

Library

MEMBERS PRESENT: Chairman Stewart
Vice Chairman Sader
Mr. Thompson
Ms. Foley
Mr. Beyer
Mr. Price
Mr. Chaney
Mr. Malone
Mrs. Cafferata
Ms. Ham
Mr. Banner

MEMBERS ABSENT: None

GUESTS PRESENT: Gene Combs; NV Division of Investigations
and Narcotics
G. R. Tucker; NV State Board of Pharmacy
Mimi Rodden; Historical Preservation and
Archaeology Division
Colleen Dolan; UNR Intern (Stewart)
Bob Evans; UNR Intern (Rusk)
James B. Flynn; The Upjohn Company
Richard C. Mehornay; Merrell-Dow Pharmaceuticals/
Pharmaceuticals Manufacturers Association
Richard G. Pugh; NV State Medical Association
Guy Louis Rocha; State, County and Municipal
Archives
Larry Wahrenbrock
Mert Crouch
Chris Brower; Comstock Historic District
Commission
John W. Borda; NV Motor Transport Association
Jim Schryvek; Comstock Tunnel and Drilling
Company
Carole Vilardo; Citizens for Private
Enterprise, Southern Office
Ken Scruggs
Daryl E. Capurro; NV Motor Transport
Association
Bob Warren; NV Mining Association
Bruce Laxalt; Washoe County District Attorney
Guy Shipler, KOH
Ralph Whitworth, UNR Intern (Vergiels)
Laura Baskerville, UNR Intern (Kosinski)
William Tayler
Dale M. Newlin
W. J. Wich
Pat Kubel

Chairman Stewart called the meeting to order at 8:10 a.m. and explained that the Committee, having terminated the public hearing on AB 112 on Monday, 30 March 1981, would first take action on this bill.

AB 112: Limits exercise of eminent domain to take land in historic districts for use in mining or related activities.

Mrs. Cafferata moved ADOPT AMENDMENT 351 TO AB 112, seconded by Ms. Ham. (See EXHIBIT B attached to the minutes for Monday, 30 March 1981.) During the discussion that followed, Mr. Thompson noted the amendment itself should be modified so as to limit the action to historic districts. Mrs. Cafferata agreed with this suggestion.

Mr. Thompson moved AMEND AMENDMENT 351 TO AB 112 so as to limit it to historic districts, seconded by Mrs. Cafferata. The motion passed with all voting in favor except Mr. Price, who voted against.

Next Mr. Stewart moved ADOPT SUBSTITUTE AMENDMENT 352 TO AB 112, seconded by Mr. Sader. (See EXHIBIT A attached to the minutes for Monday, 30 March 1981.) During the ensuing discussion the following points were made:

Mr. Stewart: Amendment 351 does provide for a public hearing, but it has no teeth to it since the body holding the public hearing could even be the mining company; thus, this could appear as though we are only throwing a sop to the people. Additionally, an elected body is a more appropriate body to determine the public need, and that is the only justification for exercising the right of eminent domain: public need.

Mr. Sader: Amendment 352 addresses and satisfies two main problems which arose with the original bill: the power is in an appointed commission rather than a public polity elected by the people, and there are no guidelines. Also, the original bill dealt only with historic districts, which could cause the mining companies to become involved in local politics vis-a-vis the establishment of these districts and the possible effect on future mining operations. Amendment 352 allows the public body to make a decision on the question in a much shorter (2-3 months) time frame than could be expected from a court proceeding (2-3 years).

Mrs. Cafferata: Amendment 352 puts too much power in the hands of the County Commissioners; it gives them veto power and the Commissioners' decision would be almost impossible to overturn in court.

Mr. Price: Mining companies should not have the right of eminent domain at all; if they didn't already have it they would almost definitely be unable to get it at present. He then related the

experiences of Butte, Montana and stated that if the profits make it worthwhile the mining companies will not hesitate to take over a whole town through eminent domain. The local companies are not as much of a problem as those from out of town who are more concerned with profits and don't really care about local sentiment. If the Legislature is not going to repeal the right of eminent domain for private mining companies, then they ought to make it as difficult as possible for these companies to exercise this right. It should also be necessary for these companies to prove beyond a doubt every point necessary prior to proceeding with this power.

Mr. Chaney: It might be preferable to recommend review of this statute a few years from now for consideration of possible repeal rather than to keep adding hurdles to it. The best action for the people and their livelihood is what should be of primary concern. This bill may be an overreaction to one single incident. There should be provision for both sides to be able to air their views, but this bill should be scrutinized from all angles: possible repeal, overreaction to one incident, etc.

Mr. Beyer: The Legislators may be overreacting rather than acting concerning this matter. Lyon County Commissioners have apparently managed to exercise some powers restricting the operations of mining companies using existing laws. If the companies are to have the power of eminent domain, there are apparently sufficient regulations at the County level to restrict their activity and still allow for the proper development of mine facilities. Additionally, mining companies do provide jobs for the people of Nevada, and the business world should not be painted as the rapist of the environment, as the bad guys, etc. all the time.

Ms. Foley: The point is whether the courts or the County Commission should have the final decision on eminent domain. It is preferable to have a judge and jury decide this type of problem.

Mr. Stewart: In response to Ms. Foley, under the current laws the judge has no choice in the matter; all the mining company must do is demonstrate need for the land in connection with a mining operation and the judge must grant eminent domain: the statutes do not allow for consideration of other counterweighing interests.

Mr. Malone: Large corporations can put a lot of pressure on County Commissioners and can cause them to pass regulations opposed by the people in the district. Although a court proceeding may take longer, it is preferable to other suggested options.

Mrs. Cafferata: Mining companies mine for minerals which are much needed by our country. While these companies do make a profit from this, they are one of the best national interests

we have and generally they proceed in proper and acceptable ways.

Mr. Price: There is nothing inherently wrong with making a profit, and mining companies do provide jobs. There should be a balance of power, however, with neither one side nor the other having the advantage.

Mr. Stewart: One of the most important of our freedoms--if not the basis for all freedoms--is the right to own and acquire property. This applies not only to big business, but also to individuals who want simply to own a house. Private companies should not have the right of eminent domain; however as a compromise, Amendment 352 which provides for checks and balances in this matter has been suggested.

Mr. Banner: There should be no right of eminent domain for public nor private companies without there also being a procedure for airing grievances as well as a provision for checks and balances. There should always be a method for working out a compromise solution. He related an incident involving an expressway and its effects upon homes and property values in the area immediately adjoining, but not directly in the path of, the expressway noting Amendment 352 might have permitted a compromise in this situation.

Ms. Ham: Amendment 352 does not apply to government entities nor to public utilities, whereas Amendment 351 does.

On Mr. Stewart's motion to ADOPT SUBSTITUTE AMENDMENT 352 TO AB 112 the motion failed with seven (7) votes against and four (4) votes in favor.

Regarding Mrs. Cafferata's motion to ADOPT AMENDMENT 351 (AS AMENDED) TO AB 112, the motion carried with seven (7) votes in favor and three (3) votes against. Mr. Banner was absent at the time of the vote.

Mrs. Cafferata moved DO PASS AB 112 AS AMENDED, seconded by Ms. Ham and passed unanimously, with Mr. Banner absent at the time of the vote.

AB 53: Amends certain provisions relating to controlled substances and dangerous drugs.

Mrs. Cafferata noted that the subcommittee appointed to work on this bill had submitted some amendments to the bill drafter's office for addition to it. Unfortunately, there was apparently some confusion and the amended version of AB 53 has portions which need to be changed. She asked the Committee to keep this in mind during this hearing.

Mrs. Cafferata said the intent of the subcommittee had been to leave in all portions referring to forgery, to raise the penalty to a felony for selling prescriptions or drugs for any type of

remuneration, and to include other amendments requested by the Department of Law Enforcement Assistance. She noted that if it were a felony to sell prescriptions or drugs, then the various licensing boards could revoke the individual's license for this violation, rather than just "slap their hands", give them a \$1,000 fine, and they're back in business the next day. (See page 2, lines 5-6, etc.)

Mr. Combs of the Division of Investigations and Narcotics (DIN) testified that the DIN agrees with the amended version of the bill, as well as with the amendments Mrs. Cafferata mentioned earlier. He noted raising the penalty throughout the bill from a gross misdemeanor to a felony was especially appropriate, since a person prescribing and/or dispensing controlled substances wrongly and knowingly should be punished as severely as the individual attempting to obtain these substances.

Mr. Combs noted there was one other area which might cause problems, and that was section 5, subsections 6 and 7 of AB 53. He explained the DIN was not concerned with how the manufacturers conduct business, but with enforcement and controls of controlled substances that either are or could get on the street without anyone being able to trace the route used to get them there. In all other instances a controlled substance must be handled by a prescription, duly recorded and "checkable". Thus, DIN can go back and verify in every instance except where samples are concerned. He cited the example of the Storey County Clinic, where apparently many drugs (including a lot of samples) which could not be accounted for were found. He also cited examples of remiss pharmacies which simply toss samples out in the garbage, since pharmacies cannot use them; he added DIN was going to take action in this area.

Mr. Combs felt if DIN could stop the dispensing of samples, it would remove one area of drug diversion and help DIN keep a better "handle" on these controlled substances.

Mr. Chaney asked how one would go about stopping out-of-state manufacturers from mailing samples of controlled substances to physicians and/or pharmacies. Mr. Combs was not certain this could be successfully accomplished. He also could not say who would be held responsible if a physician and/or pharmacy received such substances from an out-of-state supplier; he did not think it fair to penalize the physician or pharmacy. He admitted this is DIN's first attempt to place controls on samples, and it isn't clear how these controls can be enforced. He hoped the physicians and pharmacies would advise their suppliers they could no longer legally receive samples, and that this would eventually stop the suppliers from sending out these samples.

In reply to Mrs. Cafferata it was noted that the suppliers do have to fill out forms regarding samples distributed; Mr. Combs was not aware, however, of any requirement for receipt forms

for these drugs nor of any other means for verifying they were actually distributed to a physician as samples.

Mr. Stewart asked for clarification of the term "registrant" as used on page 4, line 33. He was told this referred to those individuals who can legally receive controlled substances: practitioners authorized to dispense, pharmacies, etc.

Regarding page 4, lines 34 and 35, Mr. Combs was not sure if this would prevent a salesman from delivering an order from the supplier to the requesting physician, but he assumed--and hoped--it would. He explained DIN does not want the salesman to have controlled substances in his possession, in his vehicle, etc. He then explained about the security precautions required of all those authorized to handle controlled substances, and insinuated salesmen either would not or could not take these precautions.

In reply to Mr. Price it was noted that while there are no manufacturers of controlled substances in Nevada, there are distributors. It was further explained that both these groups have to be registered by the Nevada State Board of Pharmacy in order to do business in this state, and that revocation of their licenses is one way of enforcing a law banning the sending out of samples.

Mrs. Cafferata noted that line 19, section 8, page 5 needed some work, in that as written it allows pharmacists to fill or refill prescriptions for controlled substances for use by peace officers in the performance of their duties; this was not the intent of the Committee's amendment. Additionally, this section allows the pharmacist to state he knew it was a peace officer at the time, thus his actions could not be proven to be illegal. Mr. Combs noted lines 19 and 20 could be completely deleted without any effect upon an officer's ability to perform his duties.

In reply to Mr. Price it was explained that subsection 2 of section 3 simply reinforces what is a condition of the Pharmacy's license: those individuals responsible for monitoring controlled substances have the authority to examine and, if necessary, confiscate the Pharmacy's records.

Next to testify on AB 53 was Mr. G. R. Tucker of the Nevada State Board of Pharmacy. He noted the Board was also in agreement with this bill, and in particular with Mrs. Cafferata's proposal to make the penalty a felony throughout the bill.

Mr. Tucker said he was appalled at the number of problems with controlled substances, not just in the big cities but throughout the state. He said these problems are increasing with the growth of the state, and that there is need for every tool possible to combat and control the drug problem in Nevada.

Mr. Tucker noted that the samples are getting to the street, and that while it has not been possible to trace the route via which

they get there, if samples are completely banned they will no longer be available for diversion to the street.

It was suggested that one possible solution to the problem might be to register all the detail men that carry these products; it was noted, however, that the Manufacturers' Association has already said this would be too much of a hassle.

Mr. Tucker stated that while the State does have control over the manufacturers via their licenses, there is no control over the unlicensed detail men who carry around samples of controlled substances. He added this includes no control over the storage of these substances, over the quality of the product after it has been in the salesman's possession for a period of time and possibly inadvertently left in the sun, etc.

It was explained to Mr. Chaney that physicians usually use samples of a drug in order to determine if the patient is able to tolerate that particular substance; however, Mr. Tucker noted the physician often gives out extra sample doses. If these are not used by the patient, they will often end up in the garbage can.

Mr. Tucker then described generic drugs and how they differ from name brand drugs. Mr. Chaney pointed out that since there is a difference between the two, it would appear reasonable for a physician to want to prescribe a sample dose prior to writing a prescription for a large quantity.

Mr. Price pointed out that many manufacturers send out samples because they know physicians are apt to stick with a limited range of drugs with which they have experience and are satisfied, rather than try a lot of other brands. Thus, if a doctor starts by using a sample he has received, there is a good chance he will stick with that brand.

Ms. Ham noted there had been a theft of drugs from a Nevada hospital during the month of February and that to date the only reprimand has been a \$1,000 fine and a placing of the hospital on probation. She wondered if this bill would affect that type of situation. Mr. Tucker replied this bill would not have affected that case. He said it is very difficult to do anything with hospitals, but noted that the penalties the State Board of Pharmacy will be handing down in the future will be much more severe. Mr. Tucker went on to point out that it is his intention to treat retail pharmacies and hospital pharmacies identically, since the laws governing them do not differentiate between the two.

Next to testify was Mr. Richard Mehornay, Government Affairs Area Manager for Merrell-Dow Laboratories and also representing the Pharmaceutical Manufacturers Association.

Mr. Mehornay stated he would like to limit his testimony to that portion of AB 53 concerning sampling of controlled substances, as noted on page 4, section 5, subsections 6 and 7. He said the organizations he represents feel this portion to be too far-reaching and not really necessary.

Mr. Mehornay went on to explain that prescription products are those that require a prescription of the legally authorized practitioner. They are legend drugs--they require a legend as established by the Food and Drug Administration--and they require a prescription only. He noted that only a segment of these drugs are controlled substances; i.e., controlled by the Federal Drug Enforcement Administration on the basis that there might be a potential for, or a demonstrated misuse of these or related drugs.

He stressed that controlled substances do have accepted and valid medical use, adding that these drugs are not only narcotics--which are typically scheduled in the higher schedules and are more restricted in how they are prescribed, etc.--but also cough preparations which happen to contain codeine in their mixture, tranquilizers, etc. In themselves, however, these drugs, as well as other legend drugs which require prescriptions, all have valid, accepted, legal medical use.

Mr. Mehornay agreed the entire area of substance abuse is a valid issue, as noted when in 1971 a federal law was passed which set up an exact prescribed manner for handling controlled substances and which subjects the manufacturer to a strict controlled schedule: he is controlled in exactly how much production material he receives, he has exact and restrictive inventory requirements, and his records as to the manufacture must be exacting, batch by batch. He is also charged with security of these substances: "The maintenance of effective controls against diversion."

Mr. Mehornay then described some of the valid uses of controlled substances and noted that, unfortunately, these same substances also have a misuse. He pointed out that Schedule II substances are not sampled. Schedule III through V substances, which in descending order are those drugs which tend to be the tranquilizers, anorectic agents, cough preparations, etc., are issued in sample doses. He explained that these drugs are placed where they are in the Schedules because the physician is not subject to as stringent requirements in his prescription, nor is the pharmacist subject to as strict requirements in the sense that the original prescription can be refilled five times within a six month period.

He then distributed copies of a section of the Code of Federal Regulations for Food and Drugs (EXHIBIT A). He explained that this code consists of very exacting requirements and referred to subsection (d) of EXHIBIT A which states that no sample of a controlled substance can be distributed unless several requirements

are met, including that the manufacturer or his representative receive a prior written receipt. He stressed that samples are typically given to the physician who wants them.

Mr. Mehornay then showed the Committee a copy of a multi-part form which lists, among other things, the physician's DEA number and the number of units received, and which must be signed by the physician himself. He also showed them what a typical sample packet looks like, noting that in this case the packet contains two units.

Mr. Mehornay stressed that all of the above controls are required under federal law, and that if complaints arise, the company is subject to loss of federal permission legally to manufacture the substance involved.

Next Mr. Mehornay quoted from section (f) of EXHIBIT A, which charges manufacturers, "when distributing controlled substances through agents...with providing and requiring adequate security to guard against theft and diversion while the substances are being stored or handled by the agent or agents."

Mr. Mehornay said that the whole issue of samples has been addressed previously and at the federal level. He pointed out that since the federal law went into effect in 1976, the American College of Neuropsychopharmacology asked the Drug Enforcement Administration to examine the area of controlled substances and the sampling thereof, while at the same time admitting they had no evidence of diversion or misuse. The DEA issued a survey, the National Association of Boards of Pharmacy issued a survey, and the National Institutes of Drug Abuse issued a survey, and at the end of one year DEA withdrew their proposed ban because they found no evidence of significant diversion. In fact, they praised the industry and the vast bulk of professionals for their handling of these substances. Mr. Mehornay said the issue was reviewed several more times, and the banning of sampling of controlled substances was deemed to be anti-competitive as well as unnecessary.

Next Mr. Mehornay pointed out that, since 1973, several states have considered the banning of sampling of these substances, but none have adopted such a ban.

It was further noted that the State of Colorado's Board of Pharmacy put through a regulation--at the urging of the Manufacturers' Association--requiring a signed written receipt, as is already required for controlled substances, for all legend drugs.

In reply to the question "why samples", it was explained that this a) enables the physician to determine if a substance works (in the case of a new drug), and b) enables the physician to determine how a patient reacts to a specific substance.

1018

Mr. Mehorney then raised the point that, if a physician prescribes a large quantity of a drug and following the first dose the patient reacts, the pharmacy cannot take back the unused portion of the prescription, by law. This is an unnecessary expense for the patient, and additionally, the patient is then left with this controlled substance to dispose of in whatever way he feels appropriate.

Another advantage to samples is that the physician can start therapy immediately, without waiting for the patient to arrange to get to the pharmacy in order to have his prescription filled.

Samples also allow the physician to defray some of the cost of medication for indigent patients, particularly when the condition is expected to be relatively short term.

In conclusion, Mr. Mehorney stressed that a) these substances are not narcotics, they are cough preparations, anorectic agents, etc.; b) the issue has been examined federally and by many states and it has been found that companies are acting responsibly; c) manufacturers are already required to maintain exact records and cannot distribute these drugs unless they have a prior signed receipt; and d) if there is no evidentiary base of misuse and/or diversion, then it is doubtful that this practice is a hazard to the health and safety of the public.

There followed an explanation of how the Nevada Schedule of Drugs does follow the standard federal schedule and how whether or not a salesman carries controlled substances usually depends upon the company for which he works and whether or not they manufacture such drugs.

In reply to Mr. Sader Mr. Mehorney said his testimony was only in opposition to those sections he had cited earlier, beyond that the organizations he was representing were not entering a statement.

It was further learned that there are currently five states which ban the sampling of controlled substances, while no state bans the sampling of prescription-only drugs. Those five bans were passed immediately following passage of the federal act, and those states (Massachusetts, New York, Kentucky, Kansas, and Utah) have as major a drug problem as any of the other states. It was added that those other states which considered similar bans eventually decided the benefits of sampling controlled substances far outweigh the minimum potential for abuse.

Mrs. Cafferata stated the impression that samples "flood" into doctors' offices unsolicited is an incorrect one, as far as controlled substances are concerned. Additionally, the doctors are only given those kinds of drugs which patients coming to that type of doctor or specialist would take. Also, the

1019

doctors use these samples for the benefit of the patient; not for "experimental purposes".

Mr. Price pointed out that in any place where you might end up with a number of drugs there is a potentially dangerous situation; it was added this includes the patient's home. Requiring receipting of all drugs might be one avenue for addressing this situation.

In reply to Mr. Thompson it was explained that the number of samples given to a physician often depends on the type of preparation involved; thus, the physician might receive many more samples of a cough medicine than he would of some other, more potent substance.

In reply to Ms. Ham's question as to where do the manufactured drugs which end up on the street come from, Mr. Mehornay said usually it is through diversion from either the pharmacy or the physician, often through robberies, importation from other countries, hijacking of shipments, etc.

Mr. Mehornay also passed out copies of a "Statement of the Pharmaceutical Manufacturers Association Concerning AB 53", which is attached as EXHIBIT B.

Next to testify was Mr. Richard Pugh, Executive Director of the State Medical Association.

He stated he had four points he wanted to make, and Mr. Mehornay covered every one of them. These involved: a) health care cost containment; b) very few abusers; c) the Medical Association supports all portions of AB 53, including Mrs. Cafferata's amendments, except section 5, subsections 6 and 7, which they oppose; and d) this bill will not solve the abuse problem, although it will benefit the people of Nevada.

Mr. Tucker then came forward to reiterate that these drugs were getting to the street, and that this had to be stopped. He said this was a severe problem, and samples are a part of it. Finally, he pointed out that whatever the Legislature decides regarding this bill will be the determination of what happens with drug samples on the street for the next two years.

Mr. Sader then asked Mr. Combs if there was, in the state of Nevada, a practice among drug manufacturers to give samples away in violation of federal requirements. Mr. Combs said he is aware of physicians who have been offered these substances without having solicited them. He went on to note that there is also the problem of attempting to enforce and prosecute federal laws at the state level.

Mrs. Cafferata noted that the problem with Storey County's Clinic was a unique one, involving questionable practices, and she does not feel it is a good example of what normally occurs.

1020

Mr. Stewart asked Mr. Tucker if he found there was a violation of federal regulation, could he not revoke the license of that manufacturer-supplier. Mr. Tucker replied his office has a terrible time with federal regulations, to the point that there is other legislation currently before the Legislature to help solve these problems.

Mr. Tucker also noted that the big problem with controlled substance samples occurs from the time the physician receives them, onward. He stated the reason he wants to go after the manufacturing companies is to prevent any sampling whatsoever, not because they are the violators.

Mr. Beyer wondered if incorporating some of the federal regulations regarding receipting of controlled substances, etc., might not solve at least part of the problem. Mr. Combs replied that some sort of record-keeping requirements would be helpful in tracing where these substances came from. Mr. Tucker stated that the original bill had all that mechanism in it, however it is felt to be an unworkable system, because the physician just does not have the time for all that record-keeping for one or two samples.

As there was no further testimony on AB 53, Chairman Stewart declared the public hearing closed.

As there was little time left, Chairman Stewart said he would reschedule the hearings on AB 250 and AB 362.

Mr. Price then requested Committee introduction of BDR C-606*, which deals with assessing a fine on those people convicted of misdemeanors or higher crimes to help fund the victims of the crime compensation monies and which would require a change in the state constitution, which currently requires all fines collected go into the school fund.

Mr. Price moved COMMITTEE INTRODUCTION OF BDR C-606, seconded by Mr. Sader, and passed unanimously, with Mr. Chaney and Mr. Banner absent at the time of vote.

Chairman Stewart then adjourned the meeting at 10:50 a.m.

Respectfully submitted,

Pamela B. Sleeper

*AJR 33

Pamela B. Sleeper
Assembly Attache

1021

61st NEVADA LEGISLATURE
ASSEMBLY JUDICIARY COMMITTEE
LEGISLATION ACTION

DATE: Tuesday, 31 March 1981
SUBJECT: AB 112: Limits exercise of eminent domain to take land in historic districts for use in mining or related activities.

MOTION:

DO PASS _____ AMEND XX INDEFINITELY POSTPONE _____
RECONSIDER _____

MOVED BY: MRS. CAFFERATA SECONDED BY: MS. HAM

AMENDMENT:

Amendment 351 (See EXHIBIT B attached to minutes for 30 March 1981.)
Wording which would limit its application to historic districts should be added.

MOVED BY: MR. THOMPSON SECONDED BY: MRS. CAFFERATA

AMENDMENT:

Amendment 352 (See EXHIBIT A attached to minutes for 30 March 1981.)
Substitute amendment.

MOVED BY: MR. STEWART SECONDED BY: MR. SADER

VOTE:	MOTION		AMEND (351)		AMEND (352)	
	YES	NO	YES	NO	YES	NO
Thompson	<u>X</u>	—	<u>X</u>	—	—	<u>X</u>
Foley	<u>X</u>	—	<u>X</u>	—	—	<u>X</u>
Beyer	—	<u>X</u>	<u>X</u>	—	<u>X</u>	—
Price	—	<u>X</u>	—	<u>X</u>	<u>X</u>	—
Sader	—	<u>X</u>	<u>X</u>	—	<u>X</u>	—
Stewart	<u>X</u>	—	<u>X</u>	—	<u>X</u>	—
Chaney	<u>X</u>	—	<u>X</u>	—	—	<u>X</u>
Malone	<u>X</u>	—	<u>X</u>	—	—	<u>X</u>
Cafferata	<u>X</u>	—	<u>X</u>	—	—	<u>X</u>
Ham	<u>X</u>	—	<u>X</u>	—	—	<u>X</u>
Banner	ABSENT	—	<u>X</u>	—	—	<u>X</u>
TALLY:	<u>7</u>	<u>3</u>	<u>10</u>	<u>1</u>	<u>4</u>	<u>7</u>

ORIGINAL MOTION: Passed _____ Defeated _____ Withdrawn _____
 AMENDED & PASSED XX (AMENDMENT 351) AMENDED & DEFEATED _____
 AMENDED & PASSED _____ AMENDED & DEFEATED _____

ATTACHED TO MINUTES OF Assembly Judiciary Committee
Tuesday, 31 March 1981

61st NEVADA LEGISLATURE
ASSEMBLY JUDICIARY COMMITTEE
LEGISLATION ACTION

DATE:

SUBJECT: AB 112: Limits exercise of eminent domain to take land in historic districts for use in mining or related activities.

MOTION: DO PASS AS AMENDED XX
 DO PASS _____ AMEND _____ INDEFINITELY POSTPONE _____
 RECONSIDER _____

MOVED BY: MRS. CAFFERATA SECONDED BY: MS. HAM

AMENDMENT:

MOVED BY: _____ SECONDED BY: _____

AMENDMENT:

MOVED BY: _____ SECONDED BY: _____

VOTE:	MOTION		AMEND		AMEND	
	YES	NO	YES	NO	YES	NO
Thompson	<u>X</u>	—	—	—	—	—
Foley	<u>X</u>	—	—	—	—	—
Beyer	<u>X</u>	—	—	—	—	—
Price	<u>X</u>	—	—	—	—	—
Sader	<u>X</u>	—	—	—	—	—
Stewart	<u>X</u>	—	—	—	—	—
Chaney	<u>X</u>	—	—	—	—	—
Malone	<u>X</u>	—	—	—	—	—
Cafferata	<u>X</u>	—	—	—	—	—
Ham	<u>X</u>	—	—	—	—	—
Banner	<u>ABSENT</u>	—	—	—	—	—
TALLY:	<u>10</u>	<u>0</u>	—	—	—	—

ORIGINAL MOTION: Passed XX Defeated _____ Withdrawn _____
 AMENDED & PASSED _____ AMENDED & DEFEATED _____
 AMENDED & PASSED _____ AMENDED & DEFEATED _____

ATTACHED TO MINUTES OF Assembly Judiciary Committee
 Tuesday, 31 March 1981

61st NEVADA LEGISLATURE
 ASSEMBLY JUDICIARY COMMITTEE
 LEGISLATION ACTION

DATE: Tuesday, 31 March 1981
 SUBJECT: Committee introduction of BDR C-606

MOTION: COMMITTEE INTRODUCTION FOR BDR C-606 XX
 DO PASS _____ AMEND _____ INDEFINITELY POSTPONE _____
 RECONSIDER _____

MOVED BY: MR. PRICE SECONDED BY: MR. SADER

AMENDMENT:

MOVED BY: _____ SECONDED BY: _____

AMENDMENT:

MOVED BY: _____ SECONDED BY: _____

VOTE:	MOTION		AMEND		AMEND	
	YES	NO	YES	NO	YES	NO
Thompson	<u>X</u>	—	—	—	—	—
Foley	<u>X</u>	—	—	—	—	—
Beyer	<u>X</u>	—	—	—	—	—
Price	<u>X</u>	—	—	—	—	—
Sader	<u>X</u>	—	—	—	—	—
Stewart	<u>X</u>	—	—	—	—	—
Chaney	ABSENT	—	—	—	—	—
Malone	<u>X</u>	—	—	—	—	—
Cafferata	<u>X</u>	—	—	—	—	—
Ham	<u>X</u>	—	—	—	—	—
Banner	ABSENT	—	—	—	—	—
TALLY:	<u>9</u>	<u>0</u>	—	—	—	—

ORIGINAL MOTION: Passed xx Defeated _____ Withdrawn _____
 AMENDED & PASSED _____ AMENDED & DEFEATED _____
 AMENDED & PASSED _____ AMENDED & DEFEATED _____

ATTACHED TO MINUTES OF Assembly Judiciary Committee
Tuesday, 31 March 1981

§ 1301.74

Title 21—Food and Drugs

trant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

(c) The registrant shall notify the Regional Office of the Administration in his region of any theft of significant loss of any controlled substances upon discovery of such theft or loss. The supplier shall be responsible for reporting in-transit losses of controlled substances by the common or contract carrier selected pursuant to § 1301.74(e), upon discovery of such theft or loss. The registrant shall also complete DEA Form 106 regarding such theft or loss. Thefts must be reported whether or not the controlled substances are subsequently recovered and/or the responsible parties are identified and action taken against them.

(d) The registrant shall not distribute any controlled substance listed in Schedules II through V as a complimentary sample to any potential or current customer (1) without the prior written request of the customer, (2) to be used only for satisfying the legitimate medical needs of patients of the customer, and (3) only in reasonable quantities. Such request must contain the name, address, and registration number of the customer and the name and quantity of the specific controlled substance desired. The request shall be preserved by the registrant with other records of distribution of controlled substances. In addition, the requirements of Part 1305 of the chapter shall be complied with for any distribution of a controlled substance listed in Schedule II. For purposes of this paragraph, the term 'customer' includes a person to whom a complimentary sample of a substance is given in order to encourage the prescribing or recommending of the substance by the person.

(e) When shipping controlled substances, a registrant is responsible for selecting common or contract carriers which provide adequate security to guard against in-transit losses. When storing controlled substances in a public warehouse, a registrant is responsible for selecting a warehouseman which will provide adequate security to guard against storage losses;

wherever possible, the registrant shall store controlled substances in a public warehouse which complies with the requirements set forth in § 1301.72. In addition, the registrant shall employ precautions (e.g., assuring that shipping containers do not indicate that contents are controlled substances) to guard against storage or in-transit losses.

(f) When distributing controlled substances through agents (e.g., detailmen), a registrant is responsible for providing and requiring adequate security to guard against theft and diversion while the substances are being stored or handled by the agent or agents.

(g) Before the initial distribution of etorphine hydrochloride and/or diprenorphine to any person, the registrant must verify that the person is authorized to handle the substance(s) by contacting the Drug Enforcement Administration.

(h) The acceptance of delivery of narcotic substances by a narcotic treatment program shall be made only by a licensed practitioner employed at the facility or other authorized individuals designated in writing. At the time of delivery, the licensed practitioner or other authorized individual designated in writing (excluding persons currently or previously dependent on narcotic drugs), shall sign for the narcotics and place his specific title (if any) on any invoice. Copies of these signed invoices shall be kept by the distributor.

(i) Narcotics dispensed or administered at a narcotic treatment program will be dispensed or administered directly to the patient by either (1) the licensed practitioner, (2) a registered nurse under the direction of the licensed practitioner, (3) a licensed practical nurse under the direction of the licensed practitioner, or (4) a pharmacist under the direction of the licensed practitioner.

(j) Persons enrolled in a narcotic treatment program will be required to wait in an area physically separated from the narcotic storage and dispensing area. This requirement will be enforced by the program physician and employees.

code of federal regulations



21

Food and Drugs

PART 1300 TO END

Revised as of April 1, 1980

STATEMENT OF THE
PHARMACEUTICAL MANUFACTURERS ASSOCIATION
CONCERNING A.B. 53
COMMITTEE ON JUDICIARY
NEVADA ASSEMBLY

EXHIBIT B

March 31, 1981

While PMA has supported federal and state legislation to control prescription drug sampling, we strongly oppose Section 5 of A.B. 53 because it would do away with the sampling of controlled substance drugs completely. Many pharmaceutical companies make complimentary samples of their products available to physicians to facilitate individual clinical evaluation of particular drugs and ensure prompt inauguration of patient drug therapy. PMA believes that the benefits of responsible sampling practices are significant for the physician and the patient.

The practice of sampling is obviously useful to pharmaceutical companies in marketing their products. It also improves physicians' knowledge about the drug products they use in treatment. Physicians utilize samples in the following ways:

- Samples allow physicians to make a personal clinical evaluation upon prescribing a new drug or an established drug to a patient. Physicians are able to evaluate a specific product to see if the patient tolerates it and if it has the desired effect before a prescription is filled at the patient's expense.
- Samples allow the physician to begin therapy immediately. Often it is medically desirable for the patient to receive medication as soon as possible -- even in the physician's office. Also, many times patients may not be able to have prescriptions filled at once because of the unavailability of a pharmacy because of late hours, weekends, holidays, or distance.

Drug therapy, especially for certain ailments, may require considerable trial and observation by both the doctor and patient. Samples provide a convenient and less costly way to achieve the best available therapy, without the patient's having to pay for drugs until their value and efficacy in individual cases is demonstrated.

Onerous sampling restrictions adversely affect competition. Under restrictive laws or regulations, pharmaceutical firms marketing new drugs would suffer a disadvantage in the marketplace. New products might prove more desirable and less costly than the more well-known older products for many patients. It will be much more difficult for them to achieve wide-spread acceptance if unnecessarily restrictive rules are adopted.

While samples serve a useful medical purpose and are a benefit to the patient and the doctor, there have been some instances when unwanted samples have posed a problem. Studies have been published that showed some physicians had legitimate complaints about sampling, particularly concerning types of drugs the physicians don't use in their particular specialty, drugs from unknown companies, and samples that are difficult to store.

Most responsible pharmaceutical firms have developed voluntary limitations on sampling practices. Samples are carefully inventoried several times a year. Samples presented to doctors are accompanied by a written receipt or request form with a signature and the quantity noted. This is done on each physician call. Mailed samples are sent only on a signed physician request and mailing lists are updated regularly.

Controlled Substances Sampling

Existing federal law closely regulates the distribution of samples of

controlled substances by representatives of pharmaceutical companies. Distribution of such samples may be made only upon prior written request, for the legitimate medical need of patients of the practitioner and in reasonable quantities. Federal regulations also specify the form of the request and require that detailed records be kept of all requests for samples of controlled substances. In addition, pharmaceutical companies must keep accurate inventories of all controlled substances, including those in the possession of detailmen, and must keep records of the distribution of all controlled substances, whether samples or not.

Significantly, in July 1977 the Drug Enforcement Administration of the Department of Justice withdrew a proposed rule that would have prohibited drug manufacturers and distributors from providing complimentary samples of controlled substances. The Administrator of DEA concluded that "significant diversion has not been demonstrated which would compel (DEA) to prohibit nonpractitioner registrants from distributing controlled substances in Schedules II-V as complimentary samples."

In considering this rule the DEA relied heavily upon the comments of the National Institute for Drug Abuse (NIDA). Dr. Robert E. Willette, Chief of the Research Technology Branch, Division of Research stated that in order to support the prohibition "a substantial potential for diversion or evidence of diversion must exist . . . the present written request system and accountability of samples distribution for Schedule II drugs appear to offer adequate safeguards against diversion."

The major benefits of sampling for the doctor and the patient should not be withheld entirely as the provisions of A.B. 53 would do, in order to correct some instances of sampling abuse. We appreciate and share the commitment of Nevada State officials to deal effectively with drug abuse and misuse. But we believe the ~~tool~~ that is needed is enforcement, not new legislation. For

any instance that may be cited where drug samples have been inappropriately used or disposed of, an existing state or federal law can be cited which has been broken. It is a question of enforcing existing controls and laws on samples, not passing new ones which eliminate the major benefits of samples for both patients and physicians in Nevada.

In conclusion, we urge the Committee to delete provisions 6 and 7 of Section 5. We also want the members of the Committee and other officials of the state to know that we stand willing and ready to be of whatever assistance we can in dealing with any problem involving a particular drug or manufacturer.

We want to thank you for your time and consideration.