

Legislative Analysis



ADULTERATING DRUGS, MEDICINES, AND DEVICES

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House Bill 5174 (Substitute H-1)
Sponsor: Rep. David Robertson

House Bill 5175 (Substitute H-3)
Sponsor: Rep. Mike Nofs

House Bill 5176 (Substitute H-2)
Sponsor: Rep. David Farhat

House Bill 5177 (Substitute H-1)
Sponsor: Rep. Stephen Ehardt

House Bill 5178 (Substitute H-1)
Sponsor: Rep. Tom Casperson

Committee: Criminal Justice

First Analysis (2-23-04)

BRIEF SUMMARY:

The bills would increase the penalties for knowingly adulterating, misbranding, removing, or substituting a drug or medicine so as to render the drug or medicine injurious to a person's health, and would provide for administrative sanctions against a licensed health professional who violated this prohibition.

FISCAL IMPACT:

Fiscal information is not available at present.

THE APPARENT PROBLEM:

In August of 2001, a chilling story surfaced about a Missouri pharmacist who had been arrested by federal authorities for deliberately diluting chemotherapy drugs for personal gain. He eventually confessed to diluting four chemotherapy drugs involving 34 patients and a single physician practice over a period of six months. However, it is believed that he began diluting the drugs as early as 1992, if not earlier, and affected thousands of patients. According to a Department of Justice news release dated 12-5-2002, the number of potentially affected physicians is approximately 400, the number of prescriptions is approximately 98,000, and the number of potentially affected patients is approximately 4,200.

Some premixed bags of chemotherapy drugs dispensed from his pharmacy contained only 39 percent of the prescribed cancer-fighting drug. Though it is not yet known how many, if any, of the affected patients died as a result of the adulterated drugs, experts believe that some may indeed have lost their lives as a result of not receiving the prescribed amount of medication. The pharmacist in question has since pled guilty to 20 felony charges related to the dispensing of diluted chemotherapy drugs and is now serving a 30-year sentence in a federal penitentiary.

Since that incident, lawmakers at the state and federal level have looked for ways to protect the public from future incidents. Some believe that having laws with stiff penalties provide a strong deterrent from engaging in such behaviors. In reviewing Michigan's laws regarding the deliberate adulteration of drugs, medicines, and medical devices, however, some feel that the current laws are woefully inadequate. Currently, it is only a misdemeanor offense with imprisonment of up to one year and/or a \$1,000 fine. Therefore, legislation has been offered to increase the penalties for knowing adulterating drugs with the intent to defraud the public.

THE CONTENT OF THE BILLS:

Together the bills would amend various acts to increase the penalties for adulterating, misbranding, or substituting a drug or medicine with the intent to defraud. Each of the bills would take effect 90 days after enactment.

House Bill 5174 would amend the Michigan Penal Code (MCL 750.16 and 750.18). Currently, under the penal code, a person who fraudulently adulterates, for the purpose of sale, a drug or medicine so as to render it injurious to the health of another individual is guilty of a misdemeanor punishable by imprisonment not exceeding one year and/or a fine not exceeding \$1,000.

The bill would prohibit a person, with intent to defraud, from knowingly adulterating, misbranding, removing, or substituting a drug or medicine so as to render that drug or medicine injurious to an individual's health. A person who violates this provision would be guilty of a felony punishable by imprisonment not exceeding four years and/or a fine not exceeding \$5,000. However, the penalty would increase if the violation results in a personal injury, serious impairment of bodily function, or death. If the violation results in a personal injury, it would be punishable by imprisonment not exceeding 10 years and/or a fine not exceeding \$10,000. If the violation results in a serious impairment of bodily function, it would be punishable by imprisonment not exceeding 25 years and/or a fine not exceeding \$25,000. If the violation results in death, it would be punishable by life imprisonment.

The act also currently prohibits a person from mixing, coloring, staining, or powdering a drug or medicine with another ingredient so as to render that drug or medicine injurious to another individual, and from ordering or permitting another individual from doing the same and from selling or offering for sale such an adulterated drug or medicine. A violation is a misdemeanor. The bill would specify that a violation of the above provision would be a

felony punishable in the same manner as described in the previous paragraph, except that a violation resulting in death would be punishable by imprisonment for life or any term of years and/or a fine of up to \$40,000.

House Bill 5175 would amend provisions in the Public Health Code (MCL 333.16221 et al.) relating to penalties for adulterating or selling an adulterated drug or medicine. Under the act, the Department of Community Health may investigate activities related to the practice of a health profession by a licensee. The department is required to report its findings to the appropriate disciplinary subcommittee for further disciplinary action if sufficient grounds exist to warrant further action. The act lists numerous reasons that warrant disciplinary action by the subcommittee.

The bill would add to that list knowingly and recklessly adulterating, misbranding, removing, or substituting a drug or device knowing that it will be used, or selling, offering for sale, or possessing for sale, or manufacturing for sale an adulterated or misbranded drug. If the subcommittee finds existence of a violation, the penalty would be license revocation, a fine, and restitution. (Note: The code requires the disciplinary subcommittee to impose one or more of the listed sanctions for a particular violation. Therefore, the list of allowable sanctions for each particular violation uses the conjunction “or”. The bill apparently would depart from this tradition and instead uses the conjunction “and”. Thus, it would appear that the subcommittee would not have discretion in imposing a sanction or sanctions, but would have to revoke the person’s license and also impose a fine and order restitution.)

In addition to that penalty, the health code would make those acts felonies, punishable by imprisonment and a fine in the same manner described in House Bill 5174, except that a violation that results in death would be punishable by imprisonment for life or any term of years and/or a fine not exceeding \$40,000.

House Bill 5176 would amend the sentencing guidelines portion of the Code of Criminal Procedure (MCL 777.13n) to specify in the sentencing guidelines that a violation of the provisions in the Public Health Code relating to adulterating a drug or medicine with intent to defraud would be a crime against the public safety. A violation that does not result in a personal injury, serious impairment, or death would be a class F felony with a maximum term of imprisonment of 4 years. A violation that results in a personal injury would be a class D felony with a maximum term of imprisonment of 10 years. A violation that results in a serious impairment of a bodily function would be a class A felony with a maximum term of imprisonment of 25 years. Finally, a violation that results in death would be a class A felony with a maximum term of imprisonment of life. The bill is tie-barred to House Bill 5175.

House Bill 5177 would also amend the sentencing guidelines portion of the Code of Criminal Procedure (MCL 777.16a). The bill would specify in the sentencing guidelines that a violation of the provisions in the Michigan Penal Code relating to adulterating a drug or medicine with intent to defraud would be a crime against a person. A violation that does not result in a personal injury, serious impairment, or death would be a class F felony with

a maximum term of imprisonment of 4 years. A violation that results in a personal injury would be a class D felony with a maximum term of imprisonment of 10 years. A violation that results in a serious impairment of a bodily function would be a class A felony with a maximum term of imprisonment of 25 years. A violation that resulted in death would be a class A felony with a sentence of life imprisonment.

In addition, the bill would specify that a violation of the provisions in the Michigan Penal Code relating to the prohibition against mixing, coloring, staining, or powdering a drug or medicine with another ingredient so as to cause injury with the intent to defraud would be a crime against a person. A violation that does not cause personal injury, serious impairment, or death would be a class F felony with maximum term of imprisonment of four years. A violation that results in personal injury would be a class D felony with a maximum term of imprisonment of 10 years. A violation that results in serious impairment of a bodily function would be a class A felony with a maximum term of imprisonment of 25 years. Finally, a violation that resulted in death would be a class A felony with a sentence of life imprisonment. The bill is tie-barred to House Bills 5174 and 5178.

House Bill 5178 would amend the Corrections Code of 1953 (MCL 791.234). That code currently provides that a prisoner under a life sentence who has served 10 calendar years of the sentence for a crime committed before October 1, 1992 or 15 calendar years for a crime committed on or after October 1, 1992, with certain exceptions, may be eligible for parole. The act excludes from parole eligibility a prisoner under a life sentence for first degree murder or a violation of Chapter XXXIII of the Michigan Penal Code (relating to explosives, bombs, and harmful devices). The bill would also exclude a prisoner under a life sentence under the Michigan Penal Code for adulterating a drug or medicine with the intent to defraud when it resulted in death, or mixing, coloring, staining, or powdering a drug or medicine with another ingredient with intent to defraud when it resulted in death. The bill is tie-barred to House Bill 5174 and House Bills 5177.

ARGUMENTS:

For:

The bill package is a proactive response to the story that surfaced in 2001 regarding a Missouri pharmacist who, for personal gain, deliberately diluted and adulterated thousands of prescriptions. Approximately 4,200 patients were affected. Some of the drugs involved were chemotherapy drugs used to treat several deadly cancers such as breast, ovarian, and pancreatic cancers and AIDS-related Kaposi's sarcoma. Some chemotherapy solutions contained only 39 percent of the prescribed cancer-fighting drug, and at least one bag of solution contained only one percent! It is imperative, therefore, that Michigan enact laws with strong enough penalties sufficient to deter such heinous behavior. Without the bill package, however, such a crime would remain a misdemeanor with minor penalties. House Bill 5175 would also ensure that a pharmacist or other licensed health care provider would automatically lose his or her license to practice within the state, and House Bill 5178 would require that an offender sentenced to life imprisonment be denied parole if his or her actions resulted in the death of another.

Against:

The bills really are not needed. As apparent in the case of the Missouri pharmacist, federal laws are more than adequate to prosecute any person who adulterates drugs, medicine, and medical devices to the detriment of others. The pharmacist in question was sentenced to 30 years in a federal penitentiary without parole and was ordered to pay restitution of over \$10 million to his victims in addition to a fine of \$25,000. There never has been a case of deliberate adulteration of drugs in this state, and such incidents are rare in the U.S. and are viewed as isolated incidents. Besides, Congress is already looking legislation to further strengthen federal penalties and regulation, and industry members have also been spurred by this egregious crime to look to ways that similar incidents could be prevented.

POSITIONS:

The Department of Community Health has indicated support for the bill. (2-10-04)

Legislative Analyst: S. Stutzky

■ This analysis was prepared by nonpartisan House staff for use by House members in their deliberations, and does not constitute an official statement of legislative intent.