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FISCAL IMPACT REPORT

SPONSOR	Gru	besic	DATE TYPED	03/08/05	HB	
SHORT TITI	LE	Amend Drug, Device	e and Cosmetic Act		SB	870/aSJC
				ANAL	YST	McSherry

APPROPRIATION

Appropriation Contained		Estimated Additional Impact		Recurring or Non-Rec	Fund Affected
FY05	FY06	FY05	FY06		
NFI	Indeterminate	NFI	Indeterminate	Recurring	General Fund

(Parenthesis () Indicate Expenditure Decreases)

Relates to Senate Bill 413 which also proposes amendments to the Drug, Device and Cosmetic Act.

SOURCES OF INFORMATION

LFC Files Corrections Department Regulations and Licensing Department Attorney General's Office Administrative Office of the Courts

SUMMARY

Synopsis of Senate Judiciary Committee Amendment

The Senate Judiciary Amendment removes the "Penalty" section from the proposed legislation. The section exists in current statute and was proposed to be amended in the original bill. Current established penalty is a fourth degree felony for knowingly violating the Drug Device and Cosmetic Act and a misdemeanor for first offenses and fourth degree felony for a second offense. The original bill's amendment would have increased the penalty to a third degree felony for certain violations of the Act.

Synopsis of Original Bill

Senate Bill 870 proposes to amend the Drug Device and Cosmetic Act by changing the definition of a counterfeit drug and adding pedigree requirements allowing wholesalers/pharmacies the ability to determine the sales/possession history of a drug. The bill also proposes striking the "Penalties" section of the Act.

Significant Issues

According to the Regulations and licensing Department's Board of Pharmacy (BoP), the proposed change to the definition of a counterfeit drug is simpler than the current statutory definition, and similar to the one adopted by the World Health Organization and the proposed drug "pedigree" requirements are a direct result of the growing public health problem of counterfeit drugs entering the drug distribution chain.

BoP asserts that counterfeit drugs are illegal and inherently unsafe and that the recorded history of a drug (pedigree) would allow the legitimate distributors of prescription drugs to validate a drug's history. BoP states that the proposed history should include all owners, possessors, distributors, pharmacies, brokers, and transferors of the drug and allow investigators to trace the history of counterfeit drugs that have been illegally introduced into the drug wholesale market.

The Board of Pharmacy cites support for this legislation and reports that numerous states have already enacted drug pedigree requirements in order to determine a drug's authenticity. BoP cites Florida as a state that has been inundated with illicit counterfeit activity resulting in serious harm to its citizens as well as others in the United States. They have adopted pedigree requirements for prescription drugs. The National Association of Boards of Pharmacy recently adopted model rules, for drug wholesalers, which include pedigree requirements for drugs.

BoP further reports that drug counterfeiters are known to seek wholesale licensure in states with lax pedigree and wholesale licensure requirements and that this legislation would enhance this state's ability to combat this growing public health menace. BoP suggests that the ability for the Board to further define "pedigree" would allow the flexibility needed to allow future innovations such as radio frequency identification chips that store electronic pedigrees from the drug's manufacturer all the way down to the point of dispensing.

Current law allows up to a fourth degree felony as maximum punishment for crimes involving counterfeit drugs. The maximum prison sentence for the crime as a fourth degree felony is eighteen (18) months. The maximum prison sentence for the crime as a third degree felony is three (3) years.

PERFORMANCE IMPLICATIONS

This bill may impact the district court's performance measures including clearance rates if increased penalties lead to an increased demand for jury trials and fewer plea bargains, thereby increasing the amount of judge and clerk time needed to dispose of cases.

FISCAL IMPLICATIONS

There will likely be a minimal administrative cost for statewide update, distribution, and documentation of statutory changes. Any additional fiscal impact on the criminal justice system would be proportional to the enforcement of this law and commenced prosecutions. New laws, amendments to existing laws, and new hearings have the potential to increase caseloads in the courts, and Corrections Department.

ADMINISTRATIVE IMPLICATIONS

A minimal administrative increase on the Pharmacy Board, courts and associated criminal justice agencies and prison administrative and probation/parole staff would be likely because of the increase in caseloads.

The Pharmacy Board would be required to establish corresponding rules to the proposed statute changes.

CONFLICT, DUPLICATION, COMPANIONSHIP, RELATIONSHIP

Senate Bill 870 relates to Senate Bill 413, which also proposes amendments to the Drug, Device and Cosmetic Act.

WHAT WILL BE THE CONSEQUENCES OF NOT ENACTING THIS BILL?

According to the Board of Pharmacy, drug counterfeiters may be drawn to New Mexico because the penalties for counterfeiting would not be as severe as in other states and we would not have the statutory requirement of drug pedigrees to authenticate a drug's distribution history.

No pedigree requirements would be established by the board of pharmacy. Maximum penalties under the Drug Device and Cosmetic Act would remain a fourth degree felony.

QUESTIONS

What is the intended outcome of striking the "Penalties" section of the Drug, Device and Cosmetic Act?

EM/lg