

# Waste Not, Want Not



# The quest to reduce oncology drug waste

**T**he issue of drug waste is nothing new in oncology. Over the years, many published reports have sought to put a dollar amount on this waste. In 2017, the Centers for Medicare & Medicaid Services (CMS) began requiring all physicians, hospitals, and other providers submitting Medicare Part B drug reimbursement claims to report any discarded amount of single-use vial or other single-use package drug. Based on that information, CMS now issues an annual Part B Discarded Drug Units Report that quantifies the annual amount the agency pays for discarded drugs and reports the names of the drugs wasted.

A report from CMS in January 2020 states that \$725 million worth of drugs reimbursed by Medicare Part B were discarded in 2018.<sup>1</sup> The top 10 drugs by value of the wasted product accounted for nearly \$456 million (Table 1, page 60).<sup>2</sup> Notably, 6 of these 10 drugs are anticancer medications. Collectively, the 6 drugs accounted for \$330 million worth of discarded drugs. More than 26 percent of one medication—the hematologic malignancy drug Velcade® (bortezomib)—was discarded, accounting for nearly \$123 million in waste.

Though the \$725 million in wasted medicine reported by CMS in 2018 represents only 2 percent of the \$33.3 billion the agency spent on drugs that year, that amount does not include spending by Medicaid and commercial insurers. Indeed, in 2016, researchers at Memorial Sloan Kettering Cancer Center published a study in *BMJ* in which they found that Medicare and private health insurers' combined waste near \$3 billion in cancer drugs each year.<sup>3</sup>

The authors of the article wrote that these medications are discarded because many pharmaceutical companies package individual doses of infusion drugs in one-size-fits-all, single-use vials that hold too much medication for most patients: “This is

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With drug vial optimization, single-dose vials are used for multiple patients.<sup>4</sup> Drug vial optimization has been shown to be effective in using valuable medications that would otherwise have been wasted.

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particularly true for drugs for which dosage is based on a patient's weight or body size and that come in single-dose packages,” the study's authors wrote. “These drugs must be either administered or discarded once opened, and because patients' body sizes are unlikely to match the amount of drug included in the vial, there is nearly always some left over.”<sup>3</sup>

## The Science of Dosing

Ali McBride, PharmD, MS, BCOP, former clinical coordinator of Hematology/Oncology at the University of Arizona Cancer Center and immediate past president of the Association of Community Cancer Centers, believes that discarding the drugs left over in one-sized vials can be avoided. “If we can change the sizes of vials, make them different sizes for different doses, we could significantly affect how much waste we produce,” he says.

Dr. McBride says that the current dosing system could be modified by having pharmaceutical companies replace one-size-fits-all packaging with drug vial optimization or dose banding. With drug vial optimization, single-dose vials are used for multiple

Table 1. Part B Prescription Drugs with the Highest Dollar Waste<sup>4</sup>

Brand Name	Generic Name	Amount Spent on Discarded Units	Percentage of Total Spending Per Drug
Velcade®	Bortezomib	\$122.6M	26.5%
Herceptin®	Trastuzumab	\$77.7M	9.1%
Nplate®	Romiplostim	\$48.8M	21.6%
Abraxane®	Paclitaxel protein-bound	\$38.0M	13.7%
Kyprolis®	Carfilzomib	\$32.9M	12.7%
Avastin®	Bevacizumab	\$32.5M	3.1%
Botox®	OnabotulinumtoxinA	\$27.7M	7.8%
Jevtana®	Cabazitaxel	\$26.4M	26.2%
Xolair®	Omalizumab	\$26.0M	6.3%
Simponi Aria®	Golimumab	\$23.2M	7.6%
Yervoy®	Ipilimumab	\$20.9M	7.6%
Remicade®	Infliximab	\$17.2M	1.4%
Keytruda®	Pembrolizumab	\$16.8M	0.9%
Vidaza®	Azacitidine	\$15.2M	22.1%
Dacogen®	Decitabine	\$14.9M	22.5%
Alimta®	Pemetrexed disodium	\$13.7M	2.8%



Ali McBride, PharmD, MS, BCOP

patients.<sup>5</sup> Drug vial optimization has been shown to be effective in using valuable medications that would otherwise have been wasted. But, in practicality, drug vial optimization can be difficult to implement.

For one thing, the time to repurpose leftover drugs may be limited. According to pharmacy compounding guidelines in the *United States Pharmacopeia* Chapter <797>, partial amounts of leftover drugs can currently be used for another patient for only up to six hours after the vial has been opened.<sup>6</sup> Dr. McBride says it is important for oncology pharmacists to more accurately determine the extended stability dating of drugs so that providers can safely repurpose the medication remaining in a vial for subsequent patient(s). “We need data for determining the extended life of drugs,” says Dr. McBride. “If a drug can be used up to 30 days, that is important to know and helpful to reducing waste.”

However, Dr. McBride acknowledges that optimizing some older drug therapies is not feasible. In these cases, he says, dose rounding can help mitigate waste: “We expect dose rounding policies to reduce drug waste both with infusional chemo and oral oncolytics,” says Dr. McBride. Dose banding, or the standardization of injectable chemotherapy doses into a defined set of dose ranges, or bands, is an alternative approach to precise dosing. Rather than basing dosages on body surface area, body weight, or other factors, dose banding determines a standard, pre-prepared dose of chemotherapy based on predefined ranges.<sup>7</sup> Dr. McBride says he believes that dose banding will gain traction as a method of stemming drug waste.

Melody Chang, RPh, MBA, BCOP, director of Pharmacy Operations at Florida Cancer Specialists and Research Institute, also believes more can be done to cut drug waste. She says getting manufacturers to address the waste inherent in packaging single-use vials is crucial. “When manufacturers package drugs in a limited quantity of strengths, they are most often only packaged as single dose vials (SDV), so you have no choice but to discard the leftover portion,” explains Chang. “According to the CDC, vials labeled by the manufacturer as ‘single dose’ can only be used for a single patient and should not be shared with the next patient. Even though Medicare and almost all commercial payers



Melody Chang, RPh, MBA, BCOP

will pay for the leftover amount that is discarded, patients also share the costs based on all of the drug in the vial, not the amount they received. If manufacturers could be more thoughtful in the design of vials, starting when investigators develop dosing strategies in the early phases of clinical trials and creating more multi-dose vials, there would be less waste from the start.”

Chang says that Florida Cancer Specialists is conducting research to determine how best to curb drug waste and what savings may be achieved by implementing dose rounding strategies. The practice is exploring the feasibility of this route and is currently examining the role of the EHR (electronic health record) in dose rounding. “The cost savings could be huge for payers and patients,” says Chang.

### **Leveraging a Robotics Platform**

Anthony Boyd, PharmD, BCPS, is the director of Pharmacy, Oncology Services, at Cleveland Clinic, where he is responsible for overseeing the clinical operations of the oncology infusion pharmacy on the main campus. There, Dr. Boyd’s team uses advanced robotics to prepare chemotherapy infusions. Dr. Boyd has applied some of the capabilities of these robots to help stem drug waste.

In a recent *CANCER BUZZ* podcast, Dr. Boyd discussed Cleveland Clinic’s initiative to reduce drug waste with the Association of Community Cancer Centers. He says that when CMS began requiring providers to put a specific price tag on their wasted drugs in 2016, the issue gained urgency.<sup>8</sup> “We took a look back to better understand the ins and outs of where our drugs went,” says Dr. Boyd. “As we dug a little deeper, we identified a specific problem with oncology drugs. We got a multidisciplinary team together to take a look at it: myself, our specialty pharmacy officer, our director of informatics, our director of 340B, and our supply chain folks. We launched initiatives to be better able to identify where the remainder of our drugs go after we pay for and administer them. We wanted to shrink that amount.”

Dr. Boyd said his team targeted the problem by addressing the potential waste of specific cancer drugs. “We went drug by drug,” explains Dr. Boyd. “We took a top-down approach, targeting the agents we thought had the most potential for waste. And then we worked our way down. We implemented a process for our pharmacists and technicians to help them get closer to an optimal vial size.”

Dr. Boyd says his team targeted a different drug each month. “At the end of the month, we would review our data to see if we were able to reduce waste. The exercise became a habit that enabled us to create step-by-step approaches to more accurately tailor specific drug dosages.” Although it was labor-intensive, the

initiative generated success. “For our targeted agents, we’ve been able to reduce the amount of the purchased drug that remains after it is given to a patient,” says Dr. Boyd. “But all of this is a complex, manual process, spanning from billing on the front end to technicians creating a specific patient’s vial size.”

Turning to the advanced robotics that prepare chemotherapy infusions in his oncology infusion pharmacy, Dr. Boyd sought to leverage Cleveland Clinic’s existing technology to curb drug waste. “During the past year, we’ve worked on developing a waste mitigation platform that enables our robots to make dosing alterations for specific drugs that we want to target to minimize waste,” Dr. Boyd explains. “We’ve reprogrammed our automated system to select an appropriate vial size for a given patient. Automating such a complex process has really helped our team. Especially when you get to some of these vial sizes that aren’t clean numbers, that don’t line up equally, having an automated system to help select vials to minimize waste is really important.”

Dr. Boyd says this initiative has been a coordinated effort among pharmacists, technicians, the finance team, and the supply chain team. “We work very closely with our electronic health record team to reconcile where we are and develop billing parameters for each different drug,” he adds. “We’ve also worked closely with our physician teams and nursing teams to have them review dose rounding policies to ensure everything is clinically appropriate. It’s a large, coordinated, multidisciplinary effort, and I think everyone understands the importance of it.”

### **Repurposing Oral Oncolytics**

Dr. McBride says that drug waste is not just relevant to infusion drugs; oral oncolytics are also often discarded when prescribers modify drug dosage, strength, or formulation during the course of a patient’s therapy. “The fact that oral therapies are also a source of waste illustrates how much this market is growing,” says Dr. McBride. “This is not just a problem with IVs—it is also a growing issue for the high-cost oral therapies that are starting to be used more.”

Melody Chang agrees. “Oral oncolytics come in bulk packages, one-month supplies in bottles, but a lot of time, patients’ dosages need to be adjusted,” she explains. “You cannot just cut a pill in half like you can with other non-oncology drugs when the dose gets adjusted down 50 percent. Some manufacturers will provide dose exchange programs for patient to get another strength without paying the copays. But you still need to get another prescription and get a new bottle.” Chang says that some cancer programs have launched initiatives that allow patients to donate their unused oral oncolytics to other patients rather than waste them.

In February 2020, the American Society of Clinical Oncology (ASCO) released a position statement on state drug repository programs, outlining ASCO’s support for drug repository programs for oral medications, provided that they are maintained within a closed system. According to ASCO, there are currently 13 state drug repository programs for unused anticancer drugs, supplies, and devices. ASCO contends that “widespread use of such pro-




Florida Cancer Specialists and Research Institute has nearly 100 locations across the state.

grams could lower costs for patients and payers, improve access to treatment for people who can't afford high-cost cancer drugs, all while reducing the amount of unused medications in the outpatient setting.”<sup>9</sup>

The Ohio State University Comprehensive Cancer Center Arthur G. James Cancer Hospital and Richard J. Solove Research Institute launched a program in January 2020 that enables patients with cancer to donate their unneeded prescribed oral oncolytics to other patients who cannot afford their medications. New rules adopted in October 2019 by the State of Ohio Board of Pharmacy permit donations of some anticancer drugs after pharmacists conduct an inspection of the donated drug to ensure that it is safe to re-dispense.

Dr. Boyd says his experiences with finding ways to reduce drug waste have taught him to stay flexible. “Find the data and identify where the areas of opportunity are,” he says. “Talk to the folks doing the work every day. Ask the technicians, ‘Hey, which vial sizes do you end up wasting a lot of at the end of the day?’ Asking simple questions can help frame where your greatest areas of opportunity are.”

Dr. McBride is confident that actions to combat drug waste have the potential to significantly decrease drug costs. “If we can minimize this waste, we can make a major dent in the price of these therapies,” he says. “We need to have an open conversation with pharmacies and generic companies to optimize vial sizes. If we can get this information out there before a drug changes [goes generic], we can dispense drugs with less waste, and that will decrease the cost of care.” 

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