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Michele M. Leonhart
Administrator
Drug Enforcement Administration
8701 Morrisette Drive
Springfield, VA 22152

Re: Disposal of Controlled Substances, RIN 1117-AB18, [Docket No. DEA-316]

Dear Administrator Leonhart:

On behalf of the physician and medical student members of the American Medical Association (AMA), I appreciate the opportunity to provide comments on the Drug Enforcement Administration's (DEA) proposed rule that would govern the secure disposal of controlled substances by both DEA registrants and ultimate users (e.g., patients). The AMA strongly supports the Proposed Rule provisions. It is well documented that access to unused prescription drugs, including controlled substances, is one of the contributing factors to the nation's prescription drug abuse and diversion crisis. In addition, confusion about appropriate disposal options creates other public health problems, for example the increasing prevalence of controlled substances (and other prescription drugs) in drinking water. As a result, we support the issuance of final regulations as soon as possible to educate the public, protect patients, and help curb prescription drug abuse and diversion.

The AMA is concerned, however, that many states do not have the adequate resources to fund disposal programs. Furthermore, we urge the DEA to work with other federal agencies, such as the Environmental Protection Agency (EPA), the U.S. Department of Transportation (DOT), and the U.S. Department of Labor (DOL), along with states, to harmonize the rules and regulations governing the transport and disposal of controlled substances and other prescription drugs and biologicals.

The Proposed Rule

The AMA strongly supports the provision in the Proposed Rule that would expand the options available to collect controlled substances from ultimate users for purposes of disposal, including take-back events, mail-back programs, and collection receptacle locations. In addition, the Proposed Rule expands the category of entities authorized to offer these options and will include manufacturers, distributors, reverse distributors, local law enforcement, and retail pharmacies. While the AMA supports the expansion of entities permitted to engage in collection of unused controlled substances, we urge the DEA to reconsider excluding hospitals that do not have a registered pharmacy. Building an accessible disposal infrastructure that is purely voluntary means that significant stakeholders with regular patient interactions would be important contact points for patients interested in discarding

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unused controlled substances. Hospitals have the resources, capability, and often community-based contacts to support a disposal program.

For the most part, the DEA has introduced maximum flexibility into the Proposed Rule to increase the options that patients have to dispose of unused controlled substances, including reduced paperwork requirements. We strongly support the balance struck in the Proposed Rule.

Funding and Harmonizing Federal and State Requirements

While the Proposed Rule provides for a voluntary system for disposal of unused/unwanted controlled substances by patients/end users, the costs associated with offering such an option, including liability and compliance with other federal and state laws, may be prohibitive. We strongly urge the DEA to issue a joint document with the EPA, DOL, DOT, and the Department of Health and Human Services organizing and harmonizing (to the extent permitted by law) rules and guidance governing prescription drug and biological disposal (including controlled substances). We further urge the DEA to work with other federal agencies to engage the various state agencies involved in disposal to have a similar initiative to simplify and standardize the requirements. This will decrease cost and reduce compliance liability risk. The foregoing will increase interest among authorized entities to offer voluntarily disposal options to the public.

Finally, while we are very hopeful that the Proposed Rule will result in a significant expansion in readily accessible sites to dispose of unused controlled substances, we anticipate that congressional action may be needed to fund scaling-up infrastructure such as compliance with collection efforts and support for appropriate methods of destruction options. We appreciate, though, the DEA's effort to maximize access to disposal sites while minimizing the diversion and contamination risks.

The AMA is committed to combatting prescription drug diversion and abuse. The DEA's Proposed Rule is consistent with the strategies that the AMA has proposed as part of our federal and state activities to bring an end to the epidemic of prescription drug abuse and diversion, and urge you to expand on the agency's patient education campaign on disposal. The AMA welcomes the opportunity to partner with the DEA on this important patient safety matter.

Sincerely,

James L. Madara, MD