

MINUTES

ASSEMBLY JUDICIARY COMMITTEE  
April 21, 1977

Members Present: Chairman Barengo  
Assemblyman Hayes  
Assemblyman Banner  
Assemblyman Coulter  
Assemblyman Polish  
Assemblyman Price  
Assemblyman Sena  
Assemblyman Ross  
Assemblyman Wagner

Chairman Barengo called the meeting to order at 7:20 a.m.  
Those wishing to testify were sworn before giving testimony.

AB 744: Tom Moore, representing Clark County, was first to testify on this bill and he stated this bill was directed to the clarification of language in regard to the fees for appointed attorneys who represent indigents. He said this stems from a series of cases taken to the Supreme court of Nevada by Clark County and trying to comply with the federal statutes in this area. He stated that this would change the language from "unusual" to extraordinary circumstances so that it could be referenced in case law. He then explained the bill and some of the minor changes to it. He pointed out that they wished to have an amendment to subsection three so that it would read: "shall be paid a fee which shall not..." which they felt would eliminate any possibility of state impact.

In answer to a question from Mrs. Wagner, Mr. Moore stated that under common law a lawyer does not have a right to a fee for representing an indigent because it is an incident of his license to practice law and therefore those fees must be granted and set out statutorially by the legislature. He stated that between 1969 and 1975 there was a maximum on those fees of \$1,000 and then in 1975 that was raised to \$2,500, and above that a right to exceed that amount in unusual circumstances. Discussion followed on the different fees provided in the bill and Mr. Moore stated that they are not revising the fee schedule they are simply clarifying when those fees are to be paid and for what purposes. He stated that they recently had a case in Clark County where two attorneys were assigned to a very difficult case and the total fee came to approximately \$25,000 therefore, they are currently providing for payment in these kinds of difficult cases and they are not trying to change that with anything in this bill.

Mr. Moore stated that in subsection 4 the term extraordinary circumstances is defined to mean financial burdens and hardships far in excess of those normally found in the defense of an indigent person and comes from case law. He also pointed out that the new language in 4(b), page two is the codification of past case law. This subsection would also provide for the next judge of seniority would have the responsibility if the chief judge were the trial judge.

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Mr. Moore stated that section five provides that when an attorney causes a mistrial on purpose because he is getting near the statutory limits, the fee will be prorated between the attorneys who handle the case.

He also stated that they wanted to include a new section 6 and that proposal is attached and marked Exhibit B. An outline of Mr. Moore's remarks and comments are attached and marked Exhibit A (w/attachment).

In answer to a question from Mr. Price, Mr. Moore stated that in reference to lines 33 through 36 on page two, the court can now assign two attorney to a difficult case and they are both paid their fees separately and this is not trying to eliminate one of those fees. This provision is used when someone takes a case and then withdraws and another attorney has to be appointed by the court simply because the first attorney did not want to file for an increase in fee due to extraordinary circumstances.

Mr. Price asked Mr. Moore how much was spent this past year on indigent representation in Clark County. Mr. Moore stated that in the past fiscal year in Clark County, the amount spent was \$350,000 to date and it will be \$450,000 before the fiscal year is closed. This does not include what is spent for the public defenders system. He stated that the system also includes both defenders and prosecutors for the indigent and this provides representation when both parties could not be represented by the same public office and resolves the conflict which would otherwise result.

In conclusion Mr. Moore stated that they would have to take some cases to the Supreme court for interpretation of the law because it is not clear presently.

Mr. Russ McDonald was next to testify and stated that he had had experience with this problem in Washoe County. He stated that in Washoe County their set up is somewhat different from that of Clark County and it is therefore difficult to get any of the judges to want to do any more than sign the order for the attorney requesting the excess payment and doesn't want to get the particulars of the excess charges, then the order is sent on to the comptroller for payment. He felt that this bill would provide for the complete explanation of these excess charges and eliminate the problem by clarifying what is necessary.

He stated that he thought in Washoe County the had expended somewhere around \$156,000 so far this fiscal year on this type of system, not including the public defenders system and he felt the indigent people were being treated fairly so far as legal representation was concerned.

He stated that he was in favor of the bill from both the attorney's and administrator's point of view.

Chairman Barengo introduced to the committee the amendment to

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AB 160 and read it to the committee. The amendment is attached and marked Exhibit C. He stated that the amendment was agreed to by all the parties involved and they had stated that if it did not work they would come back in two years and change it. No direct action was taken on the amendment during the meeting.

AB 355: Chairman Barengo also introduced to the committee an amendment to this bill which is attached and marked Exhibit D. Mr. Bob Faiss also addressed the committee on this change and his remarks are attached and marked Exhibit E.

Chairman Barengo stated that he would have Bud Hicks come to the committee to comment on the amendment at the first available time.

SB 263: Senator Close testified first on this bill and stated that section one was basically the same as existing law. He stated that it has been changed to include reimbursement for the deposition, even if it is not used in the trial itself and this is on line seven of the bill. He also stated that they have included payment for interpreters. He also stated that they have expanded, on line 18, the current law to pay for service by a licensed process server.

He stated that Judge Thompson had suggested this bill because of problems which they were experiencing in that area and this bill would help clarify what was and was not covered as far as costs were concerned.

He pointed out that this bill provide a means by which an attorney could enforce a lien on a clients file by placing that lien on the judgement from the trial.

Senator Close then explained to the committee the portion of the bill which provides for proration of fees in the case an attorney takes the trial to the point which approximate the ceiling on fees and then deliberately causes a mistrial so that he can end the trial. He stated to the committee that this bill is not an attorney fee bill. He also pointed out that they really had not significantly changed existing law in this bill, but had, indeed, clarified it.

SB 506: Senator Close stated that this bill would provide that mobile homes would be included in the homestead provisions where they were not included at this time.

Mrs. Wagner pointed out that due to the scarcity of housing available, mobile homes are now beginning to appreciate as regular homes do, yet they are still taxed as personal property.

Senator Close also pointed out that this bill would provide that a single person could get a homestead filed on the property, and this was covered on lines 1 and 2 of page 2, if they are responsible for minor children.

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SB 379: Senator Close stated that he would prefer that Senator Bryan address the committee on this bill.

SB 184: Senator Close concurred with the amendment which Chairman Barengo presented to him on this. They also discussed the apparent conflict in the bill among children and teenagers who are involved in the battery portion of the bill and Chairman Barengo stated that they would pass it on to the bill drafter and see if they felt there was a conflict according to Mr. Daykin. The amendment is attached and marked Exhibit F.

SB 438: Mr. George Bennett, Secretary of the State Board of Pharmacy, stated that this bill was proposed by that board to clarify the law in accordance with the current federal mandates on controlled substances. He stated that on page 1, lines 3 through 7 the bill provides that a physician cannot fill prescriptions except in conformity with the directions for use and this was put in because of the misuse of these drugs in the past and that portion of the bill is supported by the physicians.

He stated that on page 2, lines 14 through 24, there is a re-scheduling of the drugs which were covered under the federal statute. Mr. Bennett read from a copy of Chapter II, Schedule IV of the federal statutes and a copy is attached and marked Exhibit G.

Mr. Bennett also pointed out that on page 3, line 1 and page 2, line 48 this would require dispensing physicians to keep accurate records of purchases and dispensations so that they could be audited more easily. He also noted that on page 3, line 23 this would provide that the controlled substances would be by receipt only. On page 3, line 43, he stated this provides that only in an emergency situation may a doctor prescribe controlled substances to any member of his family and this is to prevent members of the family from forcing him to supply the drugs to them. He then stated to the committee that on page 3, line 46 this would provide that each controlled substance prescription would be written on a separate sheet and this is also for audit reasons.

A discussion followed concerning drugs which can be prescribed for both animals and humans and how this is combatted and what could be done with regard to regulation. No specific conclusions were drawn.

Chairman Barengo discussed briefly with the committee the possibility of combining Douglass, Carson City and Lyon Counties in to one district for the purposes of gaining another judgeship. This will be looked into and discussed at a later meeting.

AB 627: Mr. Will Crockett stated that this bill covers procedures involving liens on aircraft and motor vehicles and requires judicial hearing within 30 days on the lien or the lien expires (unless extended by agreement). He stated that these procedures have been mandated by the Supreme court.

COMMITTEE ACTION:

AB 744: Mrs. Hayes moved for a Do Pass as Amended. Mr. Banner seconded the motion and it carried.

AB 684: Mrs. Wagner moved for a Do Pass as Amended. Mrs. Hayes seconded the motion and it carried.

AB 693: Mrs. Wagner moved for a Do Pass as Amended. Mr. Banner seconded the motion and it carried.

SB 184: Mr. Banner moved to accept the amendment. Mr. Sena seconded the motion and it carried. Mrs. Wagner moved for a Do Pass as Amended. Mr. Sena seconded the motion and it carried.

AB 697: Mr. Banner move for an Indefinite Postponement. Mr. Ross seconded the motion and it carried.

AB 719: The committee concurred to delete the 10 day notice and leave the balance of the bill unchanged from existing law. Mr. Price moved for a Do Pass as Amended. Mrs. Wagner seconded the motion and it carried.

AB 730: Mrs. Wagner moved for an Indefinite Postponement. Mr. Price seconded the motion and it carried.

SB 453: Mrs. Wanger moved for a Do Pass. Mr. Sena seconded the motion and it carried

SB 379: Mrs. Hayes moved for an Indefinite Postponement. Chairman Barengo seconded the motion and it carried. Mr. Sena voted no.

AB 621: Mr. Sena moved for a Do Pass. Mrs. Wagner seconded the motion and it carried. Mrs. Hayes did not vote.

AB 518: Mr. Sena moved for an Indefinite Postponement. Mrs. Hayes seconded the motion and it carried. Mr. Price voted no.

There being no further business the meeting was adjourned at 10:50 a.m.

Respectfully submitted,

*Linda Chandler*

Linda Chandler, Secretary

EXHIBITA (w/ attachment)

Tom Moore Outline of Stmt

1. Daines v Markoff

NRS 7.260

Read op

2. 1975 revision

NRS 7.125

AB 744

§ 1 (1) delete HC & pc relief to make clear that fee to be paid after correction went at

(2) amending matters

AND

2 (d) delete used § (3)

(3) amend

(4) define extraordinary → known quantity - constitutional

limit  
on what may  
be paid basis

unusual

extraordinary

extended & complex litigation

4 (a) Title 19 § 3006 a certification  
judges in need to establish  
extraordinary circumstances

+ if chief judge trial judge

(5) bail out → federal system through  
district plans prohibits  
if a extraordinary case then proceed  
through § 4

350 → 450 by June 30

UNTIL THE 1975 SESSION, THE PROVISIONS AFFECTED BY ~~THIS BILL~~ WERE CONTAINED IN NRS 7.260. THE 1975 LEGISLATURE REVISED THESE LAWS AND CREATED A NEW SECTION, NRS 7.125, WHEN IT PASSED S.B. 555. CERTAIN PROBLEMS HAVE ARISEN AND A.B. 744, AS AMENDED, ATTEMPTS TO CORRECT THE OVERSIGHTS AND CLOSE THE LOOPHOLES.

A.B. 744 AFFECTS BOTH SPECIAL PROSECUTORS AND APPOINTED DEFENDERS EQUALLY. IT DOES NOT CHANGE ANY OF THE STATUTORY MAXIMUM FEES AUTHORIZED BY THE 1975 LEGISLATURE. IT DOES, HOWEVER, CLARIFY THAT THERE IS NO RIGHT TO:

1. A SEPARATE FEE FOR A WRIT OF HABEAS CORPUS WHEN USED AS AN ~~AUXILIARY~~ <sup>ANCILLARY</sup> MATTER TO THE TRIAL PROCEEDINGS.

2. THAT ONLY IN EXTRAORDINARY CASES SHOULD THESE STATUTORY MAXIMUMS BE EXCEEDED. THE TERM "EXTRAORDINARY" REPLACES THE PRESENT TERM "UNUSUAL" TO ELIMINATE THE NEED TO SEEK A JUDICIAL INTERPRETATION AND CONFORM THE ~~STATUTES~~ TO EXISTING CASE LAW OF THE STATE OF NEVADA.

3. IN ORDER TO GRANT FEES, THE COURT MUST CERTIFY THAT THE FEES ARE BOTH REASONABLE AND NECESSARY, AND FACTUALLY, THEIR RECORDS AND FINDINGS SHOULD REFLECT THIS ANYWAY, SINCE THEY ARE AUTHORIZING THE PAYMENT OF PUBLIC FUNDS.

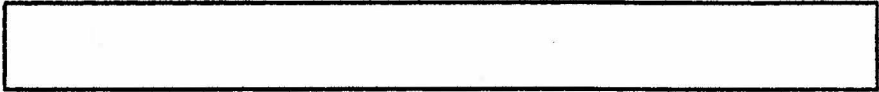
4. WHERE ONE ATTORNEY IS SUBSTITUTED FOR ANOTHER, MULTIPLE RIGHTS TO THE STATUTORY FEE MAY EXIST. A PROVISION IS ADDED THAT CLARIFIES THAT ONLY ONE FEE IS AUTHORIZED.

5. FINALLY, THE APPOINTED ATTORNEY IS REQUIRED TO PROMPTLY AND ACCURATELY SUPPORT HIS CLAIM TO THE COURTS IF HE IS TO BE PAID.

EXHIBIT B

ASSEMBLY ACTION	SENATE ACTION	ASSEMBLY / <del>SENATE</del> AMENDMENT BLANK
<input type="checkbox"/> Adopted <input type="checkbox"/> Lost Date: Initial:	<input type="checkbox"/> Adopted <input type="checkbox"/> Lost Date: Initial:	Amendments to Assembly / <del>SENATE</del> Bill / <del>Joint Resolution</del> No. <u>744</u> (BDR 1-1430)
<input type="checkbox"/> Concurred in <input type="checkbox"/> Not concurred in Date: Initial:	<input type="checkbox"/> Concurred in <input type="checkbox"/> Not concurred in Date: Initial:	Proposed by <u>Committee on Judiciary</u>

77 Amendment N<sup>o</sup> 1034 A



Amend section 1, page 2, delete lines 11 and 12 and insert:

"felony, shall be paid a fee not to exceed \$300."

Amend section 1, page 2, after line 36 insert:

"6. A claim made pursuant to this section shall not be paid unless it is submitted within 60 days after the appointment is terminated and a statement made under oath is submitted specifying:

- (a) The amount of time spent on the matter;
- (b) The type of service rendered;
- (c) The amount of expenses incurred; and
- (d) Any compensation or reimbursement which is applied for or received from any other source."

Amend the title of the bill on the second and third lines, delete:

"requiring certain fees to be paid from the reserve for statutory contingency fund;"

APR 21 1977



AN ACT creating the office of state industrial attorney; providing for representation of industrially injured claimants; making an appropriation; and providing other matters properly relating thereto.

Section 1. Chapter 616 of NRS is hereby amended by adding thereto the provisions set forth as sections 1 to 9, inclusive, of the Act.

Sec. 2. 1. The office of state industrial attorney is hereby created.

2. The state industrial attorney shall:

(a) Be an attorney licensed to practice law in the State of Nevada.

(b) Be in the unclassified service of the State.

(c) Receive a salary of not more than \$25,000.

(d) Not engage in the private practice of law.

3. No other officer or agency of the State may supervise the state industrial attorney or assign him duties in addition to those prescribed by this chapter.

4. All salaries and expenses in administering this act shall be paid from the state insurance fund.

Sec. 3. The governor shall appoint the state industrial attorney for a term of 4 years.

Sec. 4. 1. The state industrial attorney may employ:

(a) One deputy state industrial attorney who shall be in the unclassified service of the state.

(b) Clerical and other necessary staff, who shall be in the classified service of the state.

2. The deputy state industrial attorney shall be an attorney licensed to practice law in the State of Nevada, and shall not engage in the practice of law, except in performing the duties of his office.

3. The state industrial attorney and the employees of his office shall receive the traveling expenses and subsistence of his office.

Sec. 5. The state industrial attorney shall establish an office in Carson City, Nevada, and Las Vegas, Nevada.

Sec. 6. 1. The state industrial attorney shall, when designated by an appeals officer in a report, without charge, a claimant before the appeals officer or the District Court.

2. When representing a claimant, the state industrial attorney shall:

(a) Counsel, prepare, and present the claimant's case to the appeals officer,  
and

(b) Appeal to the district court any appeals officer decision that he considers  
should be appealed in the interests of justice.

Sec. 7. The state industrial attorney shall submit a report annually to the  
governor containing a statement of the number of claimants represented, the status  
of each case, and the amount and categories of the expenditures made by his office.

Sec. 8. The provisions of this act do not preclude any claimant from hiring  
private counsel at any time; however, the hiring of private counsel shall relieve  
the state industrial attorney from further presentation of the claimant's case.

Any claimant who uses the services of the state industrial attorney prior to or after  
an appearance before the appeals officer or district court and who also retains  
private counsel shall be required to reimburse the state insurance fund for the  
cost of using the state industrial attorney, such costs to be determined by the  
state industrial attorney.

Sec. 9. 1. Any claimant may request the appointment of the state industrial  
attorney to represent him.

2. Such request shall be accompanied by the claimant's affidavit, which shall  
state that he is without means of employing an attorney.

3. An appeals officer shall forthwith consider the application and shall make  
such further inquiry as he may deem necessary. If an appeals officer finds that  
the claimant should employ an attorney, the appeals officer may designate the  
state industrial attorney to represent him.

EXHIBIT D

*Faise*  
*12 355*

Sec. —. 1. The board or commission shall not assess or charge any licensee, holding company, intermediary company or publicly traded corporation which is registered with the commission for any investigation conducted subsequent to licensing or registration.

2. A licensee shall not be required to maintain within this state credit instruments, I.O.U.s, markers or other original documents evidencing indebtedness to the licensee so long as the licensee maintains exact copies thereof within this state. If the licensee elects to maintain any such original documents outside this state, the board may examine such documents at any place they are maintained. In such instance, the board may require the licensee to reimburse the board only for the costs of transportation, food and lodging, as limited by law or regulation governing out-of-state travel by state employees. The costs shall be billed to the licensee with a full and complete accounting, including an itemization of the original documents examined.

Subsection 1 of the proposed amendment provides that the board may not charge a licensee for an investigation conducted after he receives a license.

That is a simple statement of the law. There is nothing in the gaming control act which authorizes gaming to charge anybody for anything except an applicant.

In 1975, the board attempted to exercise such power without any statutory authority when auditors showed up at the casino cages of various licensees to demand advance payment of costs of audits of offices maintained outside the state in connection with the junket business. That attempt was blocked by a legal action filed by Hilton, the Sahara, Caesars Palace, the Thunderbird, the Dunes, MGM and the Union Plaza. The court ruled in favor of the casinos, saying there was no statutory authority for gaming to assess licensees for investigations or audits.

Subsection 2, which provides that licensees do not have to maintain markers in Nevada so long as they maintain exact copies here again is a restatement of the present law. In the same law suit, the court ruled that neither the law nor gaming regulations required that original markers be maintained inside the state.

The first paragraph of subsection 2 is motivated by an apprehension that, even should A.B. 355 be passed as it now stands, the clear legislative intent which has been demonstrated by this committee's action in deleting authority for the board to charge licensees for audits and investigations, might be circumvented by

adoption of a regulation requiring markers to be kept in the state. The purpose of such a regulation would not be to keep markers in the state, but to force licensees to agree to pay for outside audits and investigations in exchange for permission to send markers elsewhere for collection.

The reason for this apprehension on the part of some persons, including legislators who know the gaming industry, is the conduct which necessitated the law suit I've mentioned here today.

In June 1975, the board's audit division sent auditors to various casinos to demand money for audits of out-of-state junket offices. This was done without any advance notice and was the first time this ever had been done. The authority given for the demands was Gaming Regulation 15.1594-3, which was adopted in 1973 by the commission but never used until 1975. That regulation purported to allow gaming to charge licensees for investigations conducted after licensing. I might note that regulation has been held invalid by the court.

The casinos didn't argue with the auditors at the time of the demand, mainly because the auditors refused to leave until the money was paid. However, we then began to attempt to get the money back because there was simply no authority to force the casinos to pay it. We pointed out to the board that Regulation 15.1594-3, even if it was legal, only applied to investigations, not audits. Well, we didn't hear anything more about Regulation 15. Instead, the board switched to the position that Regulation 6.020 (1) required that

original markers be kept inside the state and they sent to the casinos for signature an agreement that would allow them to send markers outside the state for collection so long as the licensee paid for outside audits. They did this even though Regulation 6 specifically provides that copies of financial records are acceptable. At that point, we were forced to file suit for declaratory judgment, which we won on summary judgment.

So, adoption of the first sentence of subsection 2 is in concert with the intent of the law and of this committee. It takes nothing away from gaming and it relieves the possibility of adoption of a new regulation which would spark a legal action immediately.

It is not necessary or fair that licensees, who contribute nearly \$96 million a year in taxes and fees, pay for investigations or audits conducted after licensing. To my knowledge, no other regulatory body in the country imposes upon the regulated industry the costs of audits or investigations conducted after licensing. Such functions are clearly administrative expenses. These are expenses which the State of Nevada can readily underwrite from that \$96 million a year and, with the ~~30%~~ <sup>gigantice</sup> increase in budget which I understand gaming is going to receive from the legislature, there should be no difficulty in absorbing those costs.

The rest of subsection 2 restates the right of the board to audit markers anywhere, a right which no one contests, and provides that licensees will reimburse the Board for out-of-state audits, a new burden on the industry.

It may be true that sending markers out of state creates an additional burden on the board, but it must be recognized that this audit expense is minute in comparison to the additional tax revenue generated by this necessary business practice. Further, the licensees which have out-of-state offices are the ones contributing the bulk of the tax revenue. Charging them for audits would amount to a form of double taxation on the segment of the industry which pays the greatest share of taxes.

Finally, to leave the way open for gaming to charge licensees for out-of-state audits should concern the legislature more than the industry. Allowing gaming to charge the licensee directly would take a considerable amount of gaming enforcement away from the scrutiny and control of the legislature. No expenditure for an audit would have to be justified to the legislature, let alone to the licensee who would be required to pay it.

The industry generally would prefer A.B. 355 in the form the committee has amended it. Despite this preference, we have come forward with this amendment. We have been advised the amendment will make it easier for the bill to pass the senate. Because of the importance of the bill as a whole to gaming enforcement, the industry is willing to accept the assessment of ~~xxxx~~ certain audit expenses rather than see the bill as a whole endangered.

*The only change made by the amendment is to provide industry reimbursement for out-of-state audits, something gaming does not now have. The benefit in the amendment is to the board, not to the industry.*

EXHIBIT F

Sec. 4

200.508 1. Any adult person (having the care, custody or control of a minor child under the age of 18 years) who willfully causes or permits (such) a child who is less than 18 years of age to suffer unjustifiable physical pain or mental suffering as the result of abuse or neglect or who willfully causes or permits such a child to be placed in such situation that the child may suffer physical pain or mental suffering as the result of abuse or neglect, is guilty of a gross misdemeanor.

2. A person who violates a provision of subsection 1 ~~under circum-~~  
~~stances or conditions likely to produce~~ <sup>and</sup> <sup>substantial</sup> substantial bodily or <sup>mental</sup> harm or <sup>death</sup> <sup>does result</sup> shall be punished by imprisonment in the state prison for not less than 1 year nor more than 20 years.



## RULES AND REGULATIONS

The summary is available for public examination at the office of the Hearing Clerk, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20852, Monday through Friday from 9 a.m. to 4 p.m., except on Federal legal holidays.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(1))) and under authority delegated to the Commissioner (21 CFR 5.1) (recodification published in the FEDERAL REGISTER of June 15, 1976 (41 FR 24262)), Part 520 is amended in § 520.260 by revising paragraph (b) (2) to include a sponsor for a 221 milligram capsule to read as follows:

§ 520.260 n-Butyl chloride capsules.

(b) \* \* \*

(2) *Sponsors.* See No. 015563 in § 510.600(c) of this chapter for 221, 442, 884, or 1,768 milligram or 4.42 gram capsules; No. 012983 in 510.600(c) of this chapter for 884 or 1,768 milligram or 4.42 gram capsules; and No. 000069 in 510.600(c) of this chapter for 221 milligram capsules.

Effective date. This amendment shall be effective February 11, 1977.

(Sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(1)).)

Dated: February 3, 1977.

C. D. VAN HOUWELING,  
Director

Bureau of Veterinary Medicine.

[FR Doc. 77-4199 Filed 2-10-77; 8:45 am]

CHAPTER II—DRUG ENFORCEMENT ADMINISTRATION, DEPARTMENT OF JUSTICE

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

Placement of Dextropropoxyphene in Schedule IV

On September 23, 1976, the Administrator of the Drug Enforcement Administration issued a notice of proposed rulemaking to amend § 1308.14 of Title 21 of the Code of Federal Regulations (CFR) to include dextropropoxyphene in Schedule IV of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 801 et seq.). This notice was published in the FEDERAL REGISTER on September 29, 1976 (41 FR 42957) and provided an opportunity for all interested persons to submit comments, objections and requests for a hearing on the matter, no later than December 1, 1976.

The notice further provided that if objections submitted presented reasonable grounds for the proposed rule not to be finalized, and if a hearing were requested, such hearing would be held as soon as the matter could be heard before the Drug Enforcement Administration. The notice also stated that if all interested parties waived their opportunity to request or participate in a hearing, the Administrator could, without a hearing, issue his final order pursuant to 21 CFR 1308.48 after giving consideration to written comments submitted.

Ten letters setting forth comments or objections to the proposed rulemaking

were received by the Drug Enforcement Administration. Four of the letters received favored the proposed rulemaking. Of the remaining letters, most were concerned with being given enough time to install new or to expand existing security measures for the drug should a final order be issued placing the drug in Schedule IV.

In consideration of these comments, the Administrator has provided in the order issued today that all registrants shall have six months from the date of this order within which to comply with the security provisions thereof, and in the event this imposes special hardships, the Drug Enforcement Administration will entertain any justifiable requests for extension of time.

Three letters expressed opposition to the proposed rulemaking, alleging lack of evidence sufficient to justify control.

In the notice of proposed rulemaking issued September 23, 1976 there was set forth a ten-point list detailing the review of dextropropoxyphene this Agency conducted. In addition, on August 13, 1976, in response to our request, we received from the Department of Health, Education and Welfare its separate review and its recommendation that dextropropoxyphene should be controlled in Schedule IV of the Act. The Administrator therefore concludes that, contrary to the objections submitted, there is compelling evidence to justify control of the drug as proposed.

In none of the comments which were received was there a request for a hearing. On this point it is noted that Eli Lilly and Company, the principal manufacturer of dextropropoxyphene, has voluntarily shared with the Drug Enforcement Administration and the Food and Drug Administration data developed in its continuing studies relating to dextropropoxyphene. In keeping with the Company's announced policy of concern respecting matters possibly affecting the public health, Lilly has not opposed the proposed listing of dextropropoxyphene in Schedule IV, and did not request a hearing on the proposal. The Administrator appreciates the cooperation given by Lilly and commends the Company for the corporate responsibility it has so clearly demonstrated.

Based upon the investigations and review of the Drug Enforcement Administration and upon the scientific and medical evaluation and recommendation of the Department of Health, Education, and Welfare, received pursuant to sections 201(a) and 201(b) of the Act (21 U.S.C. 811(a) and 811(b)), the Administrator finds that:

1. Dextropropoxyphene has a low potential for abuse relative to the drugs or other substances currently listed in Schedule III.
2. Dextropropoxyphene has a currently accepted medical use in treatment in the United States.
3. Abuse of dextropropoxyphene may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in Schedule III.

and, under the authority vested in the Administrator of the Drug Enforcement

Administration, the Administrator hereby orders that § 1308.14 of Title 21 of the Code of Federal Regulations (CFR) be amended to read:

§ 1308.14 Schedule IV.

(e) *Other substances.* Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances, including its salts:

- (1) Dextropropoxyphene (Alpha-(+)-4-dimethylamino-1,2-diphenyl-3-methyl-2-propionoxybutane) - 8121

EFFECTIVE DATES

1. *Registration.* Any person who manufactures, distributes, dispenses, imports or exports dextropropoxyphene, or who proposes to engage in such activities, shall submit an application for registration to conduct such activities in accordance with Parts 1301 and 1311 of Title 21 of the Code of Federal Regulations on or before March 14, 1977.

2. *Security.* Dextropropoxyphene must be manufactured, distributed and stored in accordance with §§ 1301.71, 1301.72 (b)-(d), 1301.73, 1301.74 (a)-(f), 1301.75 (b)-(c), and 1301.76 of Title 21 of the Code of Federal Regulations on or before August 14, 1977. From now until the effective date of this provision, it is expected that manufacturers and distributors of dextropropoxyphene will initiate whatever preparations may be necessary, including underground handling and engineering studies and construction programs, in order to provide adequate security for dextropropoxyphene in accordance with DEA regulations so that substantial compliance with this provision can be met by August 14, 1977. In the event that this imposes special hardships, the Drug Enforcement Administration will entertain any justified requests for extensions of time.

3. *Labeling and packaging.* All labels on commercial containers of, and all labeling of dextropropoxyphene packaged after August 14, 1977, shall comply with the requirements of §§ 1302.03-1302.05 and 1302.08 of Title 21 of the Code of Federal Regulations. In the event this effective date imposes special hardships on any manufacturer, as defined in section 102(14) of the Controlled Substances Act (21 U.S.C. 802(14)), the Drug Enforcement Administration will entertain any justified requests for an extension of time.

4. *Inventory.* Every registrant required to keep records who possesses any quantity of dextropropoxyphene shall take an inventory pursuant to §§ 1304.11-1304.19 of Title 21 of the Code of Federal Regulations, of all stocks of such substances on hand, on March 14, 1977.

5. *Records.* All registrants required to keep records pursuant to §§ 1304.21-1304.27 of Title 21 of the Code of Federal Regulations shall maintain such records on dextropropoxyphene commencing on the date on which the inventory of such substances is taken.

published in the FEDERAL REGISTER of June 15, 1976 (41 FR 24262)), Part 121 is amended in § 121.2520 by alphabetically inserting in the list of substances a new item, to read as follows:

§ 121.2520 Adhesives.

- (c) \* \* \*
- (5) \* \* \*

COMPONENTS OF ADHESIVES

Substances Limitations

Poly[styrene - co - disodium maleate - co - α-(p-nonyl phenyl)-ω-omega-(p-vinylbenzyl) poly(oxyethylene)] terpolymer.

Any person who will be adversely affected by the foregoing regulation may at any time on or before March 14, 1977, file with the Hearing Clerk, Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written objections thereto. Objections shall show wherein the person filing will be adversely affected by the regulation, specify with particularity the provisions of the regulation deemed objectionable, and state the grounds for the objections. If a hearing is requested, the objections shall state the issues for the hearing, shall be supported by grounds factually and legally sufficient to justify the relief sought, and shall include a detailed description and analysis of the factual information intended to be presented in support of the objections in the event that a hearing is held. Five copies of all documents shall be filed and should be identified with the Hearing Clerk docket number found in brackets in the heading of this regulation. Received objections may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Effective date: This regulation shall become effective February 11, 1977.

(Sec. 409(c)(1), 72 Stat. 1788 (21 U.S.C. 348(c)(1)))

Dated: February 3, 1977.

JOSEPH P. HILE,  
Associate Commissioner for  
Compliance.

[FR Doc.77-4373 Filed 2-10-77; 8:45 am]

SUBCHAPTER E—ANIMAL DRUGS, FEEDS, AND RELATED PRODUCTS

[Docket No. 76N-0287]

PART 500—GENERAL

Timed-Release Dosage Form Drugs for Veterinary Use

The Food and Drug Administration is adding a regulation for timed-release dosage form drugs for animals; effective March 14, 1977.

The Commissioner of Food and Drugs issued, in the FEDERAL REGISTER of May 9, 1959 (24 FR 3758), § 200.31 *New drug status of timed-release dosage form drugs* (21 CFR 200.31, formerly § 3.512) before recodification published in the FEDERAL REGISTER of March 27, 1970 (40

FR 13996)), providing that dosage form drugs that are designed to release their active ingredient(s) over a prolonged period are not generally recognized as safe for such use and therefore are new drugs as defined in section 201(p) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(p)). When § 200.31 was promulgated, section 201(p) of the act did not distinguish between new drugs for use in man and those for use in other animals. At the time the Animal Drug Amendments of 1968 (Pub. L. 90-399) redefined section 201(p) of the act to exempt from its provisions a new animal drug and established a new section 201(w) (21 U.S.C. 321(w)) defining a new animal drug, § 200.31 was not revised accordingly, even though its provisions continued to apply to timed-release drugs for use in animals.

The Commissioner proposed, in the FEDERAL REGISTER of August 12, 1976 (41 FR 34052), a new regulation regarding timed-release drugs for use in animals; it provided that in addition to questions relating to the safety of such articles, questions relating to their effectiveness must be addressed.

One comment was received in response to the proposal. Norden Laboratories, Inc., questioned whether the statement in the preamble that "The interim marketing provisions of § 510.450 (21 CFR 510.450) do not apply to timed-release products covered under the proposed regulation below" meant that no timed-release product now being marketed without an effective new animal drug application (NADA) will be granted an interim marketing period while an NADA is being prepared, or whether this statement applied only to sulfonamide-containing drugs. The Food and Drug Administration responded to Norden Laboratories, Inc., by letter dated September 27, 1976, stating that the interim marketing provisions of § 510.450 do not apply to timed-release products.

No other comments were submitted and the Commissioner concludes that § 500.26 should be adopted as proposed.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 512, 701(a), 52 Stat. 1055, 82 Stat. 343-351 (21 U.S.C. 360b, 371(a))) and under authority delegated to the Commissioner (21 CFR 5.1) (recodification published in the FEDERAL REGISTER of June 15, 1976 (41 FR 24262)), Part 500 is amended in Subpart B by adding § 500.26 to read, as follows:

§ 500.26 Timed-release dosage form drugs.

(a) Drugs are being offered in dosage forms that are designed to release the active ingredients over a prolonged period of time. There is a possibility of unsafe overdosage or ineffective dosage if such products are improperly made and the active ingredients are released at one time, over too short or too long a period of time, or not released at all. Drugs marketed in this form, which are referred to by such terms as timed-release, controlled-release, prolonged-release, sustained-release, or delayed-release drugs, are regarded as new ani-

mal drugs within the meaning of section 201(w) of the Federal Food, Drug, and Cosmetic Act.

(b) Timed-release dosage form animal drugs that are introduced into interstate commerce are deemed to be adulterated within the meaning of section 501(a)(5) of the act and subject to regulatory action unless such animal drug is the subject of an approved new animal drug application as required by paragraph (a) of this section.

(c) The fact that the labeling of this kind of drug may claim delayed, prolonged, controlled, or sustained-release of all or only some of the active ingredients does not affect the new animal drug status of such articles. A new animal drug application is required in any such case.

(d) New animal drug applications for timed-release dosage form animal drugs must contain, among other things, data to demonstrate safety and effectiveness by establishing that the article is manufactured using procedures and controls to ensure release of the total dosage at a safe and effective rate. Data submitted in the new animal drug application must demonstrate that the formulation of the drug and the procedures used in its manufacture will ensure release of the active ingredient(s) of the drug at a safe and effective rate and that these release characteristics will be maintained until the expiration date of the drug. When the drug is intended for use in food-producing animals, data submitted must also demonstrate that, with respect to possible residues of the drug, food derived from treated animals is safe for consumption.

Effective date. This regulation shall become effective March 14, 1977.

(Secs. 512, 701(a), 52 Stat. 1055, 82 Stat. 343-351 (21 U.S.C. 360b, 371(a)).)

Dated: February 4, 1977.

JOSEPH P. HILE,  
Associate Commissioner  
for Compliance.

[FR Doc.77-4195 Filed 2-10-77; 8:45 am]

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS NOT SUBJECT TO CERTIFICATION

n-Butyl Chloride Capsules

The Food and Drug Administration approves a new animal drug application (96-509V) filed by Pfizer, Inc., 235 E. 42d St., New York, NY 10017, proposing the safe and effective use of a 221-milligram capsule of n-butyl chloride for the removal of certain roundworms and hookworms from dogs. The approval is effective February 11, 1977.

The Commissioner of Food and Drugs is amending § 520.260 (21 CFR 520.260) to reflect this approval.

In accordance with § 514.11(e)(2)(ii) (21 CFR 514.11(e)(2)(ii)) of the animal drug regulations, a summary of the safety and effectiveness data and information submitted to support the approval of this application is released publicly.

6. *Prescriptions.* All prescriptions for products containing dextropropoxyphene shall comply with §§ 1306.01-1306.06 and §§ 1306.21-1306.25 of Title 21 of the Code of Federal Regulations, beginning March 14, 1977. All prescriptions for products containing such substances issued before March 14, 1977, if authorized for refilling, shall as of that date be limited to five refills and shall not be refilled after September 14, 1977.

7. *Importation and exportation.* All importation and exportation of dextropropoxyphene shall, on or after March 14, 1977, be required to be in compliance with Part 1312 of Title 21 of the Code of Federal Regulations.

8. *Criminal liability.* Pursuant to Title 21 of the Code of Federal Regulations, § 1308.49, the Administrator, Drug Enforcement Administration, hereby orders that any activity with respect to dextropropoxyphene not authorized by, or in violation of, the Controlled Substances Act or the Controlled Substances Import and Export Act, conducted after March 14, 1977 shall be unlawful, except that any person who is not now registered to handle these substances but who is entitled to registration under such Acts may continue to conduct normal business or professional practice with dextropropoxyphene between the date on which this order is published and the date on which he obtains or is denied registration.

9. *Other.* In all other respects, this order is effective on March 14, 1977.

Dated: February 7, 1977.

PETER B. BENSINGER,  
Administrator,  
Drug Enforcement Administration.

[FR Doc. 77-4407 Filed 2-16-77; 8:45 am]

**SUPPLEMENTARY INFORMATION:** In the Federal Register of December 29, 1976, at pages 56674 and 56675, there was published a notice of proposed rule-making to amend 31 CFR Part 223 (also appearing as Department Circular 297). Interested parties were given thirty days ending on January 23, 1977, in which to submit written views or comments with regard to the amendments. As no written views or comments were received during the thirty day period, the Department finds that there is no good cause to postpone the proposed amendments' effective date. Accordingly, the proposed amendments are hereby adopted.

In addition, for additional clarity and exactness the Department finds it necessary to amend the fourth sentence of 31 CFR 223.8 by amending "N.A.I.C." to read "National Association of Insurance Commissioners." Also, in the first sentence of 31 CFR 223.9, the word "instructions" is amended to read "guidelines" for additional clarity and to provide consistency. The Department further finds that notice to the public respecting the amendments to 31 CFR 223.8 and 31 CFR 223.9 is not appropriate or necessary as their sole purpose is to clarify the regulations and the amendments have minimal public effect.

*Note.*—The Bureau of Government Financial Operations has determined that this document does not contain a major proposal requiring preparation of an Inflation Impact Statement under Executive Order 11621 and OMB Circular A-107.

Dated: February 4, 1977.

D. A. PAGLIAI,  
Commissioner, Bureau of  
Government Financial Operations.

§ 223.3 [Amended]

1. In § 223.3: Amend "(a) If, from the evidence submitted in the manner and form herein required \* \* \*" to read "(a) If, from the evidence submitted in the manner and form herein required, subject to the guidelines referred to in § 223.9 \* \* \*"

2. Section 223.7 is amended to read:

§ 223.7 Investment of capital and assets.

The cash capital and other funds of every such company must be safely invested in accordance with the laws of the State in which it is incorporated and will be valued on the basis set forth in § 223.9. The Secretary of the Treasury will periodically issue instructions (or the guidance of companies with respect to investments and other matters. These guidelines may be updated from time to time to meet changing conditions in the industry.

3. In § 223.8(a): Amend "Secretary of the Treasury" to read "Assistant Comptroller for Auditing" in the first sentence. The remaining sentences of § 223.8 (a) are amended to read:

§ 223.8 Financial reports.

(a) \* \* \* On or before the last days of April, July and October of each year, every such company shall file a financial statement with the Assistant Comptroller

for Auditing as of the last day of the preceding month. A form is prescribed by the Treasury for this purpose. The quarterly statement form of the National Association of Insurance Commissioners when modified to conform to the Treasury's requirements, may be substituted for the Treasury's form. The quarterly statement will be signed and sworn to by the company's president and secretary or their authorized designees.

4. Section 223.9 is amended to read:  
§ 223.9 Valuation of assets and liabilities.

In determining the financial condition of every such company, its assets and liabilities will be computed in accordance with the guidelines contained in the Treasury's current Annual Letter to Executive Heads of Surety Companies. However, the Secretary of the Treasury may value the assets and liabilities of such companies in his discretion. Credit will be allowed for reinsurance in all classes of risks if the reinsuring company holds a certificate of authority from the Secretary of the Treasury, or has been recognized as an admitted reinsurer in accord with § 223.12.

§ 223.11 [Amended]

5. Section 223.11(b) (2) (i) is amended to read: (i) One or more companies holding a certificate of authority from the Secretary of the Treasury as an acceptable surety on Federal bonds or one or more companies holding a certificate of authority as an acceptable reinsuring company on such bonds, or

6. In § 223.11(b) (2) (ii): Amend "Any company" to read "One or more companies."

7. In § 223.11(c) (1): Amend "of property" to read "of assets admitted by the Treasury."

8. Section 223.15 is amended to read:

§ 223.15 Paid up capital and surplus for Treasury rating purposes; how determined.

The amount of paid up capital and surplus of any such company shall be determined on an insurance accounting basis under the regulations in this part, from the company's financial statements and other information, or by such examination of the company at its own expense as the Secretary of the Treasury may deem necessary or proper.

§ 223.16 [Amended]

9. In § 223.16: Delete "a fidelity and" from its first sentence.

§ 223.17 [Amended]

10. In § 223.17: Amend "Whenever in the judgment of the Secretary of the Treasury a company is not complying with the requirements of 6 U.S.C. 6-13 and of the regulations in this part, he shall \* \* \*" to read "Whenever it appears that a company is not complying with the requirements of 6 U.S.C. 6-13 and of the regulations in this part, the Secretary of the Treasury will \* \* \*"

11. Section 223.18(a) is amended to read:

Title 31—Money and Finance: Treasury  
CHAPTER II—FISCAL SERVICE,  
DEPARTMENT OF THE TREASURY

PART 223—SURETY COMPANIES DOING  
BUSINESS WITH THE UNITED STATES

Revision of Regulations Which Govern  
Surety Companies Doing Business With  
United States

AGENCY: Bureau of Government Financial Operations.

ACTION: Final Rule.

SUMMARY: The Department of the Treasury is amending its surety regulations at 31 CFR Part 223 in order to clarify and update the regulations in light of current practices; to remove the only technical requirements contained in Part 223; and to revise its schedule of fees to recover costs related to services performed for and special benefits conferred upon surety companies by the Department.

EFFECTIVE DATE: February 4, 1977.

FOR FURTHER INFORMATION CONTACT:

Mr. Guy Kelly, Insurance Company Audit Branch, Bureau of Government Financial Operations, U.S. Department of the Treasury, Washington, D.C. 20226, (202-634-5978).