to regulation by the Environmental Protection Agency under the Federal Insecticide, Fungicide, and Rodenticide Act and not to regulation by FDA. (7 U.S.C. et seq.)

V. Other Relevant Information

A. General Comments

FDA received numerous comments on its July 9, 1982, proposal to affirm the CRAS status of certain sulfiting agents.

Three comments from the food industry related to the use of sulfiting agents on fresh fruits and fresh vegetables. One comment was from a trading association, and two were from restaurant chains. These comments simply informed FDA that they were in fact using sulfiting agents on fresh fruits and vegetables.

One comment from a private testing laboratory stated that it had tested foods for sulfite content and reported on the levels that it had measured.

B. Citizen's Petition

On October 28, 1982, the agency received a citizen petition signed by three consumers, a physician, a scientist, and representatives of the Center for Science in the Public Interest (CSPI), Washington, DC. The petitioners requested that FDA amend certain food standards and rescind certain food additive regulations, prior sanctions, and advisory opinions that permit the use of sulfiting agents at a level of more than 350 micrograms per serving. The petitioners also requested that FDA require warning labels on any food products in which sulfiting agents must be used in amounts greater than 350 micrograms per serving to perform essential public health functions.

In a supplement to this petition, which was submitted on March 15, 1983, the petitioners requested that FDA ban the use of sulfiting agents in restaurant salad bars, withdraw the prior sanction permitting the use of sodium bisulfite on potatoes, and institute appropriate enforcement action against sulfite-containing products that are labeled for use on vegetable salads because vegetable salads are a significant source of thiamine (vitamin B_1).

FDA has considered the requests made in the CSPI petition and the supplement. Because this proposed

rulemaking is intended to address only the use of sulfiting agents in fruits and vegetables intended to be served raw or sold raw to consumers, the agency will respond here only to the requests that are relevant to these uses. FDA will respond to the other issues raised in the citizen petition in future Federal Register documents.

The petitioners submitted data to support their claim that vegetable salads are a significant source of thiamine, and that products that instruct users to apply sulfiting agents to these foods are misbranded. The petitioners suggested that FDA issue an appropriate regulatory letter to all manufacturers of such products.

FDA acknowledges that it has never authorized the use of sulfites on foods that are recognized as a significant source of thiamine. Foods that can serve as significant sources of vitamins, including thiamine, are defined in 21 CFR 101.9(c)(7)(v) as those that supply

including thiamine, are defined in 21 CFR 101.9(c)(7)(v) as those that supply at least 10 percent of the minimum daily requirement for vitamins, which in the case of thiamine is 0.15 milligram. FDA has calculated the amount of thiamine present in a traditional serving of salad (1 cup lettuce, 1/2 tomato) as being less than 0.15 milligram (Ref. 6). FDA concludes, therefore, that an average serving (according to the results of the U.S. Department of Agriculture 1977-1978 Nationwide Food Consumption Survey) of a green salad does not serve as a significant source of thiamine. For this reason, FDA also concludes that it cannot grant the petitioners' request for enforcement action against products

containing sulfiting agents that are

labeled for use on vegetable salads. Nonetheless, FDA has tentatively concluded that it is necessary for the agency to take action against the use of sulfiting agents on fruits and vegetables intended to be served or sold raw to consumers. It is proposing that action in this document. Moreover, should this regulation become final, products containing sulfites and labeled for use on fresh vegetable salads would be adulterated under section 402(a)(2)(C) of the act (21 U.S.C. 342(a)(2)(C)). They would be adulterated under that section because a sulfite intended to be used to preserve the freshness of raw fruits and vegetables would be an unapproved food additive and therefore unsafe under section 409(a) (21 U.S.C. 348(a)).

VI. Conclusions

This proposed rulemaking announces that currently available information has created significant questions about whether the use of sulfiting agents in fruits and vegetables intended to be served raw or sold raw to consumers is

safe. As a result, FDA believes that this use of sulfites can no longer be considered to be GRAS. The agency is proposing in this document to amend Part 182 to exclude the use of sulfiting agents on fruits and vegetables intended to be served or sold raw to consumers as fresh from the uses of sulfiting agents that are GRAS. Such use of sulfiting agents would constitute the use of unapproved food additives and would, therefore, cause any food to which they have been added to be adulterated and in violation of section 402(a)(2)(C) of the Act. The comment period for this proposal is 30 days.

The agency requests comments from all interested persons on all relevant issues relating to this proposal. The agency especially seeks comments relating to the following:

- 1. Additional evidence concerning whether there is an association between exposure to sulfites on fresh fruits and vegetables and adverse responses in sulfite-sensitive individuals:
- 2. Data on the extent to which restaurants, other food-service establishments, grocery stores, and other produce handlers currently use sulfiting agents on fruits or vegetables: and
- 3. Practical alternatives to the use of sulfites on fresh fruits and vegetables.

VII. Economic Impact

FDA has determined that the primary cost of this proposed rule results from the substitution of other additives or procedures for sulfiting agents. In accordance with section 605(b) of the Regulatory Flexibility Act (Pub. L. 95-354), the agency has determined that no significant economic impact on a substantial number of small entities, including small businesses, will derive from this action. Further, in accordance with Executive Order 12291, FDA has analyzed the economic effects of this proposal and has determined that it is not a major rule as defined by that Order.

The agency's findings of no major economic impact and no significant impact on a substantial number of small entities, and the evidence supporting these findings, are contained in a threshold assessment which may be seen in the Dockets Management Branch (address above).

VIII. Environmental Impact

The agency has considered the potential environmental effects of this action and has concluded that the action will not have a significant impact on the human environment and that an environmental impact statement is not

required. The agency's environmental assessment and finding of no significant impact may be seen in the Dockets Management Branch, between 9 a.m. and 4 p.m., Monday through Friday.

IX. References

The following references have been placed on display in the Dockets Management Branch and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Select Committee on GRAS substances, "Insights on Food Safety Evaluation," Life Sciences Research Office, Federation of American Societies for Experimental Biology, prepared under FDA contract 223-81-2394, December 1982, and references cited therein.

2. Select Committee on GRAS Substances, "Evaluation of Health Aspects of Sulfiting Agents as Food Ingredients," Life Sciences Research Office, Federation of American Societies for Experimental Biology, prepared under FDA contract 223-75-2004, 1976.

3. "Sulfiting Agents; Proposed Affirmation of GRAS Status with Specific Limitations; Removal from GRAS Status as Direct Human Food Ingredient," 47 FR 29956; July 9, 1982.

4. Select Committee on GRAS Substances. "The Reexamination of the GRAS Status of Sulfiting Agents," Life Sciences Research Office, Federation of American Societies for Experimental Biology, prepared under FDA contract 223–83–2020, January 28, 1985.

5. Retail Food Protection Program
Information Manual, Part 6, Chapter 01,
Number 2–101, Revised September 29, 1983.

6. Memorandum from John E. Vanderveen, Director, Division of Nutrition, to John Taylor, Director, Division of Regulatory Guidance, "Thiamine Content of Foods in Reference to Sulfiting Agents," April 10, 1985.

7. National Institute of Allergy and Infectious Diseases, American Academy of Allergy and Immunology, Committee on Adverse Reactions to Foods, "Adverse Reactions to Foods," NIH publication No. 84–2442, 1984, 220p. (available from U.S. Government Printing Office, Washington, DC).

8. Kechen, J., Sulfur Dioxide, a Respiratory Tract trritant, Even if Ingested," *Pediatrics*, 52:145–146, 1973.

9. Frenner, B. M., and J. J. Stevens, "Anaphylaxis after Ingestion of Sodium Bisulfite," *Annals of Allergy*, 37:180–182, 1976.

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Allen, 7:407-415, 1977.

11. Baker, G. J., P. Collett, and D. H. Allen, "Bronchospasm Induced by Metabisulfite-Containing Foods and Drugs," Medical

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Asthmatic Subjects," Journal of Allergy and

14. Goldfarb, G., and R. Simon, "Provocation of Sulfite Sensitive Asthma,"

Clinical Immunology, 88:26-32, 1981.

Journal of Allergy and Clinical Immunology, 73:135, 1984 (Abstract).

15. Koepke, J. W., and J. C. Selner, "Sulfur Dioxide Sensitivity," Annals of Allergy, 48:258; 1982 (Abstract).

16. Buckley, C. E., III, H. A. Saltzman, and H. O. Sieker, "The Prevalence and Degree of Sensitivity to Ingested Sulfites," Journal of Allergy and Clinical Immunology, 1985 (Abstract), In press.

17. Howland, W. C., and R. A. Simon, "Restaurant-Provoked Asthma: Sulfite Sensitivity," *Journal of Allergy and Clinical Immunology*, 1985 (Abstract), In press.

18. Simon, R. A., Oral presentation given at the open meeting of the Ad Hoc Review Panel on the Reexamination of the GRAS Status of Sulfiting Agents held November 29, 1984, Bethesda, MD.

19. Sonin, L., and R. Patterson, "Metabisulfite Challenge in Patients with Idiopathic Anaphylaxis," *Journal of Allergy* and Clinical Immunology, 75:67–69, 1985.

20. Taylor, S. L., Oral presentation given at the open meeting of the Ad Hoc Review Panel on the Reexamination of the GRAS Status of Sulfiting Agents held November 29, 1984, Bethesda, MD.

21. Simon, R. A., L. Green, and D. D. Stevenson, "The Incidence of Ingested Metabisulfite Sensitivity in an Asthmatic Population," *Journal of Allergy and Clinical Immunology*, 69:118, 1982 (Abstract).

22. Patterson, R., Northwestern University, Evanston, IL., Letter plus attachments, dated July 9, 1984, to S. A. Anderson, Federation of American Societies for Experimental Biology, Bethesda, MD.

X. Miscellaneous Information

FDA is unaware of any prior sanction for the use of these ingredients in foods that covers the conditions identified in this document. Any person who intends to assert or to rely on such a sanction shall submit proof of its existence in response to this proposal. The amendments proposed above will constitute determinations that excluded prior-sanctioned uses would result in adulteration of the food in violation of section 402 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342), and the failure of any person to come forward with proof of an applicable prior sanction in response to this proposal constitutes a waiver of the right to assert or rely on the sanction

The agency believes, however, that even if a prior sanction does exist for the use of sulfiting agents on fruits and vegetables intended to be served raw or sold raw, reliance on that sanction would likely not be a sufficient justification to continue this use of sulfiting agents. FDA believes that recent information demonstrates that this use of sulfiting agents may be injurious to a significant number of people. Furthermore, present day foodprocessing practices and dietary trends could not have been anticipated before

1958, when a prior sanction would have been issued. Therefore, FDA tentatively concludes that the use of sulfiting agents on fruits and vegetables intended to be served raw to consumers or sold raw to consumers would cause the food to be adulterated within the meaning of section 402 of the act (21 U.S.C. 342).

Interested persons may, on or before September 13, 1985, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 182

Generally recognized as safe (GRAS) food ingredients, Spices and flavorings.

Therefore, under the Federal Food, Drug, and Cosmetic Act, it is proposed that Part 182 be amended as follows:

PART 182—SUBSTANCES GENERALLY RECOGNIZED AS SAFE

1. The authority citation for Part 182 continues to read as follows:

Authority: Secs. 201(s), 409, 701, 52 Stat. 1055–1056 as amended, 72 Stat. 1784–1788 as amended (21 U.S.C. 201(s), 348, 371).

2. In § 182.3616 by revising paragraph (c), to read as follows:

§ 182.3616 Potassium bisulfite.

*

- (c) Limitations, restrictions, or explanation. This substance is generally recognized as safe when used in accordance with good manufacturing practice, except that it is not used in meats or in food recognized as source of vitamin B₁, and that it is not used on fruits or vegetables intended to be served raw to consumers or sold raw to consumers or to be presented to consumers as fresh.
- 3. In § 182:3637 be revising paragraph (c), to read as follows:

§ 182.3637 Potassium metabisulfite.

(c) Limitations, restrictions, or explanation. This substance is generally recognized as safe when used in accordance with good manufacturing practice, except that it is not used in meats or in food recognized as source of vitamin B₁, and that it is not used on fruits or vegetables intended to be served raw to consumers or sold raw to

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consumers or to be presented to consumers as fresh.

4. In § 182.3739 by revising paragraph (c), to read as follows:

§ 182.3739 Sodium bisulfite.

- (c) Limitations, restrictions, or explanation. This substance is generally recognized as safe when used in accordance with good manufacturing practice, except that it is not used in meats or in food recognized as source of vitamin B;, and that it is not used on fruits or vegetables intended to be served raw to consumers or sold raw to consumers or to be presented to consumers as fresh.
- 5. In § 182.3766 be revising paragraph (c), to read as follows:

§ 182.3766 Sodium metabisufite.

(c) Limitations, restrictions, or explanation. This substance is generally

recognized as safe when used in accordance with good manufacturing practice, except that it is not used in meats or in food recognized as source of vitamin B₁, and that it is not used on fruits or vegetables intended to be served raw to consumers or sold raw to consumers or to be presented to consumers as fresh.

6. In § 182.3798 by revising paragraph (c), to read as follows:

§ 182.3798 Sodium sulfite.

(c) Limitations, restrictions, or explanation. This substance is generally recognized as safe when used in accordance with good manufacturing practice, except that it is not used in meats or in food recognized as source of vitamin B₁, and that it is not used on fruits or vegetables intended to be served raw to consumers or sold raw to consumers or to be presented to consumers as fresh.

7. In §182.3862 by revising paragraph (c), to read as follows:

§ 182.3862 Sulfur dioxide.

(c) Limitations, restrictions, or explanation. This substance is generally recognized as safe when used in accordance with good manufacturing practice, except that it is not used in meats or in food recognized as source of vitamin B₁, and that it is not used on fruits or vegetables intended to be served raw to consumers or sold raw to consumers or to be presented to consumers as fresh.

Dated: July 24, 1985.

Frank E. Young,

Commissioner of Food and Drugs.

Margaret M. Heckler,

Secretary of Health and Human Services. [FR Doc. 85–19282 Filed 8–12–85; 8:45 am] BILLING CODE 4160–01-M

SUBJECT: SUBSTITUTE FOR SULFITES

Note: The following list has been provided to us by the NRA as "substitutes" for sodium bisulfites and/or other sulfites. This list is not to be considered an endorsement of any products.

rist	is not to be considered an endorsement of a	my produc	
1.	"FRUIT FRESH"		
	Beecham Products		
	Division of Beecham, Inc. P. O. Box 1467 FF81	(412)	28-1050
	Pittsburgh, PA 15230-1467	(800)	245-3370
	11ccsbd1gn, FA 15250-1407	BRITAL BALL	
2.	"FRESH WAY"	Aures and	
	Disco, Inc.		
	P. O. Box 18146	1404)	750 0006
	Atlanta, GA 30316	(404)	758-0096
3.	"SALAD FRESH"		
	CFS-Continental		
	2550 Clybourn Avenue	(212)	477-7600
	Chicago, IL 60614	(312)	477-7000
4.	"STA-FRESH WITHOUT SULFITES"		
	Crescent Manufacturer Company		
	P. O. Box 3985	(206)	623-7140
	Seattle, WA 98124	(200)	023-7140
5.	"WHITEN-ALL #2"		
	(Company's Proprietory)		
	"RICH-IN-ALL"		
	(Private Label)		
	The Langlois Company		
	5354 E Slauson Avenue	(213)	685-7440
	Los Angeles, CA 90040	(210)	
6.	"STA-WHITE (Without sulfites)		
	Farmer Brothers		·· ·
	20333 S Normandie Avenue		
	P. O. Box 2959	(212)	775-2451
	Torrance, CA 90509	(213)	, , 5 2 3 1

7. "SANI-WASH" or "MIKRO--CHLOR"
(Distribution Line) (Direct Line)
"Multi-Purpose ---- Product can be used as antioxidant
Economics Laboratory
6101 Executive Blvd., Suite 260
Rockville, MD (301) 984-0227

(Over)

8. "VEGO-READY" - TYPE II Nuggett Food Service & International Distributors (209) 948-8122 Stockton, CA 95204

Available through: Dean Distributors 851 Burlway Road

Suite 312

Burlingame, CA 94010

(415) 340-1754(800) 227-3112

9. "SALAD CRISP" First Food Company, Inc. 414 Regal Row Dallas, TX 75247

(214) 637-0214 (800) 527-1866

10. "POTATO WHITENER" - (No Sulfites) Flavorite Laboratories, Inc. P. O. Box 1315 Memphis, TN 38101 (Located in Mississippi)

(601) 393-3610

- 11. Pfizer, Chemical Division Technical Service Center (Only sell in 1001b drums) (203) 441-5100 Eastern Point Road Groton, CT 06340 "CE-101-P" for potatoes "CE-52-5" for salads
- "SALAD FRESH" 12. Ingredient Technology Corp. 7501 E. McNichols Detroit, MI 48234

(313) 365-4900

13. "FLAVOR BRITE" Batterlite-Whitlock Strath Haven Condo Yale and Harvard Avenues P. O. Box 30 Swarthmore, PA 19081

(215) 328-9873

Manufacturing & Distributing Plant: 2520 S. Grand Avenue, East P. O. Box 259 Springfield, IL 62705-0259

(215) 528-5621

The FDA is moving toward a partial ban on sulfites...the Food and Drug Administration's (FDA) Commissioner, Dr. Frank Young, has signed off on a proposal that would ban the use of sulfiting agents in raw fruits and vegetables. Sulfites have been linked to allergic reactions and even death among sulfite-sensitive asthmatics. NRA asked its members to discontinue the use of sulfites as a freshening additive in February of 1983.

Last year NRA recommended a limited, partial ban on sulfites in testimony given before a scientific panel studying the issue. That panel subsequently recommended that FDA adopt a ban on the use of sulfites in raw fruits and vegetables and pre-cut potatoes.

The FDA-approved ban does not include pre-cut potatoes. Young has delayed action on potatoes because the potato industry strongly objects to a ban on sulfites. According to the industry, there is no adequate substitute for sulfites in potatoes and a ban would impose a severe economic hardship and loss of a significant amount of production.

HHS and OMB must clear the proposed ban before it becomes official...Health and Human Services (HHS) Secretary Margaret Heckler and the Office of Management and Budget (OMB) must approve the ban before the proposal will be published in the Federal Register for comment.

8/19/85

OMB has signed off on a proposal to ban sulfite use in fresh fruits and vegetables...the Office of Management and Budget (OMB) approved a Food and Drug Administration (FDA) proposal to ban the use of sulfites to preserve fresh fruits and vegetables in restaurants and supermarkets.

FDA and HHS had already approved a ban...both Dr. Frank Young of FDA and Health and Human Services (HHS) Secretary Margaret Heckler signed off on the ban earlier this summer. (See Weekly of August 5.)

The temporary regulations were expected to be published as this Weekly went to press...the proposal is expected to have a 30-day public comment period. A final rule should be published by the end of the year.

A proposed rule to ban limited uses of sulfites was published in the $\frac{\text{Federal}}{\text{ban}}$ Register on Aug. 15...followed a previous suggestion by NRA that FDA ban the use of sulfites on fresh fruits and vegetables and pre-cut potatoes.

FDA's ban does not cover pre-cut potatoes...FDA backed off on a ban on sulfite use in potatoes after the potato industry voiced strong opposition to such a ban. (See Weekly of August 5.) FDA has extended the ban to include thawed frozen fruits and vegetables that may be presented to the consumer as fresh.

NRA's contention that restaurant labeling can't work was supported by FDA in its proposed rule...a change from FDA's previous position that labeling in restaurants would be an effective protection for sulfite-sensitive individuals. FDA states in the proposed regulations that "labeling in restaurants and grocery stores is not a practical alternative because labeling in those environments is not customarily used and because of the difficulty of enforcing such labeling at either the Federal or State level."

Comments on the proposal are due to FDA by Sept. 13...FDA will review the comments received to determine if any changes will be made to the proposed rule. A final rule is expected to be published by the end of the year.

Since 1983, NRA has asked its members not to use sulfites...a list of sulfite substitutes is available to all interested NRA members. Contact NRA Information Services at (800)424-5156.

10/28/85

The proposed ban on sulfites has received a lot of attention recently... with the deadline for comments passed, the Food and Drug Administration (FDA) is working on the final regulations banning the use of sulfites on fresh fruits and vegetables.

Food processors and retailers came out on both sides of the ban...some regarded FDA's actions as premature and without scientific basis, while others chided FDA for not banning all uses of sulfites.

Two associations opposed the ban...the International Food Additives Council (IFAC) objected to the FDA banning any ingredient on the basis of what it termed "anecdotal information," saying FDA has no scientific fact on which to base the ban on sulfites. The Northwest Food Processors Association opposed the specific provision banning the use of sulfites on thawed fruits and vegetables that are presented as fresh, saying the sulfites are added under the supervision of trained scientists who comply strictly with federal tolerance levels.

Supporters of the ban ranged from retailers to health officials. Giant Food, Sugar Foods Corp., the National Environmental Health Association and the Joint Council of Allergy and Immunology are just a few of the groups who supported FDA's proposal to revoke the GRAS status of sulfite use on fresh fruits and vegetables.

In other related matters concerning sulfites:

- FDA must complete its evaluation of sulfites by June 1, 1986, if an amendment added to the Agriculture Department appropriations bill becomes law. Sen. Albert Gore (D-Tenn.) added the amendment, which was passed on Oct. 16. Sen. Gore sponsored, at the request of NRA, the Senate bill to ban the use of sulfites on fresh fruits and vegetables and precut potatoes.
- FDA is preparing a proposal to ban the use of sulfites on potatoes... considers the risk to sulfite-sensitive population too great to allow this use to continue. FDA exempted potatoes from its ban on the use of sulfites in fresh fruits and vegetables at the request of the potato industry, which claims that such action will have a significant negative economic impact.

FDA's decision to exempt potatoes from the ban came under fire during the first meeting of FDA's Panel on Hypersensitivity in Foods. Dr. Ronald Simon of the Scripps Clinic noted that sulfite use in potatoes has been implicated in many of the fatal reactions, and therefore needs to be addressed. Dr. Simon chairs the panel's subcommittee on sulfites.

An FDA ad hoc panel on hypersensitivity to food constituents met Dec. 12-13 in Washington...discussed questions surrounding sulfiting agents. The committee is composed of several doctors, a food scientist and an attorney...act in an advisory capacity to the Food & Drug Administration.

Among the findings aired by the group during its recent meeting:

- No effective substitute for sulfites is available for some foods, particularly for preventing browning in dried fruits, dehydrated potatoes and shrimp, and as a preservative in beer and wine.
 - Test strips to detect the presence of sulfites in foods are not reliable.
- Eight deaths have been linked to sulfite sensitivity, less than half of the 17 reported deaths originally thought to be associated with sulfites.

The panel also made a number of recommendations; among them:

- Sulfites should not be used on fresh fruits and vegetables, including fresh potatoes. However, sulfites need not be banned from use on fresh mushrooms and table grapes, since sulfite residues can be kept to less than 10 parts per million in these foods.
- Sulfites should not be used in frozen potatoes, since their use in these products is unnecessary.
 - The sale of sulfites as fresheners should be banned at the retail level.
- FDA should develop guidelines on minimum levels of sulfites required to provide the desired technical effect and urge the food industry to adhere to
- Test strips for sulfite detection should not be used by consumers because they are not accurate.
- Physician and public education programs should be developed to help individuals recognize the symptoms of sulfite sensitivity.

FOOD CHEMICAL NEWS

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BRIEF COMMENT PERIOD ALLOWED ON SULFITE BAN PROPOSAL

Proposing to ban use of sulfites on fruits and vegetables intended to be served or sold raw to consumers, as expected (See FOOD CHEMICAL NEWS, Aug. 12, Page 2), the Food and Drug Administration allowed only a 30-day period for comments.

Explaining that it is providing only 30 days for comments because of "the acute health problems," the agency noted that it normally allows 60 days for comments on a proposal to find that a substance is not Generally Recognized as Safe, adding that it "may shorten a comment period for good cause." During the one-month period, FDA requested comments on:

- "(1) Additional evidence concerning whether there is an association between exposure to sulfites on fresh fruits and vegetables and adverse responses to sulfite-sensitive individuals;
- "(2) Data on the extent to which restaurants, other food-service establishments, grocery stores, and other produce handlers currently use sulfiting agents on fruits or vegetables; and
- "(3) Practical alternatives to the use of sulfites on fresh fruits and vegetables."

In a news release, FDA said, "Pending a final regulation, FDA advises consumers concerned about sulfites in food to ask restaurant or supermarket personnel if they are used and to avoid restaurant foods, particularly salad bars, in which sulfites may be used."

The FDA proposal did not cover sulfite use on grapes as a fungicide (See FOOD CHEMICAL NEWS, July 22, Page 23). The agency noted that this use is regulated by the Environmental Protection Agency under the Federal Insecticide, Fungicide, and Rodenticide Act, rather than by FDA.

The FDA proposal would revise GRAS listings to provide that a sulfite "is GRAS when used in accordance with good manufacturing practice, except that it is not used in meats or in food recognized as a source of vitamin B-1, and that it is not used on fruits or vegetables intended to be served raw to consumers or sold raw to consumers or to be presented to consumers as fresh." This change would be made in §182.3616 for potassium bisulfite, §182.3637 for potassium metabisulfite, §182.3739 for sodium bisulfite, §182.3766 for sodium metabisulfite, §182.3798 for sodium sulfite, and §182.3862 for sulfur dioxide.

FDA said its "concerns extend to fruits and vegetables that may have undergone physical processing before sale, such as guacamole made from mashed avocado, and to raw fruits and vegetables that, to the consumer, appear to be fresh but that may have been processed in some way (e.g., freezing)." It also explained that this would cover "thawed frozen fruits and vegetables."

FOOD CHEMICAL NEWS (ISSN 0015-6337) is published weekly for \$525 per year and \$335 for additional subscriptions by Food Chemical News, Inc., 1101 Pennsylvania Ave., S.E., Washington, D.C. 20003. SecondStating that "there is no longer a basis to find that the use of sulfiting agents as a preservative on fruits or vegetables intended to be served or sold raw to consumers is GRAS," FDA said it based the proposal on the following factors:

- "(1) There are people within the U.S. population, whose number may be as high as 1 million, according to some estimates, who are sulfite sensitive and suffer allergic-type responses of unpredictable severity upon ingesting foods treated with sulfiting agents.
- "(2) The use of sulfiting agents by restaurants and other food-service establishments on fruits and vegetables presented to the consumer for sale as fresh (e.g., salad bars) is cited in the largest fraction (nearly half) of the consumer complaints of adverse responses received by FDA.
- "(3) Although sensitive individuals can possibly avoid sulfite-treated foods that are packaged and labeled, the use of signs has not proven to be effective in protecting sensitive persons in such situations as restaurant salad bars, when sulfiting agents are used on fruits and vegetables intended to be served or sold raw to consumers or presented to consumers as fresh. Adverse responses alleged to be associated with these uses have continued despite some States' efforts to require signs. Moreover, the (Federation of American Societies for Experimental Biology) Panel has stated that it believes that the use of signs will not be an effective means of protecting sensitive individuals. Furthermore, FDA believes . . . that labeling in restaurants and grocery stores is not a practical alternative because labeling in those environments is not customarily used and because of the difficulty of enforcing such labeling at either the federal or State level.
- "(4) In addition, the levels of sulfiting agents on raw fruits and vegetables are likely to vary widely and will depend upon the care exercised by food-service personnel in following use instructions for their application. Thus, a significant potential exists for abuse or misuse of these chemical preservatives.
- "(5) Because many restaurants now operate salad bars without using sulfites, it appears that substituting alternative preservatives or implementing revised operating procedures (e.g., refilling salad bar items more frequently) is a feasible course of action."

In summarizing the causes for its concern, FDA said, "Current lifestyle trends and food-processing practices point to significant exposure of individuals to sulfiting agents used on fresh fruits and vegetables," adding that "the potential for carelessness or misuse exists when sulfiting agents are applied to food by food-service establishment personnel."

Noting that industry data "indicate a decline in the use of sulfiting agents by restaurants and produce marketers," FDA said that "a significant number may still be using them and FDA is still receiving reports from individuals of allergic-type response allegedly associated with eating sulfite-treated foods."

The agency said "more Americans are eating a greater proportion of their meals away from home," and that there has been an "increase in the presence of salad bars in restaurants and other food-service establishments."

FDA said it "has received over 500 consumer complaints where the individuals reported suffering a variety of adverse allergic-type responses after eating food to which they believed sulfiting agents had been added." As many as 1 million asthmatic persons may be sulfite sensitive, the agency said, adding, "Although there is even less certainty about the degree to which nonasthmatic persons may also be sulfite sensitive, nonasthmatics were nevertheless involved in several of the complaints reported to the agency."

Recalling that it revised the Retail Food Protection Program Information Manual to provide for informing consumers at retail establishments if fresh produce was treated with

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sulfites, FDA said, "By March, 1985, however, 19 States had still not adopted this interpretation." It added that, "because of the great number of restaurants and other retail establishments, comprehensive enforcement is difficult to achieve."

Although sulfite use on raw produce has declined, FDA said the problem still exists, noting that more than 40% of consumer complaints have been received since completion of a 1984 Food Marketing Association survey. The agency described the complaints, as follows:

"... The largest segment (approximately 40%) specifically mention the occurrence of adverse responses after eating raw fruits or raw vegetables in restaurants, while 4% specifically mention fresh produce purchased in a grocery store. Thus, nearly half of all complaints received specifically mention fresh fruits or vegetables. By comparison, approximately 15% of the 500 complaints specifically mention the occurrence of adverse responses after drinking wine or beer, and 14% specifically mention processed, packaged food eaten at home. The remaining complaints were less specific about the type of food and the place of purchase or consumption."

Of the complaints, the agency said, "approximately 40%... mentioning fresh fruits or vegetables mention gastrointestinal effects, including nausea and diarrhea; about 50% mention various forms of respiratory distress; 10% mention anaphylaxis, coma, or shock; and 15% mention that hospitalization was required or emergency room care was sought." In approximately 30% of the complaints, the responses were described as "allergic," the agency said.

The FDA proposal relied heavily on the FASEB report (See FOOD CHEMICAL NEWS, Feb. 4, Page 59). FDA said the Panel "concluded, in part, that the available information contains sufficient evidence to demonstrate a hazard of unpredictable severity to sulfite-sensitive individuals when they are exposed to sulfiting agents in some foods at levels that are now being used."

While the FASEB report suggested a ban is necessary to protect those who may be hypersensitive to sulfites, the somewhat ambiguous FASEB report also said sulfites could be used safely with specific limits. It also concluded that additional labeling would not assure protection.

Stating that it does not believe a prior sanction exists for use of sulfites on raw fruits and vegetables, FDA added, however, "that even if a prior sanction does exist for the use of sulfiting agents on fruits and vegetables intended to be served raw or sold raw, reliance on that sanction would likely not be a sufficient justification to continue this use of sulfiting agents."

FDA had proposed GRAS affirmations for potassium metabisulfite, sodium bisulfite, sodium metabisulfite, and sulfur dioxide (See FOOD CHEMICAL NEWS, July 12, 1982, Page 37). The agency at the same time had proposed revoking the GRAS listings for potassium bisulfite and sodium sulfite. No changes in these proposals were indicated in last week's Federal Register document.

"Because of the acute health problems that have been associated with the use of sulfites on fresh fruits and vegetables sold in food-service establishments," the agency said, "FDA has decided to act immediately with regard to this use, before deciding whether to affirm the GRAS status of the other uses of sulfiting agents." It said it "intends to address all other uses of sulfiting agents, including their use on potatoes and potato products, in the near future." A document on sulfite use on potatoes is believed to be under preparation.

Discussing comments it received on the 1982 sulfite GRAS proposals, FDA said three comments from a trade association and two restaurant chains "simply informed FDA that they were in fact using sulfiting agents on fresh fruits and vegetables." A comment from a private testing laboratory reported on levels of sulfite it had measured in food products, the agency added.

The Center for Science in the Public Interest and some individuals had filed a petition with FDA asking that it rescind clearances for use of sulfites at more than 350 micrograms per serving, require warning labels on food products in which sulfites must be used in excess of 350 micrograms per serving, ban use of sulfites in salad bars, withdraw a prior sanction permitting use of sodium bisulfite on potatoes, and take enforcement action against sulfite-containing products labeled for use on vegetable salads because vegetable salads are a significant source of thiamine (See FOOD CHEMICAL NEWS, Nov. 1, 1982, Page 47; and March 28, 1983, Page 12).

FDA said it responded last week only to the portion of the petition dealing with sulfite use on raw fruits and vegetables, stating that it "will respond to the other issues raised in the petition in future Federal Register documents."

However, in response to the suggestion by CSPI that FDA issue regulatory letters to manufacturers of sulfite products used for vegetable salads, FDA said "that an average serving (according to the results of the U. S. Department of Agriculture 1977-1978 Nationwide Food Consumption Survey) of a green salad does not serve as a significant source of thiamine." Therefore, the agency said it "cannot grant petitioners' request for enforcement action against products containing sulfiting agents that are labeled for use in vegetable salads."

An FDA "threshold assessment" concluded "that current usage of sulfiting agents on raw fruits and vegetables is not widespread (and) that switching to either chemical or non-chemical alternatives will not result in a major cost impact." It based this conclusion on the following points:

- "(1) An economic dependency on sulfiting agents for the purposes covered by this proposal has not been demonstrated by current users. Substitutes (both chemical and production procedures) for sulfiting agents are currently available commercially and are used by many manufacturers and foodservice establishments; (and)
- "(2) Current information available to the agency indicates that the use of sulfiting agents on raw fruits and vegetables covered by this proposal in foodservice establishments and the use of sulfities by suppliers of fresh produce to such establishments is not widespread."

The assessment said sulfites are believed used on raw lettuce, broccoli, carrots, mush-rooms, cabbage, potatoes, sliced apples, grapes, carrot and raisin salad, Waldorf salad, cole slaw, and guacamole/avocado salad.

Noting that citric, ascorbic, and erythorbic acids, refrigeration, more frequent product rotation, and use of chilled chlorinated water have been used as substitutes for use of sulfites, the assessment said, "Although a number of industry sources indicate that these alternatives are not quite as effective as sulfites . . . and that available chemical substitutes are somewhat more expensive . . ., this trend away from sulfites demonstrates that there is certainly no economic dependency on sulfiting agents."

The document noted that substitute chemical substances "(1) do not provide as long a shelf life as sulfiting agents (i.e., one estimate is 3-4 days for a solution of ascorbic and citric acid versus 7-8 days for sulfiting agents); and (2) may not be capable of providing the (same) range of technological effects as sulfiting agents (reports indicate that none of these substitutes effectively replace sulfites as a bleaching agent)."

The assessment said the Produce Marketing Association has reported that 95% of its 57 member distributors do not use sodium bisulfite, and that 2 of 3 firms using sulfites do not use it on a regular basis. It said the United Fresh Fruit and Vegetable Association has indicated that "the vast majority of fresh fruits and vegetables grown in this country are not treated with sulfites at the grower/shipper level," with the two exceptions being mushrooms and table grapes.

At the wholesale level, the document said, sulfite use "is predominantly limited to its use in precut operations," noting that "the market for precut lettuce is diminishing." Three firms which supply pre-chopped lettuce, the threshold assessment said, indicate "that nothing has yet been developed which is as effective as sulfites in inhibiting browning," but that "their industry is obviously not dependent upon sulfiting agents."

The United Fresh Fruit and Vegetable Association reported "that sulfiting agents are not used by produce retailers," the document said, and "additional information . . . indicates that less than 5% of all supermarkets currently use sulfiting agents on raw fruits and vegetables."

It was estimated that "less than 5% of all restaurants, less than 5% of all government cafeterias and less than 5% of all commercial transportation foodservices...currently use sulfiting agents." The National Restaurant Association found in 1983 that 3.9% of 17,000 establishments reported using sulfites on fruits and vegetables, the assessment said, noting that this was down from 20% which reported using sulfites in 1982. "If we accept the NRA and FASEB figures as lower and upper limits," the document said, "we project 21,450 to 55,000 foodservice establishments as sulfite users."

Wyden Says He Will Press for Sulfite Ban Legislation

Rep. Wyden (D-Ore.) was quoted by the New York Times as saying he would continue to press for his bill to ban use of sulfites. An identical bill was sponsored by Sen. Gore (D-Tenn.). "There is just no reason to taint foods with sulfite just to keep them pretty," Wyden was quoted as saying. The Washington Post quoted Gore as saying "there is still more to do," specifically urging that sulfites not be permitted on cut or frozen potatoes.

The Post said CSPI called the proposal "a pathetic response to a hazardous substance that FDA has known for years can kill people." The New York Times quoted CSPI's Mitchell Zeller as saying:

"The proposal is three years too late. While the federal government has been twiddling its thumbs, by FDA's own accounts, 13 people have died and many other people have been sent to the hospital with life-threatening reactions. While a ban on fresh fruits and vegetables is a step in the right direction, it is not an adequate response to the hazards posed by sulfites. We would hope that the FDA will move quickly to ban all other uses of sulfites in foods and in drugs."

Richard E. Cristol, of the Food Additives Council, who said the proposal would have little economic impact because most restaurants have discontinued sulfite use and because "most of the volume goes in processed food, such as dried fruit and frozen potato products," alleged that FDA acted more because of Congressional pressure than from scientific merit, the New York Times reported. He was quoted as saying that "FDA should be willing to conclude rather than allege that sulfites are the problem before banning an ingredient."

Wyden was quoted by the Times as calling the proposal "very welcome news." NRA's Jeffrey R. Prince was also quoted as lauding the proposal, saying that most restaurants had stopped using sulfites.

In a news release, Secretary of Health and Human Services Margaret M. Heckler said: "While sulfites have been used for many years to preserve such processed foods as dried fruit, they only recently became a widely utilized 'ingredient' in varying amounts to keep fresh fruits and vegetables in salad bars from browning. Most Americans have been unaware of this practice."

DOMESTIC BOTTLED BEER BEING SAMPLED FOR DEHP IN HIGH PRIORITY FDA PROGRAM

Domestic bottled beer is being sampled by the Food and Drug Administration to determine if residues of the plasticizer di(2-ethylhexyl)phthalate (DEHP) are present in the beer.

Under the high priority program issued to the agency's Baltimore District Aug. 6, with sampling to be completed by Aug. 19, samples of domestic bottled beer in various sizes are to be collected from retail outlets, if possible from stock which has been packaged for at least one month.

The agency noted that concern about dietary exposure to DEHP was raised recently when samples of certain foods which had undergone retorting in jars employing DEHP-plasticized liners were found to contain levels of DEHP up to 30 p.p.m.

Although DEHP-plasticized gasket liners are used in a number of bottled food applications which subject the liner to elevated temperatures during food processing, bottled beer which has been pasteurized in the bottle at 145°-150° F for 30-40 minutes may be one of the highest potential exposures to DEHP from gasket liners, FDA said.

The agency noted its high volume consumption and the fact that nearly all bottled beer closures, whether crowns or roll-ons, employ DEHP in their liners, so that migration could occur during the pasteurization cycle as well as during normal handling and storage.

Analysis of pasteurized bottled beer for residues of DEHP should permit an assessment of the extent of plasticizer leaching as well as its possible contribution to the dietary burden of DEHP, the agency said.

While no regulatory action was anticipated as a result of the program, FDA said that where indicated by analytical results, official samples may be obtained for appropriate follow-up.

Product Safety Commission Considers DEHP Potentially Carcinogenic

A recent draft report to the U.S. Consumer Product Safety Commission by the Chronic Hazard Advisory Panel on DEHP noted that the plasticizer is readily absorbed after ingestion and must be considered potentially carcinogenic to humans (See FOOD CHEMICAL NEWS, July 15, Page 2).

"Quantitative risk estimates based on animal carcinogenicity data suggest," the Panel reported, "that the contribution of dietary DEHP could represent a substantial portion of total liver cancer deaths in humans."

CPSC said the plasticizer must be presumed to have both initiating and promoting activities, and found evidence of adverse effects on male reproductive performance, as well as concluding that the substance is fetotoxic for rats and mice and teratogenic for mice.

It estimated that average daily adult exposure to DEHP in foods is 208.9 micrograms, or 0.003 mg/kg/day, which, it said, results in a maximum likelihood estimate of increased risk of liver tumors of 26.0 x 10^{-6} .



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February 6, 1986

H.B. 2681 FOOD SERVICE ESTABLISHMENTS REQUIRED TO NOTIFY CUSTOMERS OF FOOD TREATED WITH SULFITES.

Mr. Chairman and members of the Committee, my name is Judy Schrock and I am a Registered Nurse employed in the Riley County Health Department. In 1983 I authorized a resolution which was adopted by the Kansas State Nurses' Association to support the dissemination of health alerts regarding the use of sulfiting agents to peers, colleagues, and consumers.

The FDA is scheduled to publish a final rule in June to <u>eliminate</u> the use of sulfiting agents in fresh foods and vegetables.

KSNA would support the <u>complete elimination</u> of these products from use in restaurants as they are currently used on fresh foods and vegetables.

Conceptually H.B. 2681 is good; but KSNA would support the complete elimination of sulfiting agents in restaurant use.

ATTACHMENT O

2/6/86



#11."RESTRICTION OF USE OF SULFITING AGENTS IN FOOD AND DRUGS"

(Submitted by District 18)

WHEREAS, professional nurses are strong proponents of promotional health care, including dietary and drug ingestion practices of people, and

WHEREAS, the elimination of the use of sulfiting agents in foods and drugs can help to prevent allergic reactions, as well as fear of reactions, in 400,000-500,000 susceptible Americans, therefore be it

RESOLVED, that KSNA make known via letter to the Food and Drug Administration, Center for Science in the Public Interest, and American Nurses' Association its members' support of the banning or restriction on the use of sulfiting agents as food and drug additives, and be it further

RESOLVED, that KSNA members be encouraged to disseminate health alerts regarding hazards of the use of sulfiting agents to peers, colleagues, and consumers at every opportunity.

Rationale:

The potential hazards of sulfiting agents to susceptible individuals has only recently been determined and publicized.

It is appropriate for professional nurses to support stricter regulation of such a food and drug additive when its use has been proven to cause allergic reactions from mild to severe degrees in a large segment of the human population.

Background:

A class of food and drug additives called sulfiting agents used to prevent discoloration and bacterial growth cause hypersensitivity reactions in possibly one-twentieth of 8.9 million asthmatic Americans as well as an untold number of nonasthmatics.

Beginning in 1976 physicians have published reports that, among asthma sufferers, the chemicals can cause reactions such as weakness, tightness in the chest, shortness of breath, hives, severe wheezing, and even loss of consciousness.

The highest consumption of these preservatives occurs in persons ingesting restaurant salads, vegetables, and avocado dips to which are added solutions of potassium metabisulfite. Although the chemicals have been added to foods and beverages for centuries, today their use appears to be mostly a matter of convenience since other preservatives can be used in fruit and vegetable juices, alcoholic beverages, and eliminated entirely from salad bar ingredients.

Some of the drugs used currently to treat asthma symptoms also contain sulfiting agents.

In July of 1982, the Food and Drug Administration proposed to classify the group of sulfiting agents "generally recognized as safe" until Center for Science in the Public Interest (a non-profit consumer group advocating improved national policies on health issues) petitioned the FDA to deny safe status to these additives, calling for a ban or severe restriction on their use in restaurant food, dried fruit, seafood, processed food, alcoholic beverages, and drugs, and the issuance of a public health alert advising asthmatics and others with lung problems of the hazard posed by sulfiting agents and of the foods and drugs to avoid.

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