

# Legislative Analysis



## ADULTERATING DRUGS, MEDICINES, AND DEVICES

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**House Bill 5174 as enrolled**  
**Public Act 213 of 2004**  
**Sponsor: Rep. David Robertson**

**House Bill 5175 as enrolled**  
**Public Act 214 of 2004**  
**Sponsor: Rep. Mike Nofs**

**House Bill 5177 as enrolled**  
**Public Act 216 of 2004**  
**Sponsor: Rep. Stephen Ehardt**

**House Bill 5176 as enrolled**  
**Public Act 215 of 2004**  
**Sponsor: Rep. David Farhat**

**House Bill 5178 as enrolled**  
**Public Act 218 of 2004**  
**Sponsor: Rep. Tom Casperson**

**House Committee: Criminal Justice**  
**Senate Committee: Judiciary**

### Third Analysis (3-31-05)

**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:** The bills would have an indeterminate impact on the state and local units of government, depending on how they affected felony convictions and sentencing. There are no statewide data available to indicate the frequency with which offenders are prosecuted for the misdemeanor offenses that HB 5174 would elevate to felonies. To the extent that the legislation increased felony prosecutions, convictions, and length of sentences, it could increase state costs of imprisonment, currently at about \$28,000 per prisoner annually, and costs of felony probation supervision, currently at about \$1,800 per offender annually.

### **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 occurrences. Some believe that having laws with stiff penalties provides 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, regardless of the consequences of the person's actions. Therefore, legislation has been offered to increase the penalties for knowingly 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.

Under the bill, except as otherwise provided, a person who knowingly or recklessly committed any of the following would be guilty of a felony punishable by imprisonment for up to two years, a fine of not more than \$1,000, or both:

- Adulterating, misbranding, removing, or substituting a drug or medicine so as to render that drug or medicine injurious to health.
- Selling, offering for sale, possessing for sale, causing to be sold, or manufacturing for sale a drug or medicine that has been adulterated, misbranded, removed, or substituted so as to render it injurious to health.

However, the penalty would increase if the violation resulted in a personal injury, serious impairment of bodily function, or death. If the violation resulted in a personal injury, it would be punishable by imprisonment not exceeding 4 years and/or a fine not exceeding \$4,000. If the violation resulted in a serious impairment of bodily function, it would be punishable by imprisonment not exceeding 5 years and/or a fine not exceeding \$5,000. If

the violation resulted in death, it would be punishable by imprisonment for not more than 15 years and/or a fine of not more than \$20,000.

A person who violated the bill's provisions regarding tampering with drugs with the intent to kill or to cause serious impairment of a body function of two or more individuals, and the person or persons died, would be guilty of a felony punishable by imprisonment for life without parole or a combination of life imprisonment without parole and a fine of not more than \$40,000. It would not be a defense that the offender did not intend to kill a specific individual or did not intend to seriously impair two or more specific individuals.

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 also prohibit possessing for sale, causing to be sold, or manufacturing for sale an adulterated drug or medicine and would specify that a violation of the above provisions would be a felony punishable in the same manner as described in the previous paragraph.

Lastly, an offender could still be charged with, convicted of, or punished for any other violation of law that he or she committed while violating the provisions of these section of law.

**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 would be used, or selling, offering for sale, or possessing for sale, or manufacturing for sale an adulterated or misbranded drug. If the subcommittee found 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 the administrative sanctions, the health code would be amended to prohibit acts involving adulterating drugs and medicines and to punish violations in the same manner described in House Bill 5174.

**House Bill 5176** would amend the sentencing guidelines portion of the Code of Criminal Procedure (MCL 77713n) to specify in the sentencing guidelines that a violation of the provisions in the Public Health Code relating to adulterating a drug or medicine would be a crime against the public safety. A violation that did not result in a personal injury, serious impairment, or death would be a class G felony with a maximum term of imprisonment of 2 years. A violation that resulted in a personal injury would be a class F felony with a maximum term of imprisonment of 4 years. A violation that resulted in a serious impairment of a bodily function would be a class E felony with a maximum term of imprisonment of 5 years. Finally, a violation that resulted in death would be a class C felony with a maximum term of imprisonment of 15 years. The bill is tie-barred to House Bill 5175.

**House Bill 5177** also would 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 would be a crime against a person. A violation that did not result in a personal injury, serious impairment, or death would be a class G felony with a maximum term of imprisonment of 2 years. A violation that results in a personal injury would be a class F felony with a maximum term of imprisonment of 4 years. A violation that resulted in a serious impairment of a bodily function would be a class E felony with a maximum term of imprisonment of 5 years. A violation that resulted in death would be a class C felony with a maximum sentence of 15 years.

The bill would apply these same penalties to 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. 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 offenders sentenced to life imprisonment without parole under House Bills 5174 and 5175. The bill is tie-barred to House Bill 5174 and House Bill 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 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 Bills 5174, 5175, 5178 would require that an offender sentenced to life imprisonment be denied parole if his or her actions were intended to kill or were intended to seriously impair two or more persons but resulted in a person's death.

***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 at legislation to further strengthen federal penalties and regulation, and industry members have also been spurred by this egregious crime to examine preventive measures.

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