Committee in Session at 8:35 am on Tuesday, April 24, 1979.

Senator Keith Ashworth in the Chair.

PRESENT: Chairman Keith Ashworth
Vice-Chairman Joe Neal
Senator Wilbur Faiss
Senator Jim Kosinski

ABSENT: Senator Clifton Young
Senator Rick Blakemore

GUESTS: Senator Mike Sloan, Clark County Senatorial District No. 3
Senator William Hernstadt, Clark County Senatorial District No. 3
Dr. Willis Russell, Private Practitioner
Mr. Fred Hillerby, Nevada Hospital Association
Ms. Victoria Iori, Division of Aging Services
Dr. William Thomason, Administrator, Bureau of Health Facilities
Senator Lawrence Jacobsen, Capital Senatorial District
Mr. William X. Smith, Executive Director, State Dairy Commission
Mr. Andre Aldax, Chairman, Dairy Producers Council
Mr. Herb Witt, Dairy Producer, Carson Valley
Mr. John O. Olsen, General Manager, Nevada Dairymen Incorporated
Mr. Brock Kilbourne, student in the doctoral program in Social Psychology, University of Nevada Reno
Mrs. Maria Kilbourne, doctoral candidate, State University of New York Albany
Dr. Joseph Crowley, Interim President, University of Nevada Reno
Dr. William Hudspeth, Chairman, Biomedical Research-Protection of Human Subjects, University of Nevada Reno
Dr. Carl Backman, Department of Psychology, University of Nevada Reno

Chairman Ashworth opened the hearing on S.B. 466.

Senator Mike Sloan, Clark County Senatorial District No. 3, stated that every senator is a co-sponsor on this bill. He stated that the concept of a hospice provides a missing area of health care in the United States today. He said the facilities available for the person who is dying as opposed to the person who is living are almost non-existent. He said the goal of a hospital is fundamentally different from that of a hospice; a hospital is designed to provide short-term, acute care setting with a goal of maintaining life, the concept of a hospice is to recognize that an individual is going to die and try to provide that the person will die with dignity. He expressed his support of S.B. 466 and stated his belief that the concept will be of benefit for the State.

Chairman Ashworth stated that a Conflict Notice had been received from the Legislative Counsel Bureau stating a conflict with this bill and S.B. 79.

Senator William Hernstadt, Clark County Senatorial District No. 3, spoke in support of S.B. 466. He stated that he believed the concept of a hospice was "a long time coming" to assist in difficult situations and will be of benefit to the State.

Senator Hernstadt stated that he also wished to address S.B. 447, which would indefinitely extend the life of the Dairy Commission. He stated he was strongly in opposition to the bill for two reasons: First, the language on Page 2, Section 2, which would protect distributor profits. Secondly, the Dairy Commission is now "sunsetted" at July 1, 1981. The Commission has not "pushed up" the retail price as much as might have been done otherwise. Senator Hernstadt stated that due to the "sunsetting provision," the Dairy Commission is on notice to prove itself. He commended the Commission for doing a good job but stated his concern, should the bill go onto the floor, that the "sunsetting provision" would be removed and the Commission would be less inclined to protect the public interest. He stated his belief that the Commission has accomplished the last session's legislative intent. Senator Hernstadt said that he would like to see the "sunsetting provision" remain so a determination could be made as to the necessity of the Commission at the end of four years. He urged the committee to indefinitely postpone S.B. 447.

Chairman Ashworth stated that the hearing would continue on S.B. 466.

Dr. Willis Russell, Private Practitioner who has been with Sunrise Hospital for ten years, stated that he is currently the Program Chairman for the formation of the Nathan Adelson Hospice (see Exhibit "A"). He commended the committee and all of the senators sponsoring S.B. 466. Dr. Russell stated that the "hospice" is a movement or a program. He said that permission would have to be obtained to use the word as it has been incorporated into the National Hospice Organization once the facility is operational. The definition of "hospice" is: "An autonomous program directed by a physician, centrally administered, utilizing multi-disciplinary team for in- and out-patient care 24 hours a day, seven days a week." He said the unit of care is the family as they are the ones caring for the patient; the emphasis of this program is on very good medical care. He stated that the care is delivered in two settings; the main bulk is delivered at home by the family assisted by a home health care team. He said that the facility will function as a place where the patient will be for a short term, should stabilization or pain control be needed, or when the patient can no longer be cared for by the family. He said that rules would be made to adapt to the needs of the patient and the setting as close to the home environment as possible. He stated that currently, hospices across the country have no requirement or need to pay.

Chairman Ashworth questioned the method of payment. Dr. Russell stated that the ability of a patient to pay is not considered when taking care of a patient in an autonomous hospice program. He said that third-party reimbursement is handling some of the payment, foundations, grants, all depending upon the individual setting. Chairman Ashworth questioned if federal funds are being utilized. Dr. Russell said that they were. He said there are three model facilities in the United States currently being studied. He said that the Nathan Adelson Hospice is a non-profit, community based board which will eventually take donations.

Senator Neal questioned the determination that a person is terminally ill. Dr. Russell said that the first criteria is that the intensive treatment has been seen to be no longer possible. He said the emphasis is on the quality of life in a setting that will make the best of the individual's final time. He said this is left to the choice of the patient.

Senators Young and Blakemore arrived for the meeting (8:53 am).

Senator Kosinski questioned if some insurance policies were covering this type of care. Dr. Russell stated that he had not closely reviewed that issue pending interest expressed by the committee. He said the dimension of home health care has been added to most programs. Senator Kosinski questioned if the usual group insurance plan would cover this. Dr. Russell stated that they do not; however, study is being conducted on this issue. Senator Kosinski questioned if there would be Title XIX coverage. Dr. Russell stated he did not believe so in Nevada. He said the Department of Health, Education and Welfare do not at this time recognize the program; they are awaiting further information. As to Page 1, Line 4 of the bill, Senator Kosinski questioned if a hospice has to have in-patient care. Dr. Russell stated that many of the programs do not have an in-patient facility but provides in-patient care in a variety of settings.

Chairman Ashworth questioned the potential impact upon group insurance policies. Dr. Russell stated that Blue Cross and Blue Shield are working to establish this in their programs. He did not believe it was available as yet. He stated his belief that there would be a reduction in the costs of third-party payers because many individuals are in the hospital the last 48 hours; with a hospice this would not be necessary, so the total cost to consumers should be less.

Senator Kosinski stated that by putting this section in the NRS, would not mandate group coverage. Dr. Russell stated that it would not and the intent was to remain flexible and to work within the structure of the statute already in existence.

Mr. Fred Hillerby, Nevada Hospital Association, stated that one of the basic ideas of the bill is to allow for the licensing of this type of facility. He stated that, usually, any type of insurance coverage requires that the facility be licensed. He

stated that Dr. William Thomason, Administrator, Bureau of Health Facilities, has indicated a willingness to work with the initial program to determine the best regulatory approach with the maximum amount of flexibility. He stated that part of the program is to assist other family members to cope with the fact that a family member is dying.

As to the Conflict Notice, Mr. Hillerby stated he believed that by adding "home health agency" to the language in S.B. 466, the conflict with S.B. 79 would be eliminated.

Mr. Hillerby stated that the Association was in strong support of S.B. 466 and its concept.

Ms. Victoria Iori, Division of Aging Services, spoke in support of S.B. 466. She said that patients and their families often feel captive in a hospital. She stated her belief that it is important to allow an individual a choice and the hospice program would provide that choice.

Senator Kosinski stated that the language on Page 1, definition of hospice, does not clearly indicate that a program could offer merely home care; if it did, would it have to be licensed.

Dr. William Thomason, Administrator, Bureau of Health Facilities, stated that it was his understanding an outreach type of service could be licensed similar to that of home health agencies. Dr. Thomason stated that S.B. 79 was the bill to place home health agencies into NRS Chapter 449. Senator Kosinski questioned, should S.B. 466 pass, if a person only wanted to offer home care, if they would be licensed as a hospice or as home health care. Dr. Thomason stated that a distinction would have to be made; probably it would be made on the basis of the staff that would be operating under the home health agency as opposed to those operating under the hospice. Senator Kosinski questioned if an out-patient hospice program was established, would it make any difference if the program would be licensed as a home health care program. Dr. Thomason stated that he did not believe so based upon his knowledge of the program at this time; however, should the patient be housed in a facility, a provision would be necessary for that specialized type of care under the hospice.

Senator Kosinski stated that he was having problems with the language on Page 1, Line 4. He questioned if Mr. Hillerby would have any objections to amending it to include the word "either" before the phrase "in the home or a facility,". Mr. Hillerby stated that he would have no objection.

There being no further testimony, Chairman Ashworth closed the hearing on S.B. 466.

The hearing was opened on S.B. 447.

Senator Lawrence Jacobsen, Capital Senatorial District, stated that

the Dairy Commission has been, to date, very productive and very responsive. The intent of the legislation is to eliminate the moratorium because he believes the agency is functioning as it should. Senator Jacobsen stated that the agency has in the past been "under fire" but under the present Executive Director, Mr. William Smith, it has considerably improved in the past two years. He stated that he believed the moratorium has to be removed because there are competent employees who are feeling they may no longer have a job at the end of two years. Senator Jacobsen expressed concern at losing the expertise that it has taken some time to build. He said that S.B. 447 has some small, incidental provisions because it relates to an industry that taxes itself to regulate itself.

Chairman Ashworth questioned if the emphasis on the bill is the last two lines, the repeal of Section 16 of chapter 600, Statutes of Nevada 1977. Senator Jacobsen stated that it was.

Senator Kosinski stated that it was his understanding that the "sunset provision" was as a compromise during the last legislative session. He questioned if it would be fair to repeal this provisi prior to 1981. Senator Jacobsen stated that, in a sense, he would have to agree; however, his concern is with the employees. He said that during the last session, the Commission was placed in an independent status. He stated his belief that the moratorium was placed because there were so many irregularities and discrepancies in the Commission, along with the Executive Director at that time. During the two year period, Senator Jacobsen stated that the Commission has proven it can work. He stated his belief that the moratorium now is a restriction which is curtailing the productivity of the group. He said he did not wish to see that happen. The bill also addresses reducing the reserves of the Commission which, Senator Jacobsen believes, is another indication that they are functioning properly. Senator Kosinski stated that many people speculate that the reason the Commission is working so well is because of the "sunset provision." Senator Jacobsen stated that it may possibly be but the present staff has a great deal of expertise; should that be lost, it would be like starting over again. Chairman Ashworth stated that he had spoken with one of the larger milk producers and he said that he was happy with the functioning of the Commission. Senator Jacobsen stated his belief that this was one of the real benefits of an independent board; the producers must now justify increases before people who have no ties to the industry.

Senator Neal stated that he did not believe it would be proper to remove the "sunset provision" until that provision of the law expires. Senator Jacobsen stated that if the existence of an agency to be "sunsetted" can be justified, it deserves reconsideration.

Mr. William X. Smith, Executive Director, State Dairy Commission, presented Exhibit "B" to the committee along with a copy of the

statutes of NRS under which they are governed (copy located in the Research Division, Legislative Counsel Bureau). Mr. Smith took exception to Senator Hernstadt's testimony regarding protecting distributor profits. He said it is not to protect anyone; rather, it will protect the industry as to unfair practices. Mr. Smith stated that the Dairy Commission is the only state agency found in any "sunset bill." He enumerated the advancements made by the Commission in the past two years. He said there is an excess of $195,000 in surplus funds over and above the budget; this has been generated by the licensing of additional companies. The bill provides for this money to be returned to the industry. He stated that assessments on certain products would be eliminated for a period of three months or more. As to the agency's moratorium, Mr. Smith stated that he has an exceptionally good staff that he does not wish to lose. He said there had not been an audit of the Dairy Commission since 1971 by the Legislative Counsel Bureau, staff positions had been unfilled; all this has been improved and he believes the existence of the Commission can be justified. He stated that the bill also addresses an increase in the cost of a dairy license; the present cost is $3 per year and Mr. Smith said that a license cannot be processed for that amount of money. He said that the restructuring of the board, taking it out of the "hands" of the industry, was of great benefit. He stressed the importance of removing the moratorium to maintain the present expertise.

Senator Young questioned their request for special consideration as to the removal of the "sunset provision." Mr. Smith stated that they did not wish special consideration; rather, they would like to be able to function in a normal manner, which is not possible at the present time.

Chairman Ashworth questioned the number of dairy commissions in the United States. Mr. Smith stated there are approximately 37 states with dairy commission; however, they are not necessarily the same. He said they regulate the price of milk but not at all three levels necessarily, some only set the producer price. In Nevada, the producer price is set in Western Nevada; in Eastern and Southern Nevada, they have a federal milk marketing order which sets the producer price. Senator Neal questioned when the federal milk marketing order will expire. Mr. Smith stated that it would never expire unless a petition is filed by the farmers regulated by the order, 55 percent of those producing, to have the order recinded. Mr. Smith said that the prices set by the order are much higher than those set by the Dairy Commission; in their analysis, there is no justification for the high prices.

As to the statutes that govern the Commission (in the booklet referred to in Exhibit "B"), Page 21, Section 584.583, subsection 5, Mr. Smith requested the committee consider the addition of the word "minimum" before the word "retail." The sentence would then read, "Each distributor who processes or manufactures fluid milk, fluid cream, butter or fresh dairy byproducts and each peddler-distributor shall file with the commission a list of whole-

sale, minimum retail and distributor or dock prices." He stated that the Commission sets the "minimum" price, not the "maximum;" which would be price setting. He requested the same wording to apply to a peddler-distributor. This would correspond to Page 6, Line 50 of S.B. 447. Senator Young questioned if this lack of verbage was creating an enforcement problem. Mr. Smith stated that it was not, but complaints were being received from consumers.

Senator Kosinski questioned why the new language was needed in NRS 584.633 in order to lower the assessments. Mr. Smith stated that the Commission cannot lower assessments unless it is provided for in the Nevada Revised Statutes. In order to return the surplus to the industry, this language is necessary. Senator Kosinski questioned how much would be in the surplus should this bill not pass by the next biennium. Mr. Smith stated there would be well in excess of $200,000, possibly $250,000.

Mr. Andre Aldax, Chairman, Dairy Producers Council, also a dairyman from Minden, Nevada, stated that the Council is in support of S.B. 447; especially, the last two lines pertaining to the morator He stated that they feel the performance over the last two years has been very good. He said that Nevada Class I dairy producer prices are very much lower than federal market order prices.

Mr. Herb Witt, Dairy Producer, Carson Valley, stated that producers have adhered to the minimum price set by the Dairy Commission. He spoke in support of the Commission and enumerated surrounding states prices for Class I milk, which have higher prices. He said if there were any inequities in pricing to the consumer, it does not lie in the producer area. He asked the committee's support for S.B. 447.

Mr. John Olsen, General Manager, Nevada Dairymen Incorporated, spoke in support of S.B. 447. He stated his belief that if the Commission were not to operate, half their milk would be going to California which increases the producer price. He stated that expertise is needed in the Commission to audit reports and would not like to see the Commission lose this expertise.

There being no further testimony, Chairman Ashworth closed the hearing on S.B. 447.

The hearing was opened on S.B. 471.

Mr. Brock Kilbourne, student in the doctoral program in Social Psychology, University of Nevada Reno, introduced his wife, Maria Kilbourne, a doctoral candidate at the State University of New York Albany. He stated they were present to give testimony in support of S.B. 471 and submitted Exhibit "C" to the committee. He also presented Exhibit "D" regarding federal guidelines to the committee.

Senator Blakemore questioned the number of other states which have

such a law. Mr. Kilbourne responded that California and New York have comprehensive laws of this nature; also, Virginia and Maryland are considering comprehensive laws. He added that other states have partial laws addressing this issue.

Senator Kosinski questioned the reason for the introduction of S.B. 471. Mr. Kilbourne stated that the emphasis of the bill is on prevention; it also emphasizes the creation of informed consent procedures and proper review. He said the bill is viable as strengthening existing federal requirements before possible abuses could take place. Senator Kosinski questioned how the federal regulations would apply. Mr. Kilbourne said that there is a proviso stating that those institutions which maintain a proper review board, for example the university, would be excluded from this bill to the extent that there are not provisions in the State law which are not encompassed in federal regulations. As to violations, Mr. Kilbourne referred to difficulties encountered at the mental health facility in terms of experimental treatment techniques which have been employed without proper informed consent; also, instances with children in which proper informed consent conditions were not used. He stated that "proper informed consent conditions" means that a reasonable, comprehensive explanation of procedures involved in their purposes be stated; also, a descripti of any discomforts or risks that may accompany those procedures be stated; the results of a behavioral psychological medical screening be conducted to select those individuals who may be susceptible or hyper-sensitive to extreme stimulus conditions which may be manipulated within an experimental testing or scientific investigation. As to the broad exclusions and the definition of human research, Senator Kosinski stated that he believed the "cattleprod" experimentation at the Mental Health Institute would be excluded as it could be classified as necessary for treatment of a disease. Mrs. Kilbourne stated that the point is debatable as to the necessity. Senator Kosinski stated that he believed the definition is broad enough to exclude that type of activity. Mr. Kilbourne stated that they would not want to exclude such instances. However, he did believe the language of the bill would not exclude that because they were experimental techniques an no choice was offered to the individual receiving those techniques; most importantly, proper informed consent conditions were not adhered to.

Senator Kosinski questioned the types of programs that would be under the federal regulations. Mr. Kilbourne stated that the entire University System is presently under the regulations and other institutions with which they enter into cooperative agreements. He also said State agencies which have received federal funding in the form of grants are also under federal regulations. Senator Kosinski stated that the Mental Health Institute would also come under these regulations. Mr. Kilbourne concurred. He said that part of the rationale of the bill is to strengthen federal requirements because there have been abuses. As to the sanctioning mechanism, Mrs. Kilbourne stated that they are proposing

the individual be sanctioned rather than the past procedure of an institution or individual losing their grant. She stated her belief that the sanctioning mechanism for the federal law has been weakened. She cited the example of the University Group Diabetes Program in which an investigation revealed that some individuals participating were not receiving medication and some subsequently died. She expressed her belief that sanctions are not as strong as when one is dealing with an individual who has violated the law. She said the bill does address this as there is a fine provided for violations.

Senator Neal questioned the type of research that is being referred to. Mrs. Kilbourne stated that some of the techniques with which she was familiar were participant observation techniques; some of the issues involved with these techniques involve manipulation and invasion of privacy. She enumerated some examples for the committee as did Mr. Kilbourne. Mr. Kilbourne also expressed concern as to the ramifications mentally on the subjects after the experimentation has concluded. He said there was a real danger in terms of the psychological and social consequences of this form of experimentation. He said that effects could be physical, social and psychological; to safeguard the individual, and safeguard the value of science, is through proper review and informed consent conditions.

Senator Faiss questioned the amount of research of this type being conducted in the State. Mr. Kilbourne stated it would be impossible to estimate. He said that the University of Nevada Reno does not conduct deception experimentation that could lead to compromises on the part of the individual, although it is legally possible. Chairman Ashworth questioned why the need for the proposed legislation. Mrs. Kilbourne stated that administrations change. Mr. Kilbourne stated that present safeguards are only applicable to agencies that are receiving federal funding. Mr. Kilbourne said that the reason there is a need for the proposed legislation is because the extent of the research and development industry in Nevada is unknown. He said there is no way to estimate how much research is being conducted outside the university setting. Senator Young questioned if there was any research being conducted in Nevada. Mr. Kilbourne said that he had participated in a study conducted at the Mental Health Institute where, he did not believe, proper informed consent conditions were lacking. He also said it was easy to go into the public schools where informed consent is not required and have a parent agree; however, that does not mean a parent must be told that the child may be exposed to risks. Senator Young questioned if there had been any such experiences in the schools. Mr. Kilbourne stated that he knows of no specific instances, but he stated that he knows informed consent procedures are not required in the public schools. Senator Young questioned if this bill was patterned after California law. Mr. Kilbourne stated that it was patterned after New York law, which is patterned after the federal law. He said he made some changes: one, concerning broadening the definition of what constitutes "human research"; broadening informed consent conditions to include

screening to insure the individuals would not be harmed who may participate in a study. Mr. Kilbourne stated that it is presently an "open field;" if he wished to declare himself an independent researcher, he could do whatever he wished. Mr. Kilbourne stated that he did not believe this is right.

Dr. Joseph Crowley, Interim President, University of Nevada Reno, stated that he was not opposed to the need for legislation covering human subject research in the state that would go beyond federal mandates; however, he spoke in opposition to S.B. 471. He questioned the degree that the university is excluded in the bill in Section 16 and questioned the clarity of the other language in the bill. He said that the university has been working for a number of years to evolve a policy and structure that adequately safeguards the rights of human subjects. He said they are in full compliance with federal regulations in this area. He explained how the university's system functions in this regard to the committee. Dr. Crowley said that he was opposed to this legislation because he believes it to be unnecessary as it relates to the university. He stated that some form of legislation may be needed beyond the realm of the university but the issue needs to be addressed with considerable care. Dr. Crowley said he was also opposed to S.B. 471 because he does not understand the full implications of the langua[illegible] He stated that the bill is comprehensive legislation, the language is often very broad and all-inclusive. He questioned if passage of S.B. 471 would be troublesome to all concerned. Also, as it concerns the university, Dr. Crowley stated that S.B. 471 proposes an unwieldy, bureaucratic structure for implementation which may lead to unnecessary delays. Regarding his belief that the definitions are very broad and encompassing, Dr. Crowley cited Section 3 and Section 4 of S.B. 471. He also questioned the definition of "psychological intervention" as used in Section 4. He said it was conceivable that studies undertaken by the legislature would be classified as human subject research, consumer questionnaires in industry, etc.

Senator Kosinski questioned the specific objection to Section 3. Dr. Crowley stated that it was not Section 3 alone but how it relates to the remainder of the bill. He cited the example of a newspaper reporter conducting a telephone interview and questioned the necessity of informed consent under the proposed legislation. He stated that this instance could be construed to fall under the purview of this legislation and suggested clarification. Senator Kosinski questioned if Dr. Crowley objected to the encompassing definition standing alone. Dr. Crowley stated that he did not. As to Section 5, Dr. Crowley questioned the meaning of "social injury" and "scientifically established and accepted methods." As to Section 6, Dr. Crowley questioned if every person doing research at the university would have to be licensed by the state health officer. He stated that the state health officer appears to be intimately involved in the implementation of this proposal and questioned if this may be a problem. He suggested the committee obtain testimony from the state health officer on this issue.

Senator Kosinski questioned if the problem would be eliminated should the licensing requirements be limited to, for instance, medical research. He did not believe there would be any objection to that. Mr. William Hudspeth, Chairman, Biomedical Research-Protection of Human Subjects, University of Nevada Reno, stated that there would be objection to that matter. Dr. Crowley said that his statement addressed medical research beyond the university; he repeated that the bill is not needed in relationship to any research, medical or otherwise, that is undertaken at the university.

Senator Faiss questioned if this bill, as written, would create more problems than it would solve. Dr. Crowley stated he believed that it would due to the uncertainties in language and implementation. He emphasized that the university is not opposed to the concept of applying the protections of human subject research beyond the university. He stated that it is a highly complex area that needs to be approached with caution.

As to Section 7 regarding "written statement," Dr. Crowley stated that according to the University of California Davis' model, there are certain exceptions to that need for written consent. He also stated that it appears the university would be involved in judgin the research of other agencies that did not have a committee for that purpose, he cited Section 14. He said that would impose a considerable workload upon the university.

Dr. Crowley stated that the university would be pleased to cooperate with the committee in establishing some language that would be appropriate and would respond to the very definite need to this area. He reiterated that the university takes exception to S.B. 471 as written.

Dr. Carl Backman, Department of Psychology, University of Nevada Reno, stated his belief that the federal government has this problem very well in hand and the university is working closely on this issue.

Mr. Brock Kilbourne stated his belief that the difficulties expressed by Dr. Crowley have been misdirected. He stated that his difficulties are with the federal requirements. He referred to the federal regulations and stated that each issue addressed by (Exhibit D) Dr. Crowley is under federal regulation. He questioned Dr. Crowley's difficulty with the bill as there is a specific proviso which excludes the university and all state agencies which are presently in compliance with federal guidelines, Section 16. Secondly, Mr. Kilbourne stated that the questions regarding the definition of terms are definitions of terms in federal requirements. Mr. Kilbourne concluded by expressing his belief that Dr. Crowley should be directing his questions toward the federal government rather than state law unless he wishes to submit amendments which would specifically clarify those particular terms in question. Chairman Ashworth stated that he had offered to do so.

Chairman Ashworth closed the hearing on S.B. 471.

885

S.B. 447 (Exhibit "E")

Senator Kosinski moved to "Indefinitely Postpone" S.B. 447.

Senator Young stated that he believed the testimony presented gave a good case for many of the changes. He also said that it appeared to be going back on a "deal" that had been made but the "sunset" legislation appears to be faltering. Senator Kosinski stated that the legislation was not "dead." Senator Young questioned the time left to address the issue.

Chairman Ashworth stated that the motion failed for lack of a second.

Senator Young moved to "Amend" and "Do Pass" S.B. 447.

Seconded by Senator Neal.

Discussion: Senator Young stated that the amendment would be to include the word "minimum" before the word "retail" on Page 6, Line 50. Also, delete Section 20. Senator Kosinski stated that tertimony by Senator Jacobsen was that the primary reason for introducing the legislation was to eliminate the "sunset" provision by Section 20. He stated that there are other provisions but is uncertain as to the importance of them.

Motion carried.

Yeas -- 4
Nays -- Senator Kosinski
Absent -- Senator Blakemore

S.B. 466 (Exhibit "F")

Senator Kosinski moved to "Amend" and "Do Pass" S.B. 466.

Seconded by Senator Young.

Discussion: Senator Kosinski stated that his amendment would be to insert the word "either" before the phrase "in the home" in Section 1, subsection 1, Line 4.

Motion carried.

Yeas -- 6
Nays -- None

Senator Kosinski proposed that S.B. 471 be reworked to "clean up" some of the language, remove the sanctions, and adopt the bill merely as an ethical code of standards to be placed in Title 40 of the Nevada Revised Statutes. Senator Young stated that he believed the bill is ambiguous and is uncertain as to the need. He stated that it may create legal problems and ramifications. He commended the people who introduced and supported the legislation but did not believe a need had been demonstrated for enactment; also, as it is late in the session, he questioned passage by both bodies. Senator Young suggested they "withdraw and regroup" and try again two years from now. Senator Kosinski concurred as to the lack of examples substantiating need, with the exception of the "cattleprod" example; but he stated that having a statement of legislative intent, particularly in the area of informed consent, are important provisions. He questioned any objection as to putting it into the code. Senator Neal stated that he would tend to support legislation that would place guidelines upon experimentation of humans in the area of informed consent and intent and purpose of the experiment. Senator Blakemore questioned if the study would be negated with prior information as to the experiment. Senator Kosinski stated that the language in the bill now is too broad and would have to be limited. Senator Kosinski stated that he would like a consensus of the committee as to pursuing this bill. Senator Young stated that he did not see a need. Senator Blakemore stated if there was nothing to address this issue, perhaps something should be worked out. Chairman Ashworth stated that this was an issue in an "embryo" stage and would like to see Mr. and Mrs. Kilbourne get with the university and work on this problem with the intention of returning in the next two years. He stated his belief that there is a great deal of work to be done on the bill. Senator Neal stated that he believed the matter should be addressed. The committee concurred four to two that Senator Kosinski would work on S.B. 471.

There being no further business, the committee adjourned at 10:59 am.

Respectfully submitted,

Roni Ronemus
Committee Secretary

Approved:

Chairman
Senator Keith Ashworth

# Hospice program an aid to terminally ill

By Chris Broderick
R-J Staff Writer

The late psychologist Erik Erikson once observed that the elderly experience a unique series of conflicts which revolve around the acceptance versus the denial of death — between contentment and frustration, peace and anxiety, and intimacy and bitterness.

The same conflicts are encountered by the terminally ill. According to statistics compiled by the Clark County Health District, one in 750 residents of the county will die of cancer this year alone.

The hospice movement which has swept 200 areas around the country was developed as a way to resolve some of these conflicts.

Although still on the drawing board, a Las Vegas hospice center in the memory of Sunrise Hospital founder Nathan Adelson is nearing construction. Meanwhile, the health district also has inaugurated a hospice program, and both will serve the community by helping terminally ill cancer patients die with dignity in the company of their families.

A group of civic leaders acting as the steering committee for the Adelson Hospice met last week to discuss the progress of the program.

"The hospice is not a building, an institution or an in-patient facility," reported a consultant from a hospice in Tucson, Ariz.

"The notion that hospice means the end and nothing can be done for the patient is wrong. There is a lot that can be done in terms of the quality of the life remaining for that patient. We have to focus on reuniting families, on enriching ideas, and on creating a learning experience — whatever it is that can be done to make the last part of a dying patient's life have more meaning," said Theodore Koff, a professor at the University of Arizona.

The Adelson Hospice will open on an experimental basis in a year's time, according to project director Ernest Libman, an administrator at Sunrise Hospital. He said in six months, the project is scheduled to become autonomous, evolving from its current status as an outgrowth of Sunrise Hospital to its eventual role as an independent non-profit health-care facility in the community.

"I could start a hospice tomorrow with the funds we already have received," Libman said. "It would not be very effective, but it would survive.

"But that is not the program this committee is talking about. It will not be a hospital or a nursing home," he said.

NATHAN ADELSON
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What it is projected to be, according to Libman, is a 40-80 bed facility providing 24-hour, 7-day-a-week physical, emotional and spiritual care to a terminal patient in the last few weeks of life.

The Adelson Hospice will be staffed by a carefully-selected team of physicians, clergymen, social workers and psychologists working in conjunction with the current home health care teams at Sunrise Hospital and the county health district.

A location, design plan and details of construction are scheduled to be completed within three months, Libman said.

Funding for the Adelson Hospice is being provided by private donations, foundation grants and community contributions. "There are some gaps at present, but I see those gaps being filled if we receive the community support we need," Libman said.

The hospice is aimed at serving all of the people of Clark County, both the poor and the rich. "It is imperative to the whole idea of the program to care for poor people. We don't want the Adelson Hospice to be a monument only to those who will pay," he said.

To insure that no one will be denied care, costs are planned to be covered not only by donations, but also through health insurance programs and government Medicare benefits.

Libman said the Health, Education and Welfare Department in Washington has been extremely cooperative with hospices around the country. He said he expects this assistance to continue, guaranteeing that those normally unable to pay for this kind of sophisticated service will be eligible for hospice care.

One roadblock to the project which is currently being negotiated is Nevada law. According to Libman, "We are planning to build something that does not look or act like a hospital. We don't want the bureaucrats to have to make so many exceptions to current licensing laws that the hospice won't be able to operate at some point in the future."

As a result, Renny Ashleman and David Zenoff, two members of the steering committee, are currently working with Carson City officials to draft the appropriate medical licensing statutes needed to accommodate hospice care.

Another committee member, Muriel Stevens, suggested at a hospice meeting last week that "the community ought to be educated in hospice as well." She proposed setting up a resource center, possibly at the UNLV Library, "to invite students to discuss death and dying."

"Many students at the university are interested in volunteering any services they could provide. Students are important to this project because they are young and enthusiastic. They have not yet learned to fear death like the rest of us," she said.

Other civic leaders responsible for the Nathan Adelson Hospice include Adelson's widow and son, Pearl and Merv; Dr. Willis Russell, Irwin and Susan Molasky, Al Benedict, David and Sharon Brandsness, Ken Sullivan, E. Perry Thomas, Eli Boyer and Donald Baepler.

The feelings of all involved are seemingly reflected by a statement in Theodore Koff's report: "The hospice has the potential for responding to the unique needs of the terminal patient and of reflecting the community's concern for providing the most understanding and supportive care for the dying patient."

EXHIBIT "A"

S.B. 447

Page 1, Lines 17 - 20; Page 2, Lines 1-2

Section 356.087, Paragraph 3, is amended by adding "The Dairy Commission Fund" to those other funds which receive a proportionate share of interest earned on monies deposited to the individual funds.

All monies we receive are deposited to the Dairy Commission Fund. These monies are used, by law, for the operation of the Commission. The industry, producers and distributors, are the only segments of the economy which contribute to the Dairy Commission Fund. When the fund earns interest, the interest earned is transferred to the General Fund. We want the interest to remain in the Dairy Commission Fund which will give additional revenue and thereby decrease, by some degree, the necessity of increasing assessments on producers and distributors. We receive our operating funds from the industry and feel any interest earned should stay in the Dairy Commission Fund for the benefit of the industry.

Page 2, Lines 3 - 13 (New Section to Chapter 564)

This amendment as proposed in the new Section 2, prohibits a distributor from using substitute dairy products as a means of obtaining customers' business by selling them below cost. For example, we have found a distributor giving imitation creamers to a customer for a price below his cost in order to obtain the other dairy business of the customer. Paragraph 2 of this Section (Line 7) requires the distributor to file costs of substitute dairy products so we can regulate this aforementioned "unfair practice."

Page 2, Lines 17 & 18

These amendments further define "Distributor" and "Substitute Dairy Product."

Page 2, Line 31 and 32

This addition of the words "Transport into the State" amends Section 584.345, paragraph 2(a) to allow the Dairy Commission to license a retail store, to collect assessments from the retail store and to regulate the retail store as a "Retail Distributor." A retail distributor is a retail store that brings dairy products into the state in its own conveyance for sale off the shelf.

S.B. 447

Page 3, Line 23 (Section 584.522 (1.))

We are cutting the number of copies of a petition to amend or terminate a stabilization and marketing plan from 10 copies to 4 copies. Ten copies were needed when the Commission had eight members; now there are only three members.

Page 4, Line 14 (Section 584.565 (3.))

The addition of the words "Which must be held in the area to which the plan applies" prohibits the Commission from holding a public hearing away from the area which may be affected by the results of such hearing. For example, we would not want to be able to hold a public hearing in Las Vegas on matters affecting Reno. Travel for interested persons would very likely be difficult as well as expensive.

Page 5, Line 24 (Section 584.570 2.(B))

The addition of "Substitute dairy products" prohibits the giving of such products, except to bona fide charities, by a distributor to a customer for the purpose of securing or retaining the dairy product business of the customer.

Page 5, Line 30 (Section 584.570 2.c.)

The addition of "Dairy products or substitute dairy products" covers completely those products a dairy distributor would handle and which would have to be sold under like terms and conditions.

Page 5, Line 48 (Section 584.570 2.d.)

The addition of the words "Lowest class price for milk usage established by the Commission for that area" simplifys and clarifies existing language in the statute with the language proposed above. The language contains the rationale and policy of not forcing a producer to sell at the lowest class price, if he can obtain a higher price after he has met his basic contractual obligation with a distributor.

S.B. 447

Page 6, Lines 10 and 11 (Section 584.575)

The amended language has been recommended by the staff to reflect the manner in which reports to producers are actually done and calculated; to simplify the language and insure that the language of the statute accurately reflects the manner in which the reports are prepared and calculated.

Page 6, Lines 32 and 33 (Section 584-.583 2.f.)

"Overhead Costs" contain various items of cost among various distributors. We, as the staff, cannot specify to any distributor what particulars should be included in this accounting category. Each business is individual and as long as those costs are calculated according to, and include items which can be attributed to, "generally accepted accounting principles," we will accept them.

Page 7, Lines 18 and 19

We again stress that any public hearing called by the Dairy Commission must be held in the marketing area which will be affected by the subject matter of the hearing. There are three separate and distinct marketing areas in the state, the western (Reno and vicinity); the southern (Las Vegas and vicinity), and the eastern (Elko, Ely and Eastern Nevada).

Page 7, Line 47 (Section 584.595 3.)

We ask the license application fee be increased from $3.00 to $10.00 since we cannot process and investigate a license application for the present fee. This will not increase revenue appreciably since we only have approximately 110 licensees at present. At the ten dollar amount, we expect to cover our printing, typing, mailing and telephone costs which are incurred in the initial license application processing as well as in renewal of license processing.

Page 8, Lines 11 and 12 (Section 584.595 5.)

The penalty for the late filing will rise to ten dollars as opposed to the present three dollars.

S.B. 447

Page 8, Lines 16 - 32 (Section 584.630 1.,2.,3.)

This amendment assures all imported raw milk will be assessed at the same rate as that produced in Nevada.

Page 8, Lines 34 - 42 (Section 584.633 1.,2.)

This amendment sets the ceiling on butter assessments and ice cream assessment.

Page 8, Lines 43 - 47 (Section 584.633 3.)

This suggested amendment allows a credit to be given on milk which was originally manufactured as a fluid (Class I) product and then salvaged and the fat subsequently used in the manufacture of a Class II product such as ice cream. If this amendment is not adopted, there would be double taxation on the same butterfat.

Page 9, Lines 4 - 9 (Section 584.533 5.)

This amendment allows the Commission to reduce assessments when necessary to lower surplus funds in the Dairy Commission Fund. For example, we presently have in excess of $175,000 in the fund. The Commission's ability to lower assessments to the industry would bring the surplus down and could very well deter price increase requests from producers and distributors. Assessment rates could be lowered for whatever period of time it would take to accomplish this purpose.

Page 9, Lines 31 - 36 (Section 584.635 4.)

Many distributors have very minor assessments due each month. As a result, some do not pay monthly as required by law. This poses a problem for the staff since such non-payment on a monthly basis violates the statute and the statistical information which accompanies such remittances is not available to us. We hope that a $10.00 or 1% of the amount due, whichever is greater, will encourage all distributors to submit reports and remittances in a timely manner. For example, we have spent $20.00 to collect $5.00 in the past.

Page 9, Line 41 (Section 584.650)

This amendment requires certain records be maintained for three years as opposed to the present one year. Our staff of four accountants cannot possibly audit all distributors within

a continuing twelve month period. Recent audit disclosures reflecting payment deficiencies to producers mandate the necessary extension of time in record retention.

Page 10, Lines 29 and 30 (Section 584.690 2.)

This amendment brings retail stores into the posture of paying penalties for unfair practices as well as including retail stores in the listed unfair practices under the noted sections.

Page 10, Lines 33 and 34 (Section 20)

This sentence removes the State Dairy Commission from the Sunset Provisions of A.B. 152, which was passed at the 1977 Session of the Legislature. Under the present law, The Dairy Commission will be abolished on July 1, 1981. This Section repeals that provision.

EXHIBIT B

THE STATE OF NEVADA

DAIRY COMMISSION

# SUBSTITUTE DAIRY PRODUCTS

AND

# STABILIZATION AND MARKETING OF FLUID MILK, FLUID CREAM, AND DAIRY PRODUCTS

SECTIONS 584.1759 TO 584.179, INCLUSIVE

AND

SECTIONS 584.325 TO 584.690, INCLUSIVE
OF THE NEVADA REVISED STATUTES

JULY 1, 1977

# CHAPTER 584

# DAIRY PRODUCTS AND SUBSTITUTES

## SUBSTITUTE DAIRY PRODUCTS



## STABILIZATION AND MARKETING OF FLUID MILK AND FLUID CREAM

### DEFINITIONS



### GENERAL PROVISIONS



### STATE DAIRY COMMISSION

GENERAL POWERS OF THE COMMISSION



FORMATION AND ADOPTION OF STABILIZATION AND MARKETING PLANS



MANDATORY PROVISIONS

## OPTIONAL PROVISIONS



## UNFAIR TRADE PRACTICES AND INVESTIGATION OF MARKETING AND PRICING PRACTICES



## DISTRIBUTORS' LICENSES, FEES AND BONDS



## REPORTS AND STATISTICS



## PENALTIES

## DISCIPLINARY PROCEEDINGS



## CONSTRUCTION AND INTERPRETATION

**The State Dairy Commission functions under sections 584.1759 to 584.179 and sections 584.325 to 584.690, inclusive, Nevada Revised Statutes. These sections are supported and implemented by regulations of practice before the State Dairy Commission and by the stabilization and marketing plans adopted by the commission for the western, southern and eastern marketing areas of the State of Nevada.**

**For information please contact the Nevada State Dairy Commission:**

**2500 North Valley Road**
**Reno, Nevada 89512**
**(702) 784-6221**

**2035 Paradise Road**
**Las Vegas, Nevada 89104**
**(702) 735-4175**

## SUBSTITUTE DAIRY PRODUCTS

**584.1759 Administration, enforcement by state dairy commission. [Effective until July 1, 1981.]** The state dairy commission shall administer and enforce the provisions of NRS 584.176 to 584.179, inclusive.

(Added to NRS by 1969, 140; R 1977, 1643, effective July 1, 1981)

**584.176 "Substitute dairy product" defined. [Effective until July 1, 1981.]** As used in NRS 584.177 to 584.179, inclusive, "substitute dairy product" means any substance, mixture or compound intended for human consumption as a food product other than milk or dairy products which are intended to resemble milk or dairy products, but contain fat or oil other than milk fat.

(Added to NRS by 1967, 1249; R 1977, 1643, effective July 1, 1981)

**584.177 Restrictions on labels, marks on containers containing substitute dairy products. [Effective until July 1, 1981.]**

1. No bottle, can, package or other container which contains a substitute dairy product may be labeled or marked with a brand name or trade-mark which would lead a reasonable person to believe that the contents of such bottle, can, package or container contain a dairy product.

2. No substitute dairy product which has a dairy product or dairy products as an ingredient may list such ingredient on the label in letters larger than those for any other ingredient.

(Added to NRS by 1967, 1249; R 1977, 1643, effective July 1, 1981)

**584.178 Restrictions on service of substitute dairy products in places selling prepared food for human consumption; exemptions. [Effective until July 1, 1981.]**

1. No operator, owner or proprietor of any place of business which sells prepared food for consumption either on or off the premises may serve any substitute dairy product unless:

(a) There is displayed in a prominent place in each room a sign in black letters not less than 4 inches high upon a white background bearing the words, "..... served here instead of .....";
(Name of substitute) (Genuine dairy product)

or

(b) There is contained in each menu used in such place of business a

statement printed in not less than 8-point type containing the words, "..... served here instead of ....."
(Name of substitute) (Genuine dairy product)

2. This section does not apply to:

(a) Schools, hospitals, orphanages, licensed rest homes, foster homes, licensed day nurseries or any charitable institution which serves such food free of charge.

(b) Retail grocery stores not operating lunch counters, cafes or restaurants in connection with such grocery stores.

(c) Any facility maintained by an employer primarily for the benefit of employees.

(d) The operator, owner or proprietor of any place of business which sells prepared food for consumption either on or off the premises who keeps oleomargarine for sale or use only when requested by a patron. Any such place of business shall indicate clearly upon its menu or other list of foods served that oleomargarine is available upon request.

(Added to NRS by 1967, 1249; A 1969, 140, 937; R 1977, 1643, effective July 1, 1981)

**584.179 Penalty. [Effective until July 1, 1981.]** Any person who violates any provision of NRS 584.176 to 584.179, inclusive, is guilty of a misdemeanor.

(Added to NRS by 1967, 1249; R 1977, 1643, effective July 1, 1981)

## STABILIZATION AND MARKETING OF FLUID MILK AND FLUID CREAM

### DEFINITIONS

**584.325 Definitions. [Effective until July 1, 1981.]** Unless the context otherwise requires, the definitions in NRS 584.330 to 584.385, inclusive, govern the construction of NRS 584.325 to 584.690, inclusive.

[18:387:1955]—(NRS R 1977, 1643, effective July 1, 1981)

**584.330 "Commission" defined. [Effective until July 1, 1981.]** "Commission" means the state dairy commission.

[20:387:1955]—(NRS R 1977, 1643, effective July 1, 1981)

**584.335 "Consumer" defined. [Effective until July 1, 1981.]** "Consumer" means any person who purchases fluid milk, fluid cream, or dairy products for consumption.

[30:387:1955]—(NRS R 1977, 1643, effective July 1, 1981)

**584.340 "Dairy products" defined. [Effective until July 1, 1981.]** "Dairy products" includes any product manufactured from milk or any derivative or product of milk.

[23:387:1955]—(NRS R 1977, 1643, effective July 1, 1981)

**584.345 "Distributor" defined. [Effective until July 1, 1981.]**

1. "Distributor" means any person, whether or not such person is a producer or an association of producers, who purchases or handles fluid

milk, fluid cream or any other dairy product for sale, including brokers, agents, copartnerships, cooperative corporations, and incorporated and unincorporated associations.

2. The definition of "distributor" shall not include any of the following:

(a) Any retail store that is not engaged in processing and packaging fluid milk or fluid cream and does not purchase, or otherwise receive for resale, fluid milk, fluid cream or any other dairy product from sources outside the State of Nevada.

(b) Any establishment, where fluid milk or fluid cream is sold only for consumption on the premises, that is not engaged in processing and packaging fluid milk or fluid cream.

(c) Any person owned or controlled by one or more retail stores or owned or controlled by one or more establishments where fluid milk or fluid cream is sold for consumption on the premises, which person is not actively and directly engaged in the processing and packaging of fluid milk or fluid cream.

(d) Any producer who delivers fluid milk or fluid cream only to a distributor.

[25:387:1955]—(NRS A 1959, 894; R 1977, 1643, effective July 1, 1981)

**584.350 "Fluid cream" defined. [Effective until July 1, 1981.]** "Fluid cream" means cream as defined in NRS 584.325 to 584.690, inclusive, and any combination of cream and milk, or any fluid product of milk or cream sold under any trade name whatsoever, which is not packaged in hermetically sealed containers and which contains more than 11.6 percent milk fat and conforms to the health and sanitary regulations of the place where sold or disposed of for human consumption.

[22:387:1955]—(NRS R 1977, 1643, effective July 1, 1981)

**584.355 "Fluid milk" defined. [Effective until July 1, 1981.]** "Fluid milk" means any and all whole or concentrated milk that is produced in conformity with applicable health regulations for market milk of the place where such milk is consumed.

[21:387:1955]—(NRS R 1977, 1643, effective July 1, 1981)

**584.360 "Marketing area" defined. [Effective until July 1, 1981.]** "Marketing area" is any area within this state declared to be such in the manner prescribed in NRS 584.325 to 584.690, inclusive.

[28:387:1955]—(NRS R 1977, 1643, effective July 1, 1981)

**584.365 "Person" defined. [Effective until July 1, 1981.]** "Person" means any individual, firm, corporation, association or any other business unit.

[31:387:1955]—(NRS R 1977, 1644, effective July 1, 1981)

**584.370 "Producer" defined. [Effective until July 1, 1981.]**

1. "Producer" means any person who produces fluid milk from five

or more cows or goats in conformity with the applicable health regulations of the place in which it is sold.

2. "Producer" includes any association of producers.

[24:387:1955]—(NRS R 1977, 1644, effective July 1, 1981)

**584.375 "Producer-distributor" defined. [Effective until July 1, 1981.]**

1. "Producer-distributor" means any person who is both a producer and a distributor of fluid milk and fluid cream.

2. For the purposes of NRS 584.325 to 584.690, inclusive, a producer-distributor shall be deemed to be a producer in any transaction involving the delivery of fluid milk or fluid cream produced by him to a distributor and shall be deemed to be a distributor in any transaction involving the delivery of fluid milk or fluid cream to a person who is not a distributor as defined in NRS 584.345.

[26:387:1955]—(NRS R 1977, 1644, effective July 1, 1981)

**584.380 "Retail store" defined. [Effective until July 1, 1981.]** "Retail store" means any person owning or operating a retail grocery store, restaurant, confectionery, or other similar business, where fluid milk or fluid cream is sold to the general public.

[27:387:1955]—(NRS A 1977, 1638; R 1977, 1644, effective July 1, 1981)

**584.385 "Stabilization and marketing plan" defined. [Effective until July 1, 1981.]** "Stabilization and marketing plan" means any plan formulated and made effective by the commission within the legislative standards provided by NRS 584.325 to 584.690, inclusive.

[29:387:1955]—(NRS R 1977, 1644, effective July 1, 1981)

## General Provisions

**584.390 Business affected with public interest; purpose of provisions. [Effective until July 1, 1981.]** The production and distribution of fluid milk and of fluid cream is hereby declared to be a business affected with a public interest. The provisions of NRS 584.325 to 584.690, inclusive, are enacted in the exercise of police powers of this state for the purpose of protecting the health and welfare of the people of this state.

[12:387:1955]—(NRS A 1977, 1638; R 1977, 1644, effective July 1, 1981)

**584.395 Statements of fact and policy. [Effective until July 1, 1981.]** The legislature declares that:

1. Fluid milk and fluid cream are necessary articles of food for human consumption.

2. The production and maintenance of an adequate supply of healthful milk of proper chemical and physical content, free from contamination, is vital to the public health and welfare.

3. The production, transportation, processing, storage, distribution or sale of fluid milk and fluid cream in the State of Nevada is an industry affecting the public health and welfare.

4. It is the policy of this state to promote, foster and encourage intelligent production and orderly marketing of commodities necessary to its citizens, including milk, and to eliminate speculation, waste, improper marketing, unfair and destructive trade practices and improper accounting for milk purchased from producers.

[13:387:1955]—(NRS R 1977, 1644, effective July 1, 1981)

**584.400 Necessity for marketing areas; administrative authority of commission. [Effective until July 1, 1981.]** It is recognized by the legislature that conditions within the milk industry of this state are such that it is necessary to establish marketing areas wherein different regulations are necessary, and for that purpose the commission shall have the administrative authority, with such additional duties as are herein prescribed, after investigation and public hearing, to prescribe such marketing areas and modify the same when advisable or necessary.

[14:387:1955]—(NRS R 1977, 1644, effective July 1, 1981)

**584.405 Legislative determination. [Effective until July 1, 1981.]** The foregoing statements in NRS 584.390 to 584.400, inclusive, of facts, policy and application of NRS 584.325 to 584.690, inclusive, are hereby declared a matter of legislative determination.

[15:387:1955]—(NRS R 1977, 1644, effective July 1, 1981)

**584.410 Purposes of NRS 584.325 to 584.690. [Effective until July 1, 1981.]** The purposes of NRS 584.325 to 584.690, inclusive, are:

1. To provide funds for administration and enforcement of NRS 584.325 to 584.690, inclusive, by assessments to be paid by producers of fluid milk or fluid cream or both, and from licenses issued to distributors in the manner prescribed herein.

2. To authorize and enable the commission to prescribe marketing areas and to fix prices at which fluid milk or fluid cream, or both, may be sold by producers, distributors and retailers, which areas and prices are necessary due to varying factors of costs of production, health regulations, transportation and other factors in the marketing areas of this state; but the price of fluid milk or fluid cream within any marketing area shall be uniform for all purchasers of fluid milk or fluid cream of similar grade or quality under like terms and conditions.

3. To authorize and enable the commission to formulate stabilization and marketing plans subject to the limitations prescribed in NRS 584.325 to 584.690, inclusive, with respect to the contents of such stabilization and marketing plans and declare such plans in effect for any marketing area.

4. To enable the dairy industry with the aid of the state to correct existing evils, develop and maintain satisfactory marketing conditions and

bring about a reasonable amount of stability and prosperity in the production and marketing of fluid milk and fluid cream.

[16:387:1955]—(NRS A 1959, 894; 1975, 1492; R 1977, 1644, effective July 1, 1981)

**584.415 Legislative intent: Construction. [Effective until July 1, 1981.]**

1. It is the intent of the legislature that the powers conferred in NRS 584.325 to 584.690, inclusive, shall be liberally construed.

2. Nothing in NRS 584.325 to 584.690, inclusive, shall be construed as permitting or authorizing the development of conditions of monopoly in the production or distribution of fluid milk or fluid cream.

3. The terms and conditions under which producers, distributors and retailers may sell, purchase and distribute fluid milk or fluid cream shall be established by the commission for the purpose of insuring an adequate and continuous supply of pure, fresh, wholesome fluid milk and fluid cream to consumers at fair and reasonable prices in the several localities and markets of the state and under the varying conditions of production and distribution.

[17:387:1955]—(NRS A 1959, 895; R 1977, 1644, effective July 1, 1981)

## STATE DAIRY COMMISSION

**584.420 State dairy commission: Creation; number of members. [Effective until July 1, 1981.]** The state dairy commission, consisting of three members, is hereby created.

[1:387:1955]—(NRS A 1957, 264; 1975, 1492; 1977, 1638; R 1977, 1644, effective July 1, 1981)

**584.425 Members of commission: Appointment; qualifications; terms; vacancies; chairman; connection with dairy industry prohibited; removal. [Effective until July 1, 1981.]**

1. Members of the commission shall be appointed by the governor and shall have the following qualifications:

(a) One member shall be a public accountant or certified public accountant who has been issued a permit or a certificate pursuant to the laws of this state;

(b) One member shall be an agricultural economist; and

(c) One member shall be experienced in banking or finance.

2. After the initial terms, members shall serve for terms of 3 years. A vacancy shall be filled for the unexpired term in the same manner as the original appointment.

3. The governor shall designate one of the members as chairman.

4. A member of the commission shall not have any connection with any segment of the dairy industry.

5. The governor may remove a member of the commission for malfeasance in office or neglect of duty.

[2:387:1955]—(NRS A 1975, 1492; 1977, 1638; R 1977, 1644, effective July 1, 1981)

**584.435 Grounds for removal of member. [Effective until July 1, 1981.]** Absence from two consecutive meetings of the commission constitutes good and sufficient cause for removal of a member by the governor.

[3:387:1955]—(NRS A 1975, 1493; R 1977, 1644, effective July 1, 1981)

**584.440 Meetings; hearings; quorum; employment of attorney. [Effective until July 1, 1981.]**

1. The members of the commission shall meet at least once each month and may meet at the call of the chairman or at the request of a majority of the members of the commission.
2. The commission shall conduct all hearings authorized pursuant to NRS 584.325 to 584.690, inclusive.
3. A majority of the members constitutes a quorum and a majority vote of the commission is required on all action taken by the commission.
4. The commission may retain an attorney to assist the commission in the administration of its duties.

[5:387:1955]—(NRS A 1957, 264; 1977, 1638; R 1977, 1644, effective July 1, 1981)

**584.445 Compensation, expenses of members; expenditure of funds by commission. [Effective until July 1, 1981.]**

1. Each member of the commission shall receive a salary of not more than $40 per day, as fixed by the commission, while engaged in the business of the commission.
2. Each member of the commission shall receive the per diem expense allowance and travel expenses as fixed by law while engaged in the business of the commission.
3. The commission may expend in accordance with law all moneys now or hereafter made available for its use.

[7:387:1955]—(NRS A 1967, 948; 1975, 300; R 1977, 1644, effective July 1, 1981)

**584.450 Seal. [Effective until July 1, 1981.]** The commission shall adopt a seal for its own use which shall have imprinted thereon the words "State Dairy Commission, State of Nevada." The secretary of the commission shall have the care and custody of the seal.

[11:387:1955]—(NRS R 1977, 1644, effective July 1, 1981)

**584.455 Executive director and other employees: Appointment; duties. [Effective until July 1, 1981.]**

1. The commission shall appoint an executive director, who shall serve ex officio as its secretary.
2. The executive director may appoint such assistants, deputies, agents, experts and other employees as are necessary for the administration of NRS 584.325 to 584.690, inclusive, prescribe their duties and fix their salaries in accordance with classifications made by the personnel division of the department of administration.

3. The executive director shall be in the unclassified service of the state. All assistants, deputies, agents, experts and other employees shall be in the classified service pursuant to the provisions of chapter 284 of NRS.

4. The executive director may be removed by the commission.

[6:387:1955]—(NRS A 1975, 1493; 1977, 1639; R 1977, 1644, effective July 1, 1981)

**584.460 Dairy commission fund: Source and expenditures. [Effective until July 1, 1981.]** There is hereby created in the state treasury a special fund designated as the dairy commission fund. All moneys received by the commission pursuant to NRS 584.325 to 584.690, inclusive, shall be paid into the fund and shall be expended solely for the enforcement of NRS 584.325 to 584.690, inclusive.

[8:387:1955]—(NRS R 1977, 1644, effective July 1, 1981)

**584.465 Records of income and disbursements. [Effective until July 1, 1981.]** The commission shall keep a separate record of the classes and sources of income credited to the dairy commission fund and of the disbursements therefrom.

[9:387:1955]—(NRS R 1977, 1644, effective July 1, 1981)

**584.470 Powers of commission: Hearings; oaths; witnesses. [Effective until July 1, 1981.]**

1. For the purposes of NRS 584.325 to 584.690, inclusive, the commission may hold hearings, administer oaths, certify to official acts, take depositions, issue subpenas, summon witnesses and examine the books and records of any producer, distributor or retailer. Such an examination may be made at any reasonable time or place by the commission or any agent of the commission.

2. The district court for the county in which any investigation is being conducted by the commission may compel the attendance of witnesses, the giving of testimony and the production of books and papers as required by any subpena issued by the commission.

3. In case of the refusal of any witness to attend or testify or produce any papers required by such subpena the commission may report to the district court for the county in which the investigation is pending by petition, setting forth:

(a) That due notice has been given of the time and place of attendance of the witness or the production of the books and papers;

(b) That the witness has been subpenaed in the manner prescribed in this chapter;

(c) That the witness has failed and refused to attend or produce the papers required by subpena before the commission in the investigation named in the subpena, or has refused to answer questions propounded to him in the course of such investigation,

and asking an order of the court compelling the witness to attend and testify or produce the books or papers before the commission.

4. The court, upon petition of the commission, shall enter an order directing the witness to appear before the court at a time and place to be fixed by the court in such order, the time to be not more than 10 days from the date of the order, and then and there show cause why he has not attended or testified or produced the books or papers before the commission. A certified copy of the order shall be served upon the witness. If it shall appear to the court that the subpena was regularly issued by the commission, the court shall thereupon enter an order that the witness appear before the commission at the time and place fixed in the order and testify or produce the required books or papers, and upon failure to obey the order the witness shall be dealt with as for contempt of court.

[10:387:1955]—(NRS A 1975, 1493; R 1977, 1644, effective July 1, 1981)

**584.472 Hearings: Notification, appearance of consumer affairs division. [Effective until July 1, 1981.]**

1. Written notice of any hearing held by the commission shall be mailed to the consumer affairs division of the department of commerce.

2. The division may file with the commission any statement concerning the proposed action and may appear at the hearing to give evidence concerning the proposed action.

(Added to NRS by 1977, 1637; R 1977, 1644, effective July 1, 1981)

**584.474 Regulations of commission. [Effective until July 1, 1981.]** The commission shall adopt regulations establishing procedures for:

1. Its administration and government;
2. The formation and adoption of stabilization and marketing plans;
3. The conduct of its public hearings; and
4. The manner in which cost information required of producers, distributors, producer-distributors and retailers is determined and presented to the commission; and
5. Classifying fluid milk products into three separate classes.

(Added to NRS by 1977, 1637; R 1977, 1644, effective July 1, 1981)

### General Powers of the Commission

**584.495 Enforcement of provisions. [Effective until July 1, 1981.]** The commission shall enforce the provisions of NRS 584.325 to 584.690, inclusive, and any stabilization and marketing plan initiated pursuant to the provisions of NRS 584.325 to 584.690, inclusive.

[36:387:1955]—(NRS A 1977, 1639; R 1977, 1644, effective July 1, 1981)

**584.500 State instrumentality. [Effective until July 1, 1981.]** The commission is hereby declared to be the instrumentality of this state for the purpose of administering and enforcing the provisions of NRS 584.-325 to 584.690, inclusive, and to execute the legislative intent herein expressed, and is hereby vested with the administrative authority described in NRS 584.325 to 584.690, inclusive.

[37:387:1955]—(NRS R 1977, 1644, effective July 1, 1981)

**584.505 Investigations; records of producers and distributors. [Effective until July 1, 1981.]**

1. The commission may investigate, upon reasonable notice, any and all transactions between producers and distributors or among distributors or between distributors and retail stores or between distributors and consumers or between retail stores and consumers; and the commission or its authorized agents may enter at all reasonable hours all places where milk is stored, bottled or manufactured, or where milk or milk products are bought, sold or handled, or where the books, papers, records or documents relating to such transactions are kept, and may inspect and copy any such books, papers, records or documents.

2. Each producer and distributor shall maintain adequate records concerning his transactions in fluid milk and fluid cream.

[38:387:1955]—(NRS A 1959, 895; R 1977, 1644, effective July 1, 1981)

**584.510 Licensing of distributors and registration of producers. [Effective until July 1, 1981.]** The commission may issue licenses to distributors and require the registration of producers.

[39:387:1955]—(NRS R 1977, 1644, effective July 1, 1981)

**584.515 Formulation of plan. [Effective until July 1, 1981.]** The commission may formulate any stabilization and marketing plan as prescribed in NRS 584.325 to 584.690, inclusive, and declare the same effective after public hearing and reasonable notice by mail or otherwise to all producers and distributors of record with the commission affected by such plan.

[40:387:1955]—(NRS R 1977, 1644, effective July 1, 1981)

**584.520 Amendment or termination of plan: Procedure. [Effective until July 1, 1981.]**

1. In addition to procedures provided for in subsections 3 and 4, the commission may amend or terminate any stabilization and marketing plan, after notice and public hearing as prescribed in NRS 584.550 to 584.565, inclusive, if it finds that such plan is no longer in conformity with the standards prescribed in, or will not tend to effectuate the purposes of, NRS 584.325 to 584.690, inclusive.

2. Such hearing may be held upon the motion of the commission and shall be held if a proper petition is filed.

3. If producers wish to abandon an existing stabilization and marketing plan and establish a Federal Milk Marketing Order or other similar type of milk marketing order, the commission may continue a marketing and stabilization plan in effect for any given area, insofar as wholesale and retail provisions are concerned, whenever it appears that 55 percent of the distributors in any given area, whose major interest in the fluid milk and fluid cream business consists of at least 55 percent of the fluid milk and fluid cream distributed within the area by volume, desire that the wholesale and retail provisions, including price regulations, be continued.

4. Areas which are nonproducing may terminate a stabilization and marketing plan which affects wholesale and retail prices if 55 percent of the licensed distributors delivering 55 percent of the products to such area wish to terminate such plan after notice and public hearing as prescribed in NRS 584.550 to 584.565, inclusive.

[41:387:1955]—(NRS A 1959, 895; 1977, 1639; R 1977, 1644, effective July 1, 1981)

**584.522 Amendment or termination of plan: Petition; hearing. [Effective until July 1, 1981.]**

1. An amendment or termination of a stabilization and marketing plan may be initiated by filing a petition with the commission. The petition, filed in ten copies, shall include:

(a) The name and address of every person joining in the petition. If the petitioner is a cooperative association of producers, a partnership or corporation the names of the duly authorized representative or representatives thereof shall be listed.

(b) A concise statement of the specific relief requested.

(c) A specific statement of the reasons why such relief is needed.

(d) A statement of the substantiating evidence.

2. The petition shall be signed by the petitioners and an affidavit shall accompany each such petition setting forth that the facts set forth therein are true and correct to the best of the petitioners' knowledge, information, and belief.

3. There shall be attached as an exhibit to the original copy only of each petition filed substantiating evidence in support of such petition. Additional information shall be supplied to the commission upon request.

4. Any person may, before the hearing, examine a copy of the petition and accompanying statements, but not the exhibits attached thereto and file an answer, protest or any other statement concerning the petition.

5. At the hearing, the burden of proof is on the petitioners to show by clear and satisfactory evidence that the amendment or termination of a plan is necessary.

6. After the petitioners have presented their evidence, the commission staff shall, and any other person may, present evidence in support of or in protest of the proposed action.

(Added to NRS by 1975, 1496; A 1977, 1640; R 1977, 1644, effective July 1, 1981)

**584.525 Records. [Effective until July 1, 1981.]** A full and accurate record of business or acts performed or of testimony taken by the commission in pursuance of the provisions of NRS 584.325 to 584.690, inclusive, shall be kept and placed on file in the office of the commission.

[45:387:1955]—(NRS R 1977, 1644, effective July 1, 1981)

**584.535 Injunction against violation of law or order: Joinder of defendants. [Effective until July 1, 1981.]**

1. The commission may bring an action to enjoin the violation or

threatened violation of any provisions of NRS 584.325 to 584.690, inclusive, or of any order made pursuant to NRS 584.325 to 584.690, inclusive, in the district court in the county in which such violation occurs or is about to occur.

2. There may be enjoined in one proceeding any number of defendants alleged to be violating the same provisions or orders, although their properties, interests, residence or place of business may be in several counties and the violations separate and distinct.

[47:387:1955]—(NRS R 1977, 1644, effective July 1, 1981)

**584.540 Cooperation with other authorities; enforcement of plans. [Effective until July 1, 1981.]** The commission may confer, enter into agreements, or otherwise arrange with the constituted authorities of this state, other states or agencies of the United States with respect to plans relating to the stabilization and distribution of fluid milk and fluid cream within this state or as between this state and other states or the United States, and may exercise its powers hereunder to effectuate and enforce such plans.

[48:387:1955]—(NRS R 1977, 1644, effective July 1, 1981)

**584.543 Assistance in enforcement by constables, sheriffs and police officers. [Effective until July 1, 1981.]** Constables, police officers and sheriffs may render assistance to the commission, any member of the commission or any authorized representative of the commission, in the enforcement of the provisions of NRS 584.325 to 584.690, inclusive, upon request.

(Added to NRS by 1959, 901; R 1977, 1644, effective July 1, 1981)

**584.545 Disposition of money. [Effective until July 1, 1981.]** All moneys received by the commission hereunder shall be paid monthly into the state treasury to the credit of the dairy commission fund.

[49:387:1955]—(NRS R 1977, 1644, effective July 1, 1981)

### Formation and Adoption of Stabilization and Marketing Plans

**584.550 Designation of marketing areas; additional areas; modification or consolidation of areas. [Effective until July 1, 1981.]**

1. The commission shall designate marketing areas which it deems necessary or advisable to effectuate the purposes of NRS 584.325 to 584.690, inclusive, and wherein it finds the conditions affecting the production, distribution and sale of fluid milk, fluid cream or both are reasonably uniform.

2. The commission shall have the power to establish additional areas or to modify areas theretofore established when it deems the establishment or modification of such areas necessary or advisable to effectuate the purposes of NRS 584.325 to 584.690, inclusive.

3. When the commission finds, after a public hearing in and for each particular marketing area under consideration for consolidation, that conditions of production and distribution are reasonably uniform in two

or more such marketing areas wherein stabilization and marketing plans are in effect, it may consolidate the area, provided that at the hearings more than 35 percent of the producers present who supply the areas proposed to be consolidated do not object to such consolidation.

[50:387:1955]—(NRS R 1977, 1644, effective July 1, 1981)

**584.555 Hearing to determine whether producers desire fluid milk plan. [Effective until July 1, 1981.]** The commission shall, prior to the formulation of a stabilization and marketing plan for fluid milk for any marketing area, conduct a public hearing in the area for the purpose of determining whether or not producers whose major interest in the fluid milk business is in the production of fluid milk for the marketing area, and who represent not less than 65 percent of the total number of producers whose major interest in the fluid milk business is in the production of fluid milk for the marketing area, and who produce not less than 65 percent of the total volume of the fluid milk produced for the marketing area by all such producers, desire that a stabilization and marketing plan for fluid milk be formulated for the area; but if a petition is presented to the commission by the producers whose major interest in the fluid milk business is in the production of fluid milk for the marketing area, and who represent not less than 65 percent of the total number of producers whose major interest in the fluid milk business is in the production of fluid milk for the marketing area, and who produce not less than 65 percent of the total volume of the fluid milk produced for the marketing area by all such producers, it shall not be necessary that such hearing be held.

[51:387:1955]—(NRS R 1977, 1644, effective July 1, 1981)

**584.560 Hearing to determine whether producers desire fluid cream plan. [Effective until July 1, 1981.]** The commission shall, prior to the formulation of a stabilization and marketing plan for fluid cream for any marketing area, conduct a public hearing in the area for the purpose of determining whether or not producers whose major interest in the fluid cream business is in the production of fluid milk for fluid cream for the marketing area, and who represent not less than 65 percent of the total number of producers whose major interest in the fluid cream business is in the production of fluid milk for fluid cream for the marketing area, and who produce not less than 65 percent of the total volume of fluid milk for fluid cream produced for the marketing area by all such producers, desire that a stabilization and marketing plan for fluid cream be formulated for the area; but if a petition is presented to the commission by producers whose major interest in the fluid cream business is in the production of fluid milk for fluid cream for the marketing area, and who represent not less than 65 percent of the total number of producers whose major interest in the fluid cream business is in the production of fluid milk for fluid cream for the marketing area, and who produce not less than 65 percent of the total volume of fluid milk for fluid cream produced for the marketing area by all such producers, it shall not be necessary that such hearing be held.

[52:387:1955]—(NRS R 1977, 1644, effective July 1, 1981)

**584.565 Formulation of plan: Notice; hearing; order declaring plan in effect. [Effective until July 1, 1981.]**

1. If the commission finds that a stabilization and marketing plan is necessary to accomplish the purposes of NRS 584.325 to 584.690, inclusive, it shall formulate a stabilization and marketing plan for fluid milk or fluid cream or both for such area and issue a notice of public hearing upon the plan formulated to all producers and distributors of record with the commission who may be subject to the provisions of such plan.

2. The notice of hearing may be effected by mail or by publication for 5 successive days in a newspaper of general circulation in the area designated and shall specify the time and the place of such hearing, which shall not be held prior to 10 days from the mailing or from the final publication of such notice; but if no daily newspaper of general circulation is published in the area designated, publication of notice for 2 successive weeks in a weekly newspaper of general circulation in the area will be considered proper publication of notice.

3. At the hearing, interested persons shall be heard and records kept of the proceedings of such hearing for determination by the commission whether the plan proposed will accomplish the purposes of NRS 584.325 to 584.690, inclusive.

4. If, after public hearing, the commission determines that the proposed plan will tend to accomplish the purposes of NRS 584.325 to 584.690, inclusive, within the standards herein prescribed, it shall issue an order to all producers and distributors of record with the commission and subject to the provisions of such plan, declaring such plan in effect within 30 days from the date of such hearing.

[53:387:1955]—(NRS R 1977, 1644, effective July 1, 1981)

## MANDATORY PROVISIONS

**584.568 Minimum prices; discounts. [Effective until July 1, 1981.]**

1. Each stabilization and marketing plan may contain provisions fixing the price at which fluid milk and fluid cream is sold by producers, distributors and retailers and shall contain provisions regulating all discounts allowed by producers, distributors and retailers.

2. If the commission establishes minimum prices to be paid by distributors to producers the commission shall consider, but not be limited to, the following factors:

(a) Cost of production.

(b) Reasonable return upon capital investment.

(c) Producer transportation costs.

(d) Cost of compliance with health regulations.

(e) Current and prospective supplies of fluid milk and fluid cream in relation to current and prospective demands for such fluid milk and fluid cream.

3. If the commission establishes minimum prices to be paid by retailers to wholesalers and by consumers to retailers the commission shall consider, but not be limited to, the following factors:

(a) The quantities of fluid milk or fluid cream, or both, distributed in the marketing area covered by the stabilization and marketing plan.

(b) The quantities of fluid milk or fluid cream, or both, normally required by consumers in such marketing area.

(c) The cost of fluid milk or fluid cream, or both, to distributors and retail stores, which in all cases shall be, respectively, the prices paid by distributors to producers and the minimum wholesale prices, as established pursuant to NRS 584.325 to 584.690, inclusive.

(d) The reasonable cost of handling fluid milk or fluid cream, or both, incurred by distributors and retail stores, respectively, including all costs of hauling, processing, selling and delivering by the several methods used in such marketing area in accomplishing such hauling, processing, selling and delivering, as such costs are determined by impartial audits of the books and records, or surveys, or both, of all or such portion of the distributors and retail stores, respectively, of each type or class in such marketing area as are reasonably determined by the commission to be sufficiently representative to indicate the costs of all distributors and retail stores, respectively, in such marketing area.

(Added to NRS by 1959, 899; A 1977, 1641; R 1977, 1644, effective July 1, 1981)

**584.570 Unfair practices; certain practices of distributors prohibited whether plan in effect or not. [Effective until July 1, 1981.]**

1. No distributor may engage in any of the practices set forth in paragraphs (a) to (d), inclusive, of subsection 2 of this section, whether or not a stabilization and marketing plan is in effect in the area in which he carries on his business.

2. Each stabilization and marketing plan shall contain provisions for prohibiting distributors and retail stores from engaging in the unfair practices set forth in this subsection:

(a) The payment, allowance or acceptance of secret rebates, secret refunds or unearned discounts by any person, whether in the form of money or otherwise.

(b) The giving of any milk, cream, dairy products, services or articles of any kind, except to bona fide charities, for the purpose of securing or retaining the fluid milk or fluid cream business of any customer.

(c) The extension to certain customers of special prices or services not made available to all customers who purchase fluid milk or fluid cream of like quantity under like terms and conditions.

(d) The purchase of any fluid milk in excess of 200 gallons monthly from any producer or association of producers unless a written contract has been entered into with such producer or association of producers stating the amount of fluid milk to be purchased for any period, the quantity of such milk to be paid for as class 1 in pounds of milk or pounds of milk fat or gallons of milk, and the price to be paid for all milk received. The contract shall also state the date and method of payment for such fluid milk, which shall be that payment shall be made for approximately one-half of the milk delivered in any calendar month not later than

the 1st day of the next following month and the remainder not later than the 15th day of the month, the charges for transportation if hauled by the distributor, and may contain other provisions which are not in conflict with NRS 584.325 to 584.690, inclusive. The contract shall also provide that the producer is not obligated to deliver in any calendar month fluid milk to be paid for at the minimum price for fluid milk which is used by distributors in the manufacture of butter and cheese other than cottage cheese. A signed copy of such contract shall be filed by the distributor with the commission within 5 days from the date of its execution. The provisions of this subsection relating to dates of payment do not apply to contracts for the purchase of fluid milk from nonprofit cooperative associations of producers.

[54:387:1955]—(NRS A 1957, 264; 1959, 896; 1975, 1494; 1977, 1642; R 1977, 1644, effective July 1, 1981)

### Optional Provisions

**584.575 Report to producer. [Effective until July 1, 1981.]** Each stabilization and marketing plan may contain provisions whereby distributors shall report to each producer from whom fluid milk is secured, the volume of fluid milk received from such producer in pounds of milk, and the milk fat test of such milk, and the amount of fluid milk in milk fat pounds paid for in the several classes and the prices paid for the various classes for each month.

[55:387:1955]—(NRS R 1977, 1644, effective July 1, 1981)

**584.580 Purchase of milk from noncomplying producers; limitation on production. [Effective until July 1, 1981.]** No distributor subject to the provisions of any stabilization and marketing plan shall purchase milk from producers who cannot comply with the provisions of NRS 584.325 to 584.690, inclusive, in such plan. No such plan shall involve a limitation upon the production of fluid milk or fluid cream.

[56:387:1955]—(NRS R 1977, 1644, effective July 1, 1981)

### Unfair Trade Practices and Investigation of Marketing and Pricing Practices

**584.582 Unlawful manipulation of prices. [Effective until July 1, 1981.]** It is unlawful for any distributor or retailer to manipulate the prices of fluid milk, fluid cream, butter or fresh dairy byproducts for the purpose of injuring, harassing or destroying competition.

(Added to NRS by 1975, 1497; R 1977, 1644, effective July 1, 1981)

**584.583 Sales of milk, cream, butter, fresh dairy byproducts below cost by distributors, retailers. [Effective until July 1, 1981.]**

1. No distributor or retailer may sell fluid milk, fluid cream, butter or fresh dairy byproducts below cost. "Fresh dairy byproducts" includes but

is not limited to the following items: buttermilk, skim milk, chocolate drink, ice cream, ice milk mix, sherbet, sour cream, sour cream dressing and cottage cheese; and does not necessarily define the class of fluid milk or fluid cream which is used to make such products.

2. In determining cost in the case of a distributor who processes or manufactures fluid milk, fluid cream, butter or fresh dairy byproducts, the following factors are included, but cost is not necessarily limited to such factors:

(a) Cost of raw products based on actual cost or on current and prospective supplies of fluid milk and fluid cream in relation to current and prospective demands for such fluid milk and fluid cream.

(b) Cost of production.

(c) Reasonable return upon capital investment.

(d) Producer transportation costs.

(e) Cost of compliance with health regulations.

(f) Overhead cost of handling based on a percentage of overall plant and sales operating cost.

3. In determining cost in the case of a peddler-distributor or retailer, the following factors are included, but cost is not necessarily limited to such factors:

(a) Purchase price of product.

(b) Overhead cost for handling.

(c) Reasonable return upon capital investment.

4. Each distributor who processes or manufactures fluid milk, fluid cream, butter or fresh dairy byproducts shall file with the commission a statement of costs, listing separately the items set forth in subsection 2 of this section and any other applicable cost factors. Such statements shall be kept current by supplement under regulations promulgated by the commission. All such statements shall be kept confidential by the commission except when used in judicial proceedings or administrative proceedings under NRS 584.325 to 584.690, inclusive.

5. Each distributor who processes or manufactures fluid milk, fluid cream. butter or fresh dairy byproducts and each peddler-distributor shall file with the commission a list of wholesale, retail and distributor or dock prices. No such distributor shall sell at prices other than those contained in such list. except in the case of bids to departments or agencies of federal. state and local governments; but in no case shall the distributor sell below cost as provided in this section. Prices shall not become effective until the seventh day after filing, but any other distributor may meet such price so filed if such other distributor files with the commission a schedule of prices in the manner required by NRS 584.584.

(Added to NRS by 1959, 900; A 1975, 1495; R 1977, 1644, effective July 1, 1981)

**584.584 Distributors may meet competitive prices in sales of butter, fresh dairy byproducts or fluid milk; information to be filed with commission. [Effective until July 1, 1981.]**

1. The provisions of NRS 584.583 do not permit or authorize the development of conditions of monopoly in production or distribution of

butter, fresh dairy byproducts or fluid milk products and a distributor who meets in good faith a lawful competitive price is not subject to any penalty provided in NRS 584.325 to 584.690, inclusive, if he files with the commission information detailing the circumstances surrounding the lawful competitive price within 5 days of such occurrence. Such information shall include the name and address of the distributor, the name and address of the customer involved, the competitive price met, the effective date of such price or condition, and the name and address of the competing distributor.

2. If such information is accompanied by a written statement, signed by the customer before a notary public or two competent witnesses, that such competitive price has been offered or made available to him, the statement is prima facie evidence that a distributor is meeting such competitive price or condition in good faith.

(Added to NRS by 1959, 901; A 1977, 1642; R 1977, 1644, effective July 1, 1981)

**584.585 Additional duty and authority of commission: Unfair trade practices. [Effective until July 1, 1981.]** Pursuant to the declaration and statement of facts, policy and purposes set forth in NRS 584.325 to 584.690, inclusive, the commission is hereby vested with the additional administrative duty and authority to prescribe unfair trade practices and investigate marketing and pricing practices within marketing areas for later legislative recommendation.

[57:387:1955]—(NRS R 1977, 1644, effective July 1, 1981)

**584.590 Investigation of prices in marketing area: Notice; hearing; record. [Effective until July 1, 1981.]**

1. In investigating prices in any marketing area the commission may first make an investigation in such marketing area to establish such facts as shall be necessary to permit it to carry out the intent of NRS 584.585 and this section within the standards prescribed in this section. In making such investigation, the commission may, upon notice, examine the books and records of distributors and the purchase of dairy products by retail stores in such marketing area and may hold one or more public hearings, take testimony and may subpena witnesses. All testimony received at such hearings shall be under oath.

2. Notice of any hearing held by the commission pursuant to NRS 584.585 and this section shall be given by the commission to every distributor and retail store in such marketing area whose name appears upon the records of the commission or who files a request for the same with the commission, by mail or by publication. The notice of hearing may be effected by mail, or by publication for 5 successive days in a newspaper of general circulation in the area designated, and shall specify the time and place of such hearing, which shall not be held prior to 10 days from the mailing or from the final publication of such notice; but if no daily newspaper of general circulation is published in the area designated, publication of notice for 2 successive weeks in a weekly newspaper of general circulation in the area will be considered proper publication of notice.

3. A record of any hearings held by the commission pursuant to NRS 584.585 and this section shall be made and filed in the office of the commission and shall be kept available at all times for inspection by any interested person.

[58:387:1955]—(NRS A 1977, 642; R 1977, 1644, effective July 1, 1981)

### Distributors' Licenses, Fees and Bonds

**584.595 Necessity for license; application; form and contents; term; renewal. [Effective until July 1, 1981.]**

1. No distributor may deal in fluid milk, fluid cream or any other dairy product without first having obtained a license from the commission.

2. The special licenses provided in this section are in addition to any and all licenses otherwise required by any law or ordinance of any county or municipality of this state or any law of this state.

3. Application for the licenses herein provided shall be made on forms prescribed by the commission, shall be accompanied by an application fee of $3, and shall state the name and address of the applicant and such details as to the nature of the applicant's business as the commission may require. Such applicant shall satisfy the commission:

(a) Of the applicant's good faith, character and responsibility in seeking to carry on the business stated in the application.

(b) That the applicant has complied with all laws of the State of Nevada and regulations promulgated thereunder, regardless of whether the applicant is a local or out-of-state distributor.

4. Licenses shall be issued for a period of 12 months from the 1st day of each year or for the remainder of the calendar year from the date of issuance.

5. Application for renewal of a license for the following year by a licensee, together with the application fee of $3, shall be made prior to the expiration date of the license held, and if not so made, the applicant shall pay an additional sum equal to 100 percent of the application fee before such license shall be issued.

[59:387:1955]—(NRS A 1959, 897; R 1977, 1644, effective July 1, 1981)

**584.600 Bond: Amount; form and conditions; proceedings for enforcement. [Effective until July 1, 1981.]**

1. Every distributor before purchasing any fluid milk or fluid cream from a producer must execute and deliver to the commission a surety bond in the minimum sum of $1,000 executed by the applicant as principal and by a surety company qualified and authorized to do business in this state as surety.

2. The bond shall be upon a form approved by the commission and shall be conditioned upon the payment in the manner required by NRS 584.325 to 584.690, inclusive, of all amounts due to producers for fluid

at the same rate on the content of milk fat contained in such products as Nevada distributors are assessed on fluid milk or fluid cream which go into the manufacture of such type products.

[66:387:1955]—(NRS A 1959, 898; R 1977, 1644, effective July 1, 1981)

**584.633 Distributors' assessments on butter, fresh dairy byproducts. [Effective until July 1, 1981.]**

1. The commission shall assess each distributor of butter the sum of 1 cent per pound on all butter distributed by such distributor.

2. The commission shall assess all distributors of fresh dairy byproducts the sum of 4 cents per gallon on all ice cream, sherbet, or ice cream or ice milk mixes, and the sum of one-half cent per pound on all cottage cheese and yogurt distributed by such distributors.

3. Assessments under this section shall be paid to the commission on or before the 15th of the month following the month during which the butter or fresh dairy byproducts were distributed. Late payments are subject to the same penalty as that provided by subsection 4 of NRS 584.635.

(Added to NRS by 1959, 901; A 1977, 1643; R 1977, 1644, effective July 1, 1981)

**584.635 Assessment of sellers to distributors; penalties for delinquent payments. [Effective until July 1, 1981.]**

1. Distributors who are subject to the provisions of any stabilization and marketing plan made effective by NRS 584.325 to 584.690, inclusive, including distributors who import fluid milk or fluid cream from outside the state, whether such items are finished products or in bulk, shall deduct as an assessment from payments due their sellers, whether such sellers are producers or distributors, and whether within or without the state, for fluid milk, fluid cream or both, including each distributor's own production, the sum of one-half cent per pound milk fat on all milk fat contained in fluid milk, fluid cream or both, or in the case of distributors who do not purchase or receive fluid milk, in milk fat pounds, the sum of 1½ cents for each 10 gallons of fluid milk sold. Such assessment rates are maximum rates.

2. The commission may fix the rate of such assessment at a less amount, and may adjust the rate from time to time, whenever it finds that the cost of administering the provisions of NRS 584.325 to 584.690, inclusive, can be defrayed from revenues derived from such lower rates in combination with such sums as are provided by NRS 584.630.

3. The amount of the assessment so deducted shall be paid to the commission on or before the 15th of the month following the month during which such fluid milk or fluid cream was received.

4. If payments of assessments are not made on or before the 15th day of each month following the month during which the fluid milk or fluid cream was received or following the date upon which any other

assessment falls due, the commission shall charge, as a penalty for such late payment, the amount of 1 percent per month of the total amount due and owing, but remaining unpaid.

[67:387:1955]—(NRS A 1959, 898; R 1977, 1644, effective July 1, 1981)

**584.640 Distributor purchasing from producer-distributor: When bond not required; notice to commission; record of purchases; reports. [Effective until July 1, 1981.]**

1. No bond shall be required of any distributor who purchases fluid milk or fluid cream from a producer-distributor; provided:

(a) That the buyer at the time of obtaining possession or control of each delivery pays for the same in full in lawful money of the United States; and

(b) That the fluid milk or fluid cream is purchased in package form ready for human consumption and not in bulk form.

2. Any distributor before purchasing fluid milk or fluid cream on the terms stated in subsection 1 shall notify the commission of his intention to make such purchases, stating from whom and the average daily quantity of such purchases. Such distributor shall also keep a record of such purchases, showing dates of purchases, amounts of purchases, and the name or names of seller or sellers, and shall make such other and further reports to the commission as it may from time to time require.

[68:387:1955]—(NRS R 1977, 1644, effective July 1, 1981)

**584.645 Provisions of NRS 584.595 to 584.640 inapplicable to retail stores. [Effective until July 1, 1981.]** The provisions of NRS 584.595 to 584.640, inclusive, with respect to licenses shall not apply to retail stores as such stores are defined in NRS 584.380.

[69:387:1955]—(NRS R 1977, 1644, effective July 1, 1981)

### Reports and Statistics

**584.650 Reports and records of distributors, producer cooperatives. [Effective until July 1, 1981.]** Every distributor who purchases fluid milk or fluid cream from a producer and every producer cooperative organization which handles milk for its members or other producers shall make and keep for 1 year a correct record showing in detail the following information for each producer with reference to the handling sale or storage of such fluid milk or fluid cream:

1. The name and address of the producer.
2. The date the fluid milk or fluid cream was received.
3. The amount of fluid milk or fluid cream received.
4. The official butterfat test of the fluid milk or fluid cream if purchased on a butterfat basis.
5. The usage of the fluid milk or fluid cream.
6. Evidence of payment for the fluid milk or fluid cream purchased or handled.

[70:387:1955]—(NRS A 1975, 1496; R 1977, 1644, effective July 1, 1981)

**584.655 Records and reports confidential. [Effective until July 1, 1981.]** Any record or report made to the commission pursuant to the provisions of NRS 584.650 to 584.665, inclusive, shall be confidential and shall not be divulged except when necessary for the proper determination of any court proceedings or hearing before the commission.

[71:387:1955]—(NRS R 1977, 1644, effective July 1, 1981)

**584.660 Biennial report to governor. [Effective until July 1, 1981.]** The commission shall, within 30 days prior to each general session of the legislature, submit to the governor a full and true report of the transactions under NRS 584.325 to 584.690, inclusive, during the preceding biennium, including a complete statement of receipts and expenditures during such period, together with its legislative recommendations.

[72:387:1955]—(NRS R 1977, 1644, effective July 1, 1981)

**584.665 Collection, dissemination of statistical and other data. [Effective until July 1, 1981.]** In addition to the compilation of information pertaining to fluid milk and fluid cream from the reports required by NRS 584.325 to 584.690, inclusive, the commission shall collect, assemble, compile, and distribute statistical data relative to fluid milk, fluid cream, other milk and milk products, and such other information as may relate to the dairy industry and the provisions of NRS 584.325 to 584.690, inclusive. For purposes of this section the commission may require such information as it deems necessary from distributors, producers, cooperative associations of producers, retailers and others who are engaged in the production, sale, distribution, handling or transportation of fluid milk, fluid cream or other dairy products.

[73:387:1955]—(NRS A 1975, 1496; R 1977, 1644, effective July 1, 1981)

## PENALTIES

**584.670 Misdemeanors; revocation, suspension of license; civil penalties. [Effective until July 1, 1981.]**

1. The violation of any provision of NRS 584.325 to 584.690, inclusive, or of any stabilization and marketing plan, including any price requirements of such plan, or of any of the unfair practice provisions set forth in such sections, is a misdemeanor, and also is ground for revocation or suspension of license in the manner set forth in NRS 584.325 to 584.690, inclusive.

2. Every distributor must pay for fluid milk or fluid cream delivered to him or it at the time and in the manner specified in the contract with the producer. Failure to make such payment is ground for refusal, suspension or revocation of license in the manner set forth in NRS 584.325 to 584.690, inclusive.

3. In addition to, or in lieu of, any other penalty provided by NRS 584.325 to 584.690, inclusive, the commission may impose a penalty of

not more than $1,000 for each violation, to be recovered by the commission in a civil action in a court of competent jurisdiction. All sums recovered under this subsection shall be deposited with the state treasurer to the credit of the dairy commission fund and shall be expended solely for the enforcement of NRS 584.325 to 584.690, inclusive.

[74:387:1955]—(NRS A 1959, 899; 1977, 1643; R 1977, 1644, effective July 1, 1981)

DISCIPLINARY PROCEEDINGS

**584.675 Refusal, revocation or suspension of license. [Effective until July 1, 1981.]**

1. The commission may refuse to grant any license herein provided and may revoke or suspend any such license as the case may require when it is satisfied that any applicant or licensee has violated any provision of NRS 584.325 to 584.690, inclusive; but no order shall be made refusing, revoking or suspending any license except after hearing upon at least 10 days' notice to the applicant or licensee.

2. The decision may include an order refusing, revoking or suspending the license applied for or held by the respondent, or fixing such other conditional and probationary orders as may be proper for the enforcement of NRS 584.325 to 584.690, inclusive.

3. After any decision, including any conditional or probationary orders, should respondent fail, refuse or neglect to comply with any such orders, the commission may suspend or revoke the license in accordance with the procedure provided in this section.

4. Previous violation by any applicant or by any person connected with the applicant of any provision of NRS 584.325 to 584.690, inclusive, shall be good and sufficient ground for denial, revocation or suspension of a license.

[75:387:1955]—(NRS R 1977, 1644, effective July 1, 1981)

**584.680 Emergency cases: Shortening time for hearing; service of notice; place of hearing. [Effective until July 1, 1981.]**

1. Whenever the commission is satisfied, either by investigation or after hearing, that a distributor is unable to pay for fluid milk or fluid cream purchased from producers and is further satisfied that to permit the distributor to continue to purchase and receive fluid milk or fluid cream from producers would be likely to cause serious and irreparable loss to producer-creditors and other producers, then the commission within its discretion may thereupon and forthwith shorten the time for hearing and thereupon may issue an order to show cause why the license of the distributor should not be forthwith suspended or revoked; but the time of notice of the hearing shall in no event be less than 5 days.

2. At such hearing the distributor proceeded against shall be ordered to show cause why his or its license should not be suspended or revoked or continued under such conditions and provisions, if any, as the commission may consider just and proper and for the protection of the best

interests of the producer-creditors and producers from whom the distributor has been and is receiving fluid milk or fluid cream.

3. Following such hearing, the decision of the commission shall become effective at its discretion.

4. The hearing, in the case of such emergency, may be called upon written notice, the notice to be served personally or by mail on the distributor involved, and may be held at the nearest office of the commission or at such place as may be most convenient in the discretion of the commission for the attendance of all parties involved.

[76:387:1955]—(NRS R 1977, 1644, effective July 1, 1981)

### CONSTRUCTION AND INTERPRETATION

**584.690 Applicability to retail stores. [Effective until July 1, 1981.]** NRS 584.325 to 584.685, inclusive, shall apply to retail stores in the following particulars only:

1. The examination by the commission of the purchase records of retail stores from distributors.

2. The unfair practices prohibited in NRS 584.570.

3. The provisions of any stabilization and marketing plan which includes retailers.

[78:387:1955]—(NRS A 1957, 265; 1959, 899; R 1977, 1644, effective July 1, 1981)

EXHIBIT "C"

S.B. 471--Limits scientific research upon human beings

Brock and Maria Kilbourne

The purpose of S.B. 471 is to safeguard the rights, dignity, and welfare of human subjects in the conduct of human research through the establishment of informed consent procedures and proper review. At present, no such law exists in the Nevada Revised Statutes and Federal law is limited to protecting subjects in the conduct of human research to the extent that an institution or agency receives federal funding.

S.B. 471 would both extend and expand federal requirements, concerning the conduct of human research, to all public and private institutions and agencies in the state of Nevada. Most importantly, the enactment of S.B. 471 would mean the State of Nevada has assumed an active role in protecting the rights and dignity of each and every person in this state who participates in any form of scientific research.

While this bill essentially mirrors federal guidelines, we believe it is important to emphasize certain differences which insure, at the state level, the full protection of subjects in the conduct of human research. First, S.B. 471 creates a sanctioning mechanism at the State level to deal directly with any "human rights" violations that pertain to the protection of human subjects. Second, S.B. 471 provides a more comprehensive and unambiguous definition of what constitutes human research. That is, all forms of scientific research (medical, psychological, social experimentation, survey, observation, testing or scientific investigation which uses human subjects and involves physical, chemical, molecular or psychological intervention by the researcher) are explicitly encompassed. Third, the definition of informed consent is expanded to prohibit any form of misrepresentation or deceit on the part of the researcher. Additionally, psychological and medical screening, when appropriate, as well as debriefing procedures are included within the required conditions of informed consent. Fourth, S.B. 471 insures full confidentiality for those individuals who participate in any form of scientific research.

EXHIBIT "D"



[4110-08-M]

Title 45—Public Welfare

SUBTITLE A—DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE, GENERAL ADMINISTRATION

PART 46—PROTECTION OF HUMAN SUBJECTS

## Informed Consent — Definition Amended To Include Advice on Compensation

AGENCY: Department of Health, Education, and Welfare.

ACTION: Interim final regulation.

SUMMARY: The Department of Health, Education, and Welfare hereby amends the definition of informed consent in its regulations on protection of human subjects, by requiring that prospective subjects be advised as to the availability or nonavailability of medical treatment or compensation for physical injuries incurred as the result of participating in biomedical or behavioral research.

EFFECTIVE DATE: January 2, 1979.

ADDRESS: Comments and requests for information and requests for additional copies of this notice to: Robert Backus, Ph. D., Acting Director, Office for Protection From Research Risks, National Institutes of Health, 9000 Rockville Pike, Bethesda, Md. 20014, 301-496-4705.

SUPPLEMENTARY INFORMATION: On May 30, 1974, the Department of Health, Education, and Welfare published in the FEDERAL REGISTER regulations for the protection of human subjects (39 FR 18914). These regulations (codified at 45 CFR Part 46) include a requirement that no subject may be involved in activities covered by the regulations, which would place the subject at risk, unless legally effective informed consent is first obtained from the subject or the subject's legally authorized representative. Section 46.103(c) of the regulations sets forth a detailed definition of "informed consent" including six basic elements of information necessary to such consent.

Shortly thereafter, a Department task force was formed to develop a mechanism to compensate persons injured as a result of their participation in research. The task force issued a report in January 1977 making a number of recommendations for compensating injured subjects (DHEW Publication No. OS-77-003). This report was sent to the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research for comment. The Commission's reply, received in June 1977, was generally favorable to the task force's recommendations. However, the Commission urged that the existence or absence of a compensation mechanism be disclosed as part of the informed consent process.

More recently, in its own Report and Recommendations on Institutional Review Boards (IRBs) dated September 1, 1978, the Commission recommended that subjects should be informed "whether treatment or compensation is available if harm occurs" (HEW Publication No. OS-78-008, at page 21). The Department will be publishing the Commission's recommendations on IRBs in the FEDERAL REGISTER for public comment.

The Department believes, however, that, at least where research presents risk of physical harm, subjects should be advised at the outset whether there will be any financial protection for them in the event they are injured. The public interest would therefore be served by adding this element of information to the Department's informed consent requirements as soon as possible. I therefore find that good cause exists for issuing this as an interim final regulation, subject to possible future changes after consideration of public comment.

Consequently, pending consideration of, and response to the Commission's overall recommendations on IRBs, the Department is hereby amending the definition of informed consent along lines suggested by the Commission. Since the amendment is being adopted prior to public comment, its scope will be limited to treatment and compensation for physical injury, and only to those physical injuries arising from biomedical or behavioral research. Also, it will be extended to research conducted in collaboration with foreign governments or international organization, absent the explicit nonconcurrence of those governments or organizations.

The amendment to the regulations will be effective on a prospective basis, on January 2, 1979. After that date, IRBs, in carrying out their normal responsibilities for review of new research proposals and ongoing projects, under 45 CFR Part 46, shall utilize the definition of informed consent in section 46.103(c), as amended.

Although the amendment is being adopted as an interim final regulation, public comment is requested both on the basic issue of advising subjects regarding the availability or nonavailability of compensation and medical treatment for injuries and the specific amendment itself, including the limitations on its scope. The Department recognizes that limiting the amendment to the regulations to physical injury and to biomedical and behavioral research may be artificial and unduly restraining. At the same time, however, the Department is reviewing the issue of the applicability of the affected regulations and the scope and substance of this amendment will be examined in light of the outcome of that review.

Dated: September 5, 1978.

CHARLES MILLER,
*Acting Assistant Secretary for Health.*

Approved: October 21, 1978.

JOSEPH A. CALIFANO, Jr.,
*Secretary.*

Accordingly, Part 46 of 45 CFR, Subtitle A, is amended by:

1. Deleting the word "and" at the end of § 46.103(c)(5).

2. Changing the period at the end of § 46.103(c)(6) to a semicolon, and adding the word "and" after the semicolon.

3. Adding the following new § 46.103(c)(7):

§ 46.103 Definitions.

* * * * *

(c) * * *

(7) With respect to biomedical or behavioral research which may result in physical injury, an explanation as to whether compensation and medical treatment is available if physical injury occurs and, if so, what it consists of or where further information may be obtained. This subparagraph will apply to research conducted abroad in collaboration with foreign governments or international organizations absent the explicit nonconcurrence of those governments or organizations.

* * * * *

[FR Doc. 78-30752 Filed 11-2-78; 8:45 am]

to the attorney whose address shall appear on the voucher.

§ 35.8 Release.

Acceptance by the claimant, his agent or legal representative, of any award, compromise or settlement made hereunder, shall be final and conclusive on the claimant, his agent or legal representative and any other person on whose behalf or for whose benefit the claim has been presented, and shall constitute a complete release of any claim against the United States and against any employee of the Government whose act or omission gave rise to the claim, by reason of the same subject matter.

§ 35.9 Penalties.

A person who files a false claim or makes a false or fraudulent statement in a claim against the United States may be liable to a fine of not more than $10,000 or to imprisonment of not more than 5 years, or both (18 U.S.C. 287,1001), and, in addition, to a forfeiture of $2,000 and a penalty of double the loss or damage sustained by the United States (31 U.S.C. 231).

§ 35.10 Limitation on Department's authority.

(a) An award, compromise or settlement of a claim hereunder in excess of $25,000 shall be effected only with the prior written approval of the Attorney General or his designee. For the purposes of this paragraph, a principal claim and any derivative or subrogated claim shall be treated as a single claim.

(b) An administrative claim may be adjusted, determined, compromised or settled hereunder only after consultation with the Department of Justice when, in the opinion of the Department:

(1) A new precedent or a new point of law is involved; or

(2) A question of policy is or may be involved; or

(3) The United States is or may be entitled to indemnity or contribution from a third party and the Department is unable to adjust the third party claim; or

(4) The compromise of a particular claim, as a practical matter, will or may control the disposition of a related claim in which the amount to be paid may exceed $25,000.

(c) An administrative claim may be adjusted, determined, compromised or settled only after consultation with the Department of Justice when it is learned that the United States or an employee, agent or cost plus contractor of the United States is involved in litigation based on a claim arising out of the same incident or transaction.

## PART 46—PROTECTION OF HUMAN SUBJECTS

### Subpart A

Sec.







Subpart B—Additional Protections Pertaining to Research, Development, and Related Activities Involving Fetuses, Pregnant Women, and Human In Vitro Fertilization

Sec.



Subpart C—General Provisions



AUTHORITY: 5 U.S.C. 301; sec. 474(a), 88 Stat. 352 (42 U.S.C. 2891-3(a)) unless otherwise noted.

### Subpart A

SOURCE: 40 FR 11854, Mar. 13, 1975. Redesignated at 40 FR 33528, Aug. 8, 1975.

§ 46.101 Applicability.

(a) The regulations in this part are applicable to all Department of Health, Education, and Welfare grants and contracts supporting research, development, and related activities in which human subjects are involved.

(b) The Secretary may, from time to time, determine in advance whether specific programs, methods, or procedures to which this part is applicable place subjects at risk, as defined in § 46.103(b). Such determinations will be published as notices in the FEDERAL REGISTER and will be included in an appendix to this part.

§ 46.102 Policy.

(a) Safeguarding the rights and welfare of subjects at risk in activities supported under grants and contracts from DHEW is primarily the responsibility of the institution which receives or is accountable to DHEW for the funds awarded for the support of the activity. In order to provide for the adequate discharge of this institutional responsibility, it is the policy of DHEW that no activity involving human subjects to be supported by DHEW grants or contracts shall be undertaken unless an Institutional Review Board has reviewed and approved such activity, and the institution has submitted to DHEW a certification of such review and approval, in accordance with the requirements of this part.

(b) This review shall determine whether these subjects will be placed at risk, and, if risk is involved, whether:

(1) The risks to the subject are so outweighed by the sum of the benefit to the subject and the importance of the knowledge to be gained as to warrant a decision to allow the subject to accept these risks;

(2) The rights and welfare of any such subjects will be adequately protected; and

(3) Legally effective informed consent will be obtained by adequate and appropriate methods in accordance with the provisions of this part.

(c) Unless the activity is covered by subpart B of this part, if it involves as subjects women who could become pregnant, the Board shall also determine as part of its review that adequate and appropriate steps will be taken to avoid involvement of women who are in fact pregnant (as evidenced by any of the presumptive signs of pregnancy, such as missed menses, or by a medically acceptable pregnancy test), when such activity would involve risk to a fetus.

(d) Where the Board finds risk is involved under paragraph (b) of this section, it shall review the conduct of the activity at timely intervals.

(e) No grant or contract involving human subjects at risk shall be made to an individual unless he is affiliated with or sponsored by an institution which can and does assume responsibility for the subjects involved.

[40 FR 11854, Mar. 13, 1975. Redesignated and amended at 40 FR 33528, Aug. 8, 1975; 43 FR 1759, Jan. 11, 1978]

§ 46.103 Definitions.

(a) "Institution" means any public or private institution or agency (including Federal, State, and local government agencies).

(b) "Subject at risk" [1] means any individual who may be exposed to the possibility of injury, including physical, psychological, or social injury, as a consequence of participation as a subject in any research, development, or related activity which departs from the application of those established and accepted methods necessary to meet his needs, or which increases the ordinary risks of daily life, including the recognized risks inherent in a chosen occupation or field of service.

(c) "Informed consent" means the knowing consent of an individual or his legally authorized representative, so situated as to be able to exercise free power of choice without undue inducement or any element of force, fraud, deceit, duress, or other form of constraint or coercion. The basic elements of information necessary to such consent include:

(1) A fair explanation of the procedures to be followed, and their purposes, including identification of any procedures which are experimental;

(2) A description of any attendant discomforts and risks reasonably to be expected;

(3) A description of any benefits reasonably to be expected;

(4) A disclosure of any appropriate alternative procedures that might be advantageous for the subject;

(5) An offer to answer any inquiries concerning the procedures; and

(6) An instruction that the person is free to withdraw his consent and to discontinue participation in the project or activity at any time without prejudice to the subject.

(d) "Secretary" means the Secretary of Health, Education, and Welfare or any other officer or employee of the Department of Health, Education, and Welfare to whom authority has been delegated.

(e) "DHEW" means the Department of Health, Education, and Welfare.

(f) "Approved assurance" means a document that fulfills the requirements of this part and is approved by the Secretary.

(g) "Certification" means the official institutional notification to DHEW in accordance with the requirements of this part that a project or activity involving human subjects at risk has been reviewed and approved by the institution in accordance with the "approved assurance" on file at DHEW.

(h) "Legally authorized representative" means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to such subject's participation in the particular activity or procedure.

§ 46.104 Submission of assurances.

(a) Recipients or prospective recipients of DHEW support under a grant or contract involving subjects at risk shall provide written assurance acceptable to DHEW that they will comply with DHEW policy as set forth in this part. Each assurance shall embody a statement of compliance with DHEW requirements for initial and continuing Institutional Review Board review of the supported activities; a set of implementing guidelines, including identification of the Board and a description of its review procedures; or, in the case of special assurances concerned with single activities or projects, a report of initial findings of the Board and of its proposed continuing review procedures.

(b) Such assurance shall be executed by an individual authorized to act for the institution and to assume on behalf of the institution the obligations imposed by this part, and shall be filed in such form and manner as the Secretary may require.

§ 46.105 Types of assurances.

(a) *General assurances.* A general assurance describes the review and implementation procedures applicable to all DHEW-supported activities conducted by an institution regardless of the number, location, or types of its components or field activities. General assurances will be required from institutions having a significant number of concurrent DHEW-supported projects or activities involving human subjects.

(b) *Special assurances.* A special assurance will, as a rule, describe those review and implementation procedures applicable to a single activity or project. A special assurance will not be solicited or accepted from an institution which has on file with DHEW an approved general assurance.

§ 46.106 Minimum requirements for general assurances.

General assurances shall be submitted in such form and manner as the Secretary may require. The institution must include, as part of its general assurance, implementing guidelines that specifically provide for:

(a) A statement of principles which will govern the institution in the discharge of its responsibilities for protecting the rights and welfare of subjects. This may include appropriate existing codes or declarations, or statements formulated by the institution itself. It is to be understood that no such principles supersede DHEW policy or applicable law.

(b) An Institutional Review Board or Board structure which will conduct initial and continuing reviews in accordance with the policy outlined in § 46.102. Such Board structure or Board shall meet the following requirements:

(1) The Board must be composed of not less than five persons with varying backgrounds to assure complete and adequate review of activities commonly conducted by the institution. The Board must be sufficiently qualified through the maturity, experience, and expertise of its members and diversity of its membership to insure respect for its advice and counsel for safeguarding the rights and welfare of human subjects. In addition to possessing the professional competence necessary to review specific activities, the Board must be able to ascertain the acceptability of applications and proposals in terms of institutional commitments and regulations, applicable law, standards of professional conduct and practice, and community attitudes. The Board must therefore include persons whose concerns are in these areas.

(2) The Board members shall be identified to DHEW by name; earned degrees, if any; position or occupation; representative capacity; and by other pertinent indications of experience such as board certification, licenses, etc., sufficient to describe each member's chief anticipated contributions to Board deliberations. Any employment or other relationship between each member and the institution shall be identified, i.e., full-time employee, part-time employee, member of governing panel or board, paid consultant, unpaid consultant. Changes in Board membership shall be reported to DHEW in such form and at such times as the Secretary may require.

(3) No member of a Board shall be involved in either the initial or continuing review of an activity in which he has a conflicting interest, except to provide information requested by the Board.

(4) No Board shall consist entirely of persons who are officers, employees, or agents, of, or are otherwise associated with the institution, apart from their membership on the Board.

(5) No Board shall consist entirely of members of a single professional group.

(6) The quorum of the Board shall be defined, but may in no event be less than a majority of the total membership duly convened to carry out the Board's responsibilities under the terms of the assurance.

(c) Procedures which the institution will follow in its initial and continuing review of applications, proposals, and activities.

(d) Procedures which the Board will follow (1) to provide advice and counsel to activity directors and investigators with regard to the Board's actions, (2) to insure prompt reporting to the Board of proposed changes in an activity and of unanticipated problems involving risk to subjects or others, and (3) to insure that any such problems, including adverse reactions to biologicals, drugs, radioisotope labeled drugs, or to medical devices, are promptly reported to DHEW.

[1] See interpretation document at 41 FR 26572, June 28, 1976.

(c) Procedures which the institution will follow to maintain an active and effective Board and to implement its recommendations.

**§ 46.107 Minimum requirements for special assurances.**

Special assurances shall be submitted in such form and manner as the Secretary may require. An acceptable special assurance shall:

(a) Identify the specific grant or contract involved by its full title; and by the name of the activity or project director, principal investigator, fellow, or other person immediately responsible for the conduct of the activity.

(b) Include a statement, executed by an appropriate institutional official, indicating that the institution has established an Institutional Review Board satisfying the requirements of § 46.106 (b).

(c) Describe the makeup of the Board and the training, experience, and background of its members, as required by § 46.106(b)(2).

(d) Describe in general terms the risks to subjects that the Board recognizes as inherent in the activity, and justify its decision that these risks are so outweighed by the sum of the benefit to the subject and the importance of the knowledge to be gained as to warrant the Board's decision to permit the subject to accept these risks.

(e) Describe the informed consent procedures to be used and attach documentation as required by § 46.110.

(f) Describe procedures which the Board will follow to insure prompt reporting to the Board of proposed changes in the activity and of any unanticipated problems, involving risks to subjects or others and to insure that any such problems, including adverse reactions to biologicals, drugs, radioisotope labelled drugs, or to medical devices are promptly reported to DHEW.

(g) Indicate at what time intervals the Board will meet to provide for continuing review. Such review must occur no less than annually.

(h) Be signed by the individual members of the Board and be endorsed by an appropriate institutional official.

**§ 46.108 Evaluation and disposition of assurances.**

(a) All assurances submitted in accordance with §§ 46.106 and 46.107 shall be evaluated by the Secretary through such officers and employees of DHEW and such experts or consultants engaged for this purpose as he determines to be appropriate. The Secretary's evaluation shall take into consideration, among other pertinent factors, the adequacy of the proposed Institutional Review Board in the light of the anticipated scope of the applicant institution's activities and the types of subject populations likely to be involved, the appropriateness of the proposed initial and continuing review procedures in the light of the probable risks, and the size and complexity of the institution.

(b) On the basis of his evaluation of an assurance pursuant to paragraph (a) of this section, the Secretary shall (1) approve, (2) enter into negotiations to develop a more satisfactory assurance, or (3) disapprove. With respect to approved assurances, the Secretary may determine the period during which any particular assurance or class of assurances shall remain effective or otherwise condition or restrict his approval. With respect to negotiations, the Secretary may, pending completion of negotiations for a general assurance, require an institution otherwise eligible for such an assurance, to submit special assurances.

**§ 46.109 Obligation to obtain informed consent; prohibition of exculpatory clauses.**

Any institution proposing to place any subject at risk is obligated to obtain and document legally effective informed consent. No such informed consent, oral or written, obtained under an assurance provided pursuant to this part shall include any exculpatory language through which the subject is made to waive, or to appear to waive, any of his legal rights, including any release of the institution or its agents from liability for negligence.





**§ 46.110 Documentation of informed consent.**

The actual procedure utilized in obtaining legally effective informed consent and the basis for Institutional Review Board determinations that the procedures are adequate and appropriate shall be fully documented. The documentation of consent will employ one of the following three forms:

(a) Provision of a written consent document embodying all of the basic elements of informed consent. This may be read to the subject or to his legally authorized representative, but in any event he or his legally authorized representative must be given adequate opportunity to read it. This document is to be signed by the subject or his legally authorized representative. Sample copies of the consent form as approved by the Board are to be retained in its records.

(b) Provision of a "short form" written consent document indicating that the basic elements of informed consent have been presented orally to the subject or his legally authorized representative. Written summaries of what is to be said to the patient are to be approved by the Board. The short form is to be signed by the subject or his legally authorized representative and by an auditor witness to the oral presentation and to the subject's signature. A copy of the approved summary, annotated to show any additions, is to be signed by the persons officially obtaining the consent and by the auditor witness. Sample copies of the consent form and of the summaries as approved by the Board are to be retained in its records.

(c) Modification of either of the primary procedures outlined in paragraphs (a) and (b) of this section. Granting of permission to use modified procedures imposes additional responsibility upon the Board and the institution to establish: (1) That the risk to any subject is minimal, (2) that the use of either of the primary procedures for obtaining informed consent would surely invalidate objectives of considerable immediate importance, and (3) that any reasonable alternative means for attaining these objectives would be less advantageous to the subjects. The Board's reasons for permitting the use of modified procedures must be individually and specifically documented in the minutes and in reports of Board actions to the files of the institution. All such modifications should be regularly reconsidered as a function of continuing review and as required for annual review, with documentation of reaffirmation, revision, or discontinuation, as appropriate.

**§ 46.111 Submission and certification of applications and proposals, general assurances.**

(a) *Timely review.* Any institution having an approved general assurance shall indicate in each application or proposal for support of activities covered by this part (or in a separate document submitted with such application or proposal) that it has on file with DHEW such an assurance. In addition, unless the Secretary otherwise provides, each such application or proposal must be given review and, when found to involve subjects at risk, approval, prior to submission to DHEW. In the event the Secretary provides for the performance of institutional review of an application or proposal after its submission to DHEW, processing of such application or proposal by DHEW will under no circumstances be completed until such institutional review and approval has been certified. Except where the institution determines that human subjects are not involved, the application or proposal should be appropriately certified in the spaces provided on forms, or one of the following certifications, as appropriate, should be typed on the lower or right hand margin of the page bearing the name of an official authorized to sign or execute applications or proposals for the institution.

Human Subjects: Reviewed, Not at Risk.

(Date)

Human Subjects: Reviewed, At Risk, Approved

(Date)

(b) *Applications and proposals not certified.* Applications and proposals not properly certified, or submitted as not involving human subjects and found by the operating agency to involve human subjects, will be returned to the institution concerned.

**§ 46.112 Submission and certification of applications and proposals, special assurances.**

(a) Except as provided in paragraph (b) of this section, institutions not having an approved general assurance shall submit in or with each application or proposal for support of activities covered by this part a separate special assurance and certification of its review and approval.

(b) If the Secretary so provides, the assurance which must be submitted in or with the application or proposal under paragraph (a) of this section need satisfy only the requirements of §§ 46.107 (a) and 46.107(b). Under such circumstances, processing of such application or proposal by DHEW will not be completed until a further assurance satisfying the remaining requirements of § 46.107 has been submitted to DHEW.

(c) An assurance and certification prepared in accordance with this part and approved by DHEW shall be considered to have met the requirement for certification for the initial grant or contract period concerned. If the terms of the grant or contract recommend additional support periods, each application or proposal for continuation or renewal of support must satisfy the requirements of this section or § 48.111 whichever is applicable at the time of its submission.

**§ 46.113 Applications and proposals lacking definite plans for involvement of human subjects.**

Certain types of applications or proposals are submitted with the knowledge that subjects are to be involved within the support period, but definite plans for this involvement would not normally be set forth in the application or proposal. These include such activities as (a) institutional type grants where selection of projects is the responsibility of the institution, (b) training grants where training projects remain to be selected, and (c) research, pilot, or developmental studies in which involvement depends upon such things as the completion of instruments, or of prior animal studies, or upon the purification of compounds. Such applications or proposals shall be reviewed and certified in the same manner as more definitive applications or proposals. The initial certification indicates institutional approval of the applications or proposals as submitted, and commits the institution to later review of the plans when completed. Such later review and certification to DHEW should be completed prior to the beginning of the budget period during which actual involvement of human subjects is to begin. Review and certification to DHEW must in any event be completed prior to involvement of human subjects.

**§ 46.114 Applications and proposals submitted with the intent of not involving human subjects.**

If an application or proposal does not anticipate involving or intend to involve human subjects, no certification should be included with the initial submission of the application or proposal. In those instances, however, when later it becomes appropriate to use all or part of awarded funds for one or more activities which will involve subjects, each such activity shall be reviewed and approved in accordance with the assurance of the institution prior to the involvement of subjects. In addition, no such activity shall be undertaken until the institution has submitted to DHEW. (a) A certification that the activity has been reviewed and approved in accordance with this part, and (b) a detailed description of the proposed activity (including any protocol or similar document). Also, where support is provided by project grants or contracts, subjects shall not be involved prior to certification and institutional receipt of DHEW approval and, in the case of contracts, prior to negotiation and approval of an amended contract description of work.





**§ 46.115 Evaluation and disposition of applications and proposals.**

(a) Notwithstanding any prior review, approval, and certification by the institution all applications or proposals involving human subjects at risk submitted to DHEW shall be evaluated by the Secretary for compliance with this part through such officers and employees of the Department and such experts or consultants engaged for this purpose as he determines to be appropriate. This evaluation may take into account, among other pertinent factors, the apparent risks to the subjects, the adequacy of protection against these risks, the potential benefits of the activity to the subjects and to others, and the importance of the knowledge to be gained.

(b) Disposition. On the basis of his evaluation of an application or proposal pursuant to paragraph (a) of this section and subject to such approval or recommendation by or consultation with appropriate councils, committees, or other bodies as may be required by law, the Secretary shall (1) approve, (2) defer for further evaluation, or (3) disapprove support of the proposed activity in whole or in part. With respect to any approved grant or contract, the Secretary may impose conditions, including restrictions on the use of certain procedures, or certain subject groups, or requiring use of specified safeguards or informed consent procedures when in his judgment such conditions are necessary for the protection of human subjects.

**§ 46.116 Cooperative activities.**

Cooperative activities are those which involve institutions in addition to the grantee or prime contractor (such as a contractor under a grantee or a subcontractor under a prime contractor). If, in such instances, the grantee or prime contractor obtains access to all or some of the subjects involved through one or more cooperating institutions, the basic DHEW policy applies and the grantee or prime contractor remains responsible for safeguarding the rights and welfare of the subjects.

(a) *Institution with approved general assurance.* Initial and continuing review by the institution may be carried out by one or a combination of procedures:

(1) Cooperating institution with approved general assurance. When the cooperating institution has on file with DHEW an approved general assurance, the grantee or contractor may, in addition to its own review, request the cooperating institution to conduct an independent review and to report its recommendations on those aspects of the activity that concern individuals for whom the cooperating institution has responsibility under its own assurance to the grantee's or contractor's Institutional Review Board. The grantee or contractor may, at its discretion, concur with or further restrict the recommendations of the cooperating institution. It is the responsibility of the grantee or contractor to maintain communication with the Boards of the cooperating institution. However, the cooperating institution shall promptly notify the grantee or contracting institution whenever the cooperating institution finds the conduct of the project or activity within its purview unsatisfactory.

(2) Cooperating institution with no approved general assurance. When the cooperating institution does not have an approved general assurance on file with DHEW, the DHEW may require the submission of a general or special assurance which, if approved, will permit the grantee or contractor to follow the procedure outlined in the preceding subparagraph.

(3) Interinstitutional joint review. The grantee or contracting institution may wish to develop an agreement with cooperating institutions to provide for an Institutional Review Board with representatives from cooperating institutions. Representatives of cooperating institutions may be appointed as ad hoc members of the grantee or contracting institution's existing Institutional Review Board or, if cooperation is on a frequent or continuing basis as between a medical school and a group of affiliated hospitals, appointments for extended periods may be made. All such cooperative arrangements must be approved by DHEW as

part of a general assurance, or as an amendment to a general assurance.

(b) *Institutions with special assurances.* While responsibility for initial and continuing review necessarily lies with the grantee or contracting institution, DHEW may also require approved assurances from those cooperating institutions having immediate responsibility for subjects.

If the cooperating institution has on file with DHEW an approved general assurance, the grantee or contractor shall request the cooperating institution to conduct its own independent review of those aspects of the project or activity which will involve human subjects for which it has responsibility. Such a request shall be in writing and should provide for direct notification of the grantee's or contractor's Institutional Review Board in the event that the cooperating institution's Board finds the conduct of the activity to be unsatisfactory. If the cooperating institution does not have an approved general assurance on file with DHEW, it must submit to DHEW a general or special assurance which is determined by DHEW to comply with the provisions of this part.

**§ 46.117 Investigational new drug 30-day delay requirement.**

Where an institution is required to prepare or to submit a certification under §§ 46.111, 46.112, 46.113, or § 46.114 and the application or proposal involves an investigational new drug within the meaning of The Food, Drug, and Cosmetic Act, the drug shall be identified in the certification together with a statement that the 30-day delay required by 21 CFR 312.1(a)(2) has elapsed and the Food and Drug Administration has not, prior to expiration of such 30-day interval, requested that the sponsor continue to withhold or to restrict use of the drug in human subjects; or that the Food and Drug Administration has waived the 30-day delay requirement: *Provided, however,* That in those cases in which the 30-day delay interval has neither expired nor been waived, a statement shall be forwarded to DHEW upon such expiration or upon receipt of a waiver. No certification shall be considered acceptable until such statement has been received.

**§ 46.118 Institution's executive responsibility.**

Specific executive functions to be conducted by the institution include policy development and promulgation and continuing indoctrination of personnel. Appropriate administrative assistance and support shall be provided for the Board's functions. Implementation of the Board's recommendations through appropriate administrative action and followup is a condition of DHEW approval of an assurance. Board approvals, favorable actions, and recommendations are subject to review and to disapproval or further restriction by the institution officials. Board disapprovals, restrictions, or conditions cannot be rescinded or removed except by action of a Board described in the assurance approved by DHEW.

**§ 46.119 Institution's records; confidentiality.**

(a) Copies of all documents presented or required for initial and continuing review by the Institutional Review Board, such as Board minutes, records of subject's consent, transmittals on actions, instructions, and conditions resulting from Board deliberations addressed to the activity director, are to be retained by the institution, subject to the terms and conditions of grant and contract awards.

(b) Except as otherwise provided by law information in the records or possession of an institution acquired in connection with an activity covered by this part, which information refers to or can be identified with a particular subject, may not be disclosed except:

(1) With the consent of the subject or his legally authorized representative; or

(2) As may be necessary for the Secretary to carry out his responsibilities under this part.

**§ 46.120 Reports.**

Each institution with an approved assurance shall provide the Secretary with such reports and other information as the Secretary may from time to time prescribe.





**§ 46.121 Early termination of awards; evaluation of subsequent applications and proposals.**

(a) If, in the judgment of the Secretary an institution has failed materially to comply with the terms of this policy with respect to a particular DHEW grant or contract, he may require that said grant or contract be terminated or suspended in the manner prescribed in applicable grant or procurement regulations.

(b) In evaluating applications or proposals for support of activities covered by this part, the Secretary may take into account, in addition to all other eligibility requirements and program criteria, such factors as: (1) Whether the applicant or offeror has been subject to a termination or suspension under paragraph (a) of this section, (2) whether the applicant or offeror or the person who would direct the scientific and technical aspects of an activity has in the judgment of the Secretary failed materially to discharge his, her, or its responsibility for the protection of the rights and welfare of subjects in his, her, or its care (whether or not DHEW funds were involved), and (3) whether, where past deficiencies have existed in discharging such responsibility, adequate steps have in the judgment of the Secretary been taken to eliminate these deficiencies.

**§ 46.122 Conditions.**

The Secretary may with respect to any grant or contract or any class of grants or contracts impose additional conditions prior to or at the time of any award when in his judgment such conditions are necessary for the protection of human subjects.

## Subpart B—Additional Protections Pertaining to Research, Development, and Related Activities Involving Fetuses, Pregnant Women, and Human In Vitro Fertilization

Source: 40 FR 33528, Aug. 8, 1975, unless otherwise noted.

**§ 46.201 Applicability.**

(a) The regulations in this subpart are applicable to all Department of Health, Education, and Welfare grants and contracts supporting research, development, and related activities involving: (1) The fetus, (2) pregnant women, and (3) human *in vitro* fertilization.

(b) Nothing in this subpart shall be construed as indicating that compliance with the procedures set forth herein will in any way render inapplicable pertinent State or local laws bearing upon activities covered by this subpart.

(c) The requirements of this subpart are in addition to those imposed under the other subparts of this part.

**§ 46.202 Purpose.**

It is the purpose of this subpart to provide additional safeguards in reviewing activities to which this subpart is applicable to assure that they conform to appropriate ethical standards and relate to important societal needs.

**§ 46.203 Definitions.**

As used in this subpart:

(a) "Secretary" means the Secretary of Health, Education, and Welfare and any other officer or employee of the Department of Health, Education, and Welfare to whom authority has been delegated.

(b) "Pregnancy" encompasses the period of time from confirmation of implantation (through any of the presumptive signs of pregnancy, such as missed menses, or by a medically acceptable pregnancy test), until expulsion or extraction of the fetus.

(c) "Fetus" means the product of conception from the time of implantation (as evidenced by any of the presumptive signs of pregnancy, such as missed menses, or a medically acceptable pregnancy test), until a determination is made, following expulsion or extraction of the fetus, that it is viable.

(d) "Viable" as it pertains to the fetus means being able, after either spontaneous or induced delivery, to survive (given the benefit of available medical therapy) to the point of inde-

EXHIBIT "E"

# S. B. 447

SENATE BILL NO. 447—SENATOR JACOBSEN

APRIL 10, 1979

Referred to Committee on Human Resources and Facilities

SUMMARY—Makes various changes to law pertaining to dairy products and substitutes. (BDR 51-458)

FISCAL NOTE: Effect on Local Government: No.
Effect on the State or on Industrial Insurance: Effect less than $2,000.

EXPLANATION—Matter in *italics* is new; matter in brackets [ ] is material to be omitted.

AN ACT relating to dairy products and substitutes; providing for allocation of certain interest to the dairy commission fund to retain interest; prohibiting the sale of a substitute dairy product below cost; increasing a license application fee; providing credit for certain assessments against other assessments; increasing the time records must be retained; preserving the state dairy commission and its authority beyond 1981; and providing other matters properly relating thereto.

***The People of the State of Nevada, represented in Senate and Assembly, do enact as follows:***

SECTION 1. NRS 356.087 is hereby amended to read as follows:

356.087 1. Except as provided in subsections 2 and 3, all interest paid on money belonging to the State of Nevada [shall] *must* be deposited in the state general fund.

2. At the end of each quarter of each fiscal year, the state treasurer shall:

(a) Compute the proportion of total deposits of state moneys pursuant to the provisions of this chapter which were attributable during the quarter to the state highway fund, the motor vehicle fund and the taxicab authority fund created by NRS 408.235, NRS 482.180 and NRS 706.8825, respectively;

(b) Apply such proportion to the total amount of interest paid during that quarter to the state treasurer on deposits of state moneys; and

(c) Credit to the state highway fund and the taxicab authority fund an amount equal to the amount arrived at by the computation in paragraph (b).

3. The legislators' retirement fund, *the dairy commission fund,* the public employees' retirement fund, the state permanent school fund, the silicosis and disabled pension fund and the fish and game fund [shall] *must* have allocated to it its proportionate share of the interest earned

EXHIBIT "F"

(REPRINTED WITH ADOPTED AMENDMENTS)

FIRST REPRINT

# S. B. 466

SENATE BILL NO. 466—SENATORS SLOAN, DON ASHWORTH, KEITH ASHWORTH, BLAKEMORE, CLOSE, DODGE, ECHOLS, FAISS, FORD, GIBSON, GLASER, HERNSTADT, JACOBSEN, KOSINSKI, LAMB, McCORKLE, NEAL, RAGGIO, WILSON AND YOUNG

APRIL 12, 1979

Referred to Committee on Human Resources and Facilities

SUMMARY—Adds special provisions for institutions which care for dying persons. (BDR 40-1490)

FISCAL NOTE: Effect on Local Government: No.
Effect on the State or on Industrial Insurance: No.

EXPLANATION—Matter in *italics* is new; matter in brackets [ ] is material to be omitted.

AN ACT relating to care of the dying; adding special provisions for institutions which care for terminally ill persons; and providing other matters properly relating thereto.

*The People of the State of Nevada, represented in Senate and Assembly, do enact as follows:*

SECTION 1. Chapter 449 of NRS is hereby amended by adding thereto a new section which shall read as follows:

*"Hospice" means an establishment which is staffed and equipped to:*

*1. Provide care, either in the home or in a facility, or both, for persons who are terminally ill and do not require the full services of a hospital or skilled nursing facility;*

*2. Offer medical services under the direction of a physician and a 24-hour professional nursing staff; and*

*3. Provide, directly or by arrangement, social, psychological or spiritual services for the patient and his family.*

SEC. 2. NRS 449.001 is hereby amended to read as follows:

449.001 As used in NRS 449.001 to 449.245, inclusive, unless the context otherwise requires, the words and terms defined in NRS 449.002 to 449.018, inclusive, [and section 1 of this act] *section 2 of Senate Bill No. 79 of the 60th session of the legislature and section 1 of this act* have the meanings ascribed to them in those sections.

SEC. 3. NRS 449.007 is hereby amended to read as follows:

449.007 "Health and care facility" includes alcohol or drug treatment facility, ambulatory surgical center, child care facility, group care