SUMMARY OF KEY MESSAGES AND RECOMMENDATIONS

The study committee was charged with examining the federal health care costs, safety, and quality concerns associated with discarded drugs that result from weight-based dosing of medicines contained in single-dose vials. The committee developed one overarching recommendation and eight more to support two broad goals for reducing inefficiencies that lead to discarded drugs while ensuring patient safety and quality care.

OVERALL CONCLUSION AND RECOMMENDATION

The committee's economic analysis of weight-based drugs in single-dose vials led to one overall conclusion:

> ***Under the current system in which drugs are developed, administered, or paid for in the United States, when a drug is discarded, there is no money to recoup. Therefore, there is limited economic value to discarded injectable or infused drugs from single-dose vials.***

However, there are opportunities for payers, drug manufacturers, and patients to make the entire U.S. system for producing, distributing, and paying for injectable drug therapies more efficient.

RECOMMENDATION 5-1: Drug developers, health care providers, and payers should focus their efforts on reducing inefficiencies in drug development, delivery, and payment systems that lead to excess costs for both the health care system and for patients rather than on trying to recoup payments associated with the discarded drugs.

GOAL 1: PROMOTE THE EFFECTIVE, EFFICIENT, AND SAFE USE OF INFUSED OR INJECTABLE DRUGS

Evidence supporting the use of weight-based rather than fixed dosing for many injectable or infused drugs is limited. Fixed dosing might be just as safe and effective, but pivotal trials rarely compare weight-based dosing with alternative dosing.

RECOMMENDATION 2-1: The U.S. Food and Drug Administration should require sponsors of pivotal trials for new or extended therapeutic indications to use fixed dosing for a given clinical indication unless safety and efficacy would be compromised. Manufacturers of products already in the market should consider conducting additional studies after approval so that these drugs can, when indicated, be converted to fixed dosing.

Concerns about sterility and storage have led to conflicting federal regulation and guidance on dividing the content of a single-dose vial into multiple individual doses. However, some countries have well-established approaches that allow for delivering medication to multiple patients from a single vial.

RECOMMENDATION 2-2: The Secretary of the U.S. Department of Health and Human Services should direct the Centers for Disease Control and Prevention, the Centers for Medicare & Medicaid Services, and the U.S. Food and Drug Administration to work with the United States Pharmacopeia and other nonfederal partners, pharmacists, and infectious disease experts to review and harmonize existing policies and guidelines on drug administration and repackaging. These policies and guidelines should be informed by the successful experiences from other industrialized countries in reducing the amounts of discarded drugs.

RECOMMENDATION 4-1: The Secretary of the U.S. Department of Health and Human Services should direct the Centers for Disease Control and Prevention, the Centers for Medicare & Medicaid Services, and the U.S. Food and Drug Administration to initiate a partnership with other agencies, including the U.S. Department of Defense and the U.S. Department of Veterans Affairs, to work with health care and other organizations with expertise in areas such as industrial design and systems engineering to identify and implement technological systems that allow single-dose vials to be used safely across multiple patients.

RECOMMENDATION 4-2: The Secretary of the U.S. Department of Health and Human Services (HHS) should develop and implement policies that require drug manufacturers to produce injectable and infused drugs in multi-dose vials when it is safe to do so. The Secretary of HHS should routinely review and evaluate the impact of such policies.

GOAL 2: IMPLEMENT AN EFFICIENT AND EFFECTIVE REIMBURSEMENT SYSTEM FOR THE CLINICIAN ADMINISTRATION OF INFUSED OR INJECTED DRUGS

Health care providers receive reimbursement for the full quantity of drug in single-dose vials. There is no incentive to minimize the amount of discarded drug. Also, Medicare and private payers reimburse based on the drug's average sales price plus a percentage for administering the drug. As a result, the dollar amount of the add-on is larger for more expensive drugs, which may encourage selection and administration of more expensive drugs.

RECOMMENDATION 2-3: The Secretary of the U.S. Department of Health and Human Services should require the Centers for Medicare & Medicaid Services (CMS) to uncouple add-on payments to clinicians for infused or injected drugs under Medicare Part B from the drug average sales price, focusing the add-on payment instead on CMS's assessment of the time and complexity of drug management and safety monitoring.

RECOMMENDATION 2-4: The Secretary of the U.S. Department of Health and Human Services should require the Center for Medicare & Medicaid Innovation to design and evaluate new payment models that reimburse health care providers by treatment episode rather than by the volume or the cost of a drug vial. Findings from the demonstrations should be disseminated widely to other relevant federal agencies, private payers, purchasers, clinicians, and consumers.

The JW modifier is used to document and reimburse the discarded amount of drug. However, the JW modifier is not used by all health care providers. Compliance with the JW requirement would not offer practical ways to reduce the amount of discarded drugs or estimate their economic value.

RECOMMENDATION 3-1: While the current Medicare Part B drug reimbursement system is in place, the Centers for Medicare & Medicaid Services should discontinue the use of the JW modifier.

Regardless of health insurance provider, patient cost-sharing is based on the cost of the full vial used in the treatment. The financial burden on the most vulnerable patients might be overwhelming.

Several versions of draft congressional legislation have proposed rebates from manufacturers to health care providers and payers for discarded drugs from single-dose vials but most do not address refunds to patients to offset their out-of-pocket costs. Although the committee's assessment shows that there is limited economic value for discarded drugs, if rebates are implemented, the committee asserts that patients should be included.

RECOMMENDATION 4-3: In the event that legislation is enacted or regulatory action is taken to require rebates from manufacturers for discarded drugs, the U.S. Congress should require that rebates be directed first to cover the patient's out-of-pocket expense for the discarded drug and thereafter to health care providers and payers.

INTERDEPENDENCE OF RECOMMENDATIONS

This report's recommendations are interdependent and aim to achieve greater efficiencies in the manufacturing, distribution, and use of injected or infused drugs. The case for these recommendations is based mainly on nonfinancial considerations, such as safety, equity, and overall efficiency.

To read the full report, please visit
nationalacademies.org/drugvialsize

The National Academies of
SCIENCES • ENGINEERING • MEDICINE

The nation turns to the National Academies of Sciences, Engineering, and Medicine for independent, objective advice on issues that affect people's lives worldwide.
www.nationalacademies.org