Estimated Cost and Savings in a Patient Management Program for Oral Oncology Medications: Impact of a Split-Fill Component

Francis C. Staskon, PhD¹; Heather S. Kirkham, PhD, MPH¹; Amy Pfeifer, PharmD²; and Richard T. Miller, MBA, MS, RPh²

QUESTION ASKED: What are the impacts of estimated pharmacy costs, discontinuations, potential wastage, and reported rates of adverse effects on patients with a split-fill option compared with similar patients who do not have this option?

SUMMARY ANSWER: The split-fill patient managed subcomponent had lower discontinuation rates, significantly reduced pharmacy costs, and reduced potential wastage when compared with the non–split-fill cohort for the first 3 months. Cost and wastage levels remained lower in the split-fill patient group than in the non–split-fill patient group 6 months after index for the patient's new oncolytic therapy.

WHAT WE DID: A 1:1 greedy match algorithm was conducted using propensity variables to match patients from each cohort. Per-month discontinuation rates were determined for both split-fill and non–split-fill groups. Potential wastage for the non–split-fill group was calculated as monthly costs for discontinuations in the following month and weighted by split-fill discontinuation rates.

WHAT WE FOUND: In all, 2,363 program patients met selection criteria for the 11 medications; 671

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patients from each group were matched. Payers with a split-fill program had significant cumulative monthly medication savings (\$2,147.60 at 1 month; \$928.00 at 6 months). Modeled wastage indicated that payers without a split-fill program could expect to save \$2,646.74 monthly if they used this option. Both cohorts had similar rates of adverse effects and time until first reported adverse effect.

BIAS, CONFOUNDING FACTORS: A patient's individual choice on management in pharmacy can limit or bias information on discontinuations when a patient chooses a different pharmacy but does not discontinue therapy.

REAL-LIFE IMPLICATIONS: For a growing number of oral cancer medications, the split-fill component can lead directly to significant savings in pharmacy costs and reduced wastage costs. Given that oral oncolytic therapy is costly to both payers and patients, it is important for participants to be able to gain savings from activities within the pharmacy management program.

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bstract

PURPOSE A national specialty pharmacy implemented a split-fill option within an oral oncology patient management program to reduce pharmacy costs and medication wastage resulting from early discontinuations. Payers covered dispensed medications at half-quantity intervals for each dispense up to 3 months. Proactive outreach to patients before they had used up the initial dispensed medication quantity helped assess the patient's tolerance to the new medication and adverse effects. This study compared costs for patients with a split-fill option to similar costs for patients without this option taking into account patient discontinuation rates, patient-reported adverse effects rates, estimated pharmacy costs, and potential wastage.

METHODS This retrospective cohort study included patients who were new to therapy on a split-fill medication between September 2015 and August 2017. A 1:1 greedy match algorithm was conducted using propensity variables to match patients from each cohort. Per-month discontinuation rates were determined for both split-fill and non-split-fill groups. The non-split-fill potential wastage was calculated as monthly costs for discontinuations in the following month and weighted by split-fill discontinuation rates.

RESULTS Of the 2,363 program patients who met selection criteria for the 11 medications, 671 patients from each group were matched. Payers with a split-fill program had significant medication savings per covered month (\$2,147.60 at 1 month) and at a cumulative 6 months. Modeled wastage indicated that payers without a split-fill program could expect to save \$2,646.74 monthly by using this option. Both cohorts had similar rates of adverse effects and time until first reported adverse effect.

CONCLUSION In the first 6 months, the split-fill patient managed program had lower discontinuation rates, significantly reduced pharmacy costs, and reduced potential wastage.

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INTRODUCTION

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In the United States from 1971 to 2016, cancer survival has increased from three million to 15.5 million.¹ Mariotto et al² projected that by 2020, the United States will have an estimated 18.1 million cancer survivors incurring \$173 billion in health care costs. Biopharmaceutical companies have attributed approximately 73% of the gains in cancer survival to new medicines.³ In 2017, eight of the 14 new oncology drug approvals were for oral medications,⁴ and as of 2018, 71.4% of US Food and Drug Administrationapproved oncology medications were oral (M. Kleinrock, personal communication, December 2018). A study by Kaisaeng et al⁵ found that discontinuation rates for oral oncolytic medications ranged from 35%

to 70% among older adults. Discontinuation of oral oncolytic medications may occur for many reasons, including dose change, adverse events, disease progression, or death.^{6,7} When medications are discontinued before the full-month supply has been used up, medication wastage has undesirable cost implications for both patients and health insurers.

Previous research found support for the effectiveness of a pharmacy-led, split-fill program to prevent wasting medication for patients who receive oral oncolytic medications.^{8,9} Split-fill allows for a 14- to 16-day supply (also known as a "monitored dispense") for oral oncolytic medications rather than a full 28 to 30 days' supply. Savings in pharmacy costs for third-party payers that allow a split-fill program are achieved when

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the oral oncolytic medication for the second half of the first month of therapy is not dispensed if the oncologist changes the dose or discontinues the current treatment. Third-party payers approve coverage for dispensing oral oncolytic medications at half-quantity intervals, including copay modifications for each dispense. The national specialty pharmacy, working together with third-party payers, can implement the split-fill component for the first month of oral oncolytic medication therapy and continue that component up to the third month of therapy. For those third-party payers who do not include a split-fill component within their benefit design, there would be no savings to the payer or patient if a therapy modification is made because the full month of therapy drug would have been dispensed at the initiation of therapy.

Previous analyses evaluated the impact of a cycle management program (CMP) split-fill component as an independent, central specialty program.^{8,9} After this program was implemented, multiple updates and modifications were incorporated with Food and Drug Administration approval of new oral oncolytic medications along with realworld data analysis of the use of oral oncolytic medication. These previous studies evaluated the original program, which covered three oral oncolytic medications (ie, sorafenib, erlotinib, and sunitinib). As of May 2014, the splitfill program expanded to include six more medications: everolimus, dasatinib, bexarotene, nilotinib, pazopanib, and vorinostat. In February 2017, crizotinib and ceritinib were added. This study examines and updates the previous studies by using the expanded list of 11 oral oncolytics and pharmacy cost information.

The first two retrospective intervention-control studies had 1,069 patients in the CMP intervention group and 351 patients in the control group. Outcomes included reasons for discontinued medication or hospital admissions and a potential indirect savings per patient from reduced wastage and reduced hospital admissions. In the CMP group, patients discontinued their medication for various reasons such as death (21.9%), physician decision (10.1%), and ineffective therapy (9.7%). Patients in the CMP group also had a 2.9% probability of reductions in hospital admissions and a potential indirect savings of \$440 per patient. Combined estimated savings in the CMP cohort from reduced medication wastage (\$934.20) and hospital admissions (\$439.87) totaled \$1,374 per patient. In a study by Khandelwal et al,9 an additional control cohort was matched from an outside data source on the basis of national claims data from a propensity analysis. Propensity matching was conducted across cohorts on the basis of age, sex, drug, and cancer type. The CMP group's adherence (44.8% v41.5%) and persistency (23.8% v7.8%) levels were higher when compared with that of the control group. The study also found significant potential wastage savings per patient (33.8% of CMP patients [\$2,765.65 per patient]) and estimated wastage savings in the CMP split-fill

program (\$934.20 per patient). In addition, hospitalizations were reduced for CMP split-fill patients by an average of 3.4% across four models of comparison, with an estimated savings of \$452.21 per patient. Deutsch et al⁷ examined the assessment process for the expanded nine medications mentioned previously and for patient responses to questions regarding adverse events for a sample of 557 patients. In that study, adverse events reported by patients confirmed expected adverse events rates on the basis of the product labeling of the medications. Most adverse events were reported in the first month from start of therapy (76%), and a majority of all adverse events (83%) were of grade 1 severity.

Therefore, the objective of this study was to compare discontinuation rates, estimated pharmacy costs, and potential wastage costs for patients who have a thirdparty payer pharmacy benefit design that does include a split-fill subcomponent with those of patients who have a third-party payer pharmacy benefit design that does not include a split-fill component for the 11 oral oncolytic medications within the oncology-focused patient managed program. Medical cost differences were not addressed given the focus is to demonstrate the pharmacy cost savings from the split-fill component within the CMP program, not to compare to non-program patients. Given all patients are in the CMP program, patient-reported side effect rates are expected to be similar across the comparison groups.

METHODS

We conducted a retrospective cohort study comparing patients new to therapy from September 2015 through August 2017 who started an oral oncolytic medication with a split-fill component with patients who had a non–split-fill (ie, complete fill) component. Excluded were all off-label pediatric patients or any on-label pediatric patients younger than age 6 years, patients residing in US territories, patients who had a greater than 1 month supply on initial dispense (that would last for more than 40 days), or patients starting with two oral oncolytic medications. This study was approved by Quorum institutional review board (#28495).

Program

Initiated in 2008, the CMP is a therapy management program intended to identify therapy challenges, improve medication adherence, and provide a split-fill option for payers with patients who take oral oncolytic medications. All patients who are new to therapy with eligible oral oncology medications are automatically enrolled in the CMP. The CMP focuses on patient counseling and education and was developed and is maintained by clinical pharmacists with oversight and approval provided by medical directors. Inclusion of medications in the split-fill option for payers is based on an internally developed proprietary algorithm that

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includes reviewing each oral oncolytic medication for dosage form, dosing schedule, medication discontinuation rates (both published and internal data), storage requirements, risk evaluation and mitigation strategy requirements, and dispensing in combination with other medications. In addition, the oncology-focused patient management program is designed to identify patients who may not be tolerating a newly prescribed oral oncolytic medication by early detection of adverse events and other therapy challenges as identified by and reported by the patient or caregiver. The CMP includes proactive patient outreach approximately 10 days into treatment and before the dispensed medication supply is exhausted. If a patient indicates tolerability issues and/or other therapy challenges during the midcycle patient outreach, the national specialty pharmacy contacts the prescribing oncologist to provide patient-reported data and to discuss therapy continuation and/or modification. Outreach to the oncologist will occur for all CMP patients at the midcycle patient assessment regardless of the split-fill option. Under the split-fill option, any discontinuation of therapy by the oncologist at this midcycle point reduces patient exposure to a poorly tolerated oral oncolytic medication and saves pharmacy costs for third-party payers and patients by decreasing medication wastage.

Outcome Variables

Per-month discontinuation rates were determined for both split-fill and non–split-fill patients. The non–split-fill potential wastage was calculated as per-month costs for those who discontinued in the following month and was weighted by split-fill discontinuation rates. For split-fill, two discontinuation rates were estimated: (1) a rate based on patients who started therapy in the first half of the first month and discontinued during the second half of the same month, and (2) a rate based on patients who started therapy during the second half of the first half of the following month (Fig 1). The split-fill pattern A or B weights were used for the corresponding non–split-fill adjustments to monthly costs. For split-fill patients, potential waste is averted when discontinuation occurs before the sixteenth day of the month; therefore, fills

on days 16 through 30 of the given supply are not modeled for wastage.

Statistical Analysis

A 1:1 greedy match algorithm was conducted using propensity variables of patient age, sex, state census areas, index medication, start date as historical half-year segmentation, and use of more than a single medication. Paired t tests were conducted on the outcomes of payer costs, on plan copay costs, and on persistency of matched patients. Wastage was modeled for only the non-split-fill patients using the split-fill patient discontinuation rate, and no statistical analysis was performed. For rates of adverse effects, statistical analysis was performed on the subset of matched patients who had adverse-effect assessments. Patients were coded as having affirmed a given adverse effect from any medication in their responses or not (ie. affirmed "none"). This was examined by using McNemar's test for 2 \times 2 tabulations and a paired t test was used to assess the adverse effects by months from index.

RESULTS

Of the 2,473 patients within the oncology-focused patient management program, 2,363 met selection criteria; 672 patients were identified in the split-fill program, and 1,691 were identified in a non–split-fill subcomponent for the 11 medications listed in Table 1. One patient was not matched to a control patient, which reduced the split-fill matched count to 671. Postmatched comparisons on propensity variables indicated that only index drug proportions had the largest difference, but within the 10% value of standardized differences (Table 1).

Medication use during the index month and up to the 6-month follow-up indicated that the split-fill patients had a total of 517 more fills than the non–split-fill patients. Trends suggest that a higher percentage of the split-fill patients died in the first 3 months from index date compared with patients in the non–split-fill group, with an overall higher 3.4% death rate in the split-fill group. An examination of persistency rates per month (defined as drug therapy not discontinued because of a gap in supply of

Cohort		Discontinuations During the First 2 Months						
	Pattern	Month 1, First Half	Month 1, Second Half	Month 2, First Half	Month 2, Second Half			
Non-split-fill	А	30-days' fill	>	No fill				
	В		30-days' fill	No fill				
Split-fill	А	First 14-day fill	Second 14-day fill	No fill				
	В		First 14- day fill	Second 14-day fill	No fill			

FIG 1. Rationale for potential wastage in fill patterns for non–split-fill based on rates of discontinuations in split-fill patterns. Split-fill discontinuation rate for pattern A was used to weight wastage estimates for the non–split-fill pattern A group, and split-fill pattern B was the weight for non–split-fill pattern B wastage.

TABLE 1.	Standardized Differences	Pre- and	Post-Propensity	Matching and	l Post-
Propensity	/ Descriptive Statistics				

	Stand Diffe	ardized rences	Post-Propensity Descriptive Statistics			
Variable	Prematch	Postmatch	Case (%)	Control (%)		
Age (mean)	-0.047	0.002	57.6*	57.6†		
Female sex	-0.091	-0.015	49.6	50.3		
Census area	0.498‡	0.014				
Central-EN, WN, ES			50.3	49.7		
New England, Mid-Atlantic			50.2	49.8		
South Atlantic, WS Central			49.2	50.8		
Mountain, Pacific			49.8	50.2		
Index medication	0.144‡	0.082				
Sorafenib			20.2	20.2		
Everolimus			15.2	15.2		
Sunitinib			15.0	16.8		
Pazopanib			13.9	12.7		
Erlotinib			13.1	12.4		
Dasatinib			9.9	10.1		
Nilotinib			6.1	6.3		
Crizotinib			3.6	3.4		
Ceritinib			1.9	2.1		
Vorinostat			0.6	0.3		
Bexarotene			0.3	0.2		
Use two or more medications	0.057	0.015	48.8	51.2		
Historical 6-month segment	0.144‡	0.023				
First			49.9	50.1		
Second			49.2	50.8		
Third			50.6	49.4		
Fourth			50.5	49.5		

Abbreviations: EN, east north central; ES, east south central, WS, west south; WN, west north central.

*Mean value, standard deviation (SD)=11.8

†SD = 13.9.

‡Difference exceeds 0.10 criterion.

at least 45 days) showed that persistency was significantly higher (P < .001) for the split-fill patients when compared with that for non–split-fill patients in the second month (71.6% v 67.0%). The mean number of gap days between medication refills was significantly higher over 6 months for the non–split-fill patients than for the split-fill patients by 1.7 days per month (P < .003).

Plan copay values did not differ significantly across matched patients overall for 6 months or per month. As expected, cumulative plan costs as average wholesale price (AWP) per patient were significantly higher per month from index for the non–split-fill patients (monthly differences in Table 2, left four columns) compared with those for the split-fill patients; there was an average first-month

difference of \$2,147.60 and diminishing differences per new month until the final 6-month difference of \$928.60 (P < .001). However, after stratifying the per-month differences by how many months a given plan included splitfill, the cumulative monthly differences were similar to those in the first through third months past index fill (Table 2, right four columns).

In Table 3, the estimated costs for the wastage in medication supply for the 28.2% of non-split-fill patients who discontinued is presented in plan costs as AWP average and the cost for the lost 14 days. The average plan cost was \$2,646.73 (AWP) for the non-split-fill patients who discontinued after their last fill, assuming that the last 14 days of the month would not have been used and was modeled upon the pattern A and pattern B discontinuation rates shown in Figure 1 for the split-fill group. Estimated per patient per month savings was also calculated. For example, based on model discontinuation trends in Figure 1, AWP costs for discontinued non-split-fill patients among the matched sample would total \$1,444,946.73. This total divided by our 671-patient sample is \$2,153.43 per month. Therefore, the value of an individual 14-day split-fill (compared with a typical 30-day supply) per member per month savings is \$1,012.11 (ie, $$2,153.43 \times [14/30]$).

We examined rates of patient-reported adverse effects from program assessment data within the first 182 days from index medication. In the unmatched CMP patient population, 70% completed at least one adverse-effect assessment. For the matched 1:1 cohort sample, 293 patients (43.7%) completed at least one adverse-effect assessment; three additional patients did not answer adverse-effects questions. The rate for adverse effects (ie, affirmed over the total of all responses) was 55.3% for the split-fill cohort versus 54.6% for the non–split-fill cohort (P < .87). Finally, the difference in months since index date that an adverse effect was reported trended toward being earlier for the split-fill group but not significantly earlier (P < .07).

A sensitivity analysis was conducted on comparisons using significance testing by excluding the 13 patients who were younger than age 18 years with their matched adult patients; the results for the adults only sample (n = 658) were similar to the results for the total sample. The difference in costs between the split-fill and non–split-fill cohorts was \$2,086.30 (P < .001) for the first month and \$873.00 (P < .001) at 6 months. No significant copay differences were noted, and there were similar rates of adverse effects across cohorts (within 1%).

DISCUSSION

The previous Khandelwal et al^{8,9} studies examined the initial version of the split-fill program for three oral oncolytic medications, with estimated savings from potential wastage at \$2,765.65 (AWP) per patient eligible for split-fill. In those studies, 33.8% of patients discontinued before the next supply, whereas we estimated 28.2% wastage for the

TABLE 2.	Monthly Cumulative	e Plan Cost	Differences f	or Non-	-Split-Fill	Patients	Compared	With	Matched	Split-Fill	Patients	for A	ll Plans,
Segmente	ed by Duration of Pla	in Coverage	Э										

All	I Plans by Month	End Point		Plan Duration Segments at Month End Point					
Cumulative Month	AWP (\$)	SD (\$)	P *	Months Covered	AWP (\$)	SD (\$)	P *		
1	2,147.60	8,402.20	< .001	1	2,147.60	8,402.20	< .001		
2	1,366.20	8,546.70	< .001	2†	1,954.50	7,816.20	< .001		
3	1,163.70	8,435.90	< .001	3‡	2,015.40	7,738.40	< .001		
4	1,075.50	8,374.40	< .001						
5	938.40	8,235.80	< .001						
6	928.60	8,152.80	< .001						

NOTE. Monthly cumulative cost difference end points: non-split-fill v split-fill.

Abbreviations: AWP, average wholesale price, SD, standard deviation.

*Significant paired T test.

†Excluded patients with plans that allowed only the first month of split-fill (73%).

‡Excluded patients with plans that allowed only up to the second month of split-fill (75%).

non–split-fill group in our study. The lower discontinuation rate in our study also reduced the estimated savings from potential wastage to \$2,646.73 (AWP) per average month, even though pharmacy costs had increased. The lower percentage in this study likely reflects the continued quality improvement within the CMP program overall, a greater number of covered medications with fewer adverse effects, and possible differences in the case mix of patients.

The original studies did not compare a matched CMP group with split-fill to a CMP group without split-fill, but instead matched all CMP patients to all non-CMP patients. Hence, the direct savings in only the first 3 months is presented in this study (\$2,147.60 AWP in month 1, with the first 3 months showing a similar cumulative cost difference when adjusting for the number of months covered per payer plan). The 14-day wastage of \$1,012 per member per month is somewhat higher than the estimate from Khandelwal et al⁸ of \$934 because of

 TABLE 3. Monthly Mean Plan Cost Differences for Non–Split-Fill

 Patients Compared With Matched Split-Fill Patients, and Non–Split-Fill

 for Potential Wastage as a Result of Discontinuation

New Cullin Fill Meeters

	Null-Split-rill Wastage						
Month Filled	AWP PUPM (\$)	AWP for 14 Days (\$)					
1	5,180.87	2,612.64					
2	5,144.93	2,680.95					
3	5,908.20	3,053.28					
4	4,921.14	2,607.58					
5	4,599.40	2,387.40					
6	4,897.08	2,538.58					
6-month mean	5,108.60	2,646.73					

NOTE. Pattern A and B were averaged for the final wastage values. Weight applied for the split-fill discontinuations in pattern A was 36.4%, and for pattern B, the weight was 40.9%.

Abbreviations: AWP, average wholesale price, PUPM, per using patient per month.

the newer medications since 2009. The comparability of the assessment process across the matched groups of patients was supported, but the details on patient-reported issues were not examined. A previous study on the CMP split-fill assessments⁷ noted the prevalence of and influence of adverse events on a patient's medication use, including discontinuations and missed and held doses.

There is an increasing number of related studies on the impact of wastage for cancer medications. Recently, Monga et al⁶ estimated that chemotherapy medication wastage occurred in 41% of 88 patients and varied by reason for discontinuation (toxicity, progression to another therapy, dose increase, or death). Their total cost for wastage from 1,179 tablets or capsules was \$248,595.69. Notably, the authors suggested that a possible solution for reducing the costs and wastage was to have the insurance payer agree to dispense initial dosages with shorter supply (ie, split-fill). Chillari et al¹⁰ suggested cost containment for antineoplastic agents by reducing dosage by 5% or 10%; savings were \$22,849 in wastage with a 5% dose reduction and \$30,911 with a 10% dose reduction. Other research found cost reductions for pharmacy programs that monitor the quantity of the initial fills to a 14-day supply for 10 oncolytics that also significantly increased adherence compared with a 30-day supply.¹¹

Finally, this study did not examine adherence, given that the split-fill option is currently up to a 3-month option. However, persistency was significantly higher in the second month for the split-fill group but was not significantly different from that for the non–split-fill group across remaining months or overall. In addition to a positive increase in medication possession ratio in Young et al,¹¹ there are many studies reporting a positive impact upon medication adherence from pharmacy management programs (Khandelwal et al^{8,9}; Mathes et al¹²; Middendorff et al¹³).

One limitation of this study is that pharmacy claims were from a single national pharmacy. This might bias discontinuation estimates for those who switch pharmacies and not therapies. Patient-reported adverse effects are biased by patient engagement in the program and are not present for those not engaged in the management program. Although it is important information for payers, patient satisfaction was not measured for our study sample because we were not able to link our patient data to the deidentified national pharmacy standardized satisfaction survey. And propensity scores did not include socioeconomic variables, comorbidity information, or health status information to match patients on possible case mix differences.

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AUTHORS' DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST AND DATA AVAILABILITY STATEMENT

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The split-fill component of the program in this national specialty pharmacy has been examined in three previous studies (Deutsch et al⁷ and Khandelwal et al^{8,9}) and in our study. Even after noted modifications were made for new therapies, the split-fill patient managed component had lower discontinuation rates, significantly reduced pharmacy costs, and reduced potential wastage. By adopting a split-fill option, insurance payers have a means of reducing the pharmacy cost for new oncolytic therapy drugs, providing additional benefits to patients regarding copay, and addressing adverse events.

AUTHOR CONTRIBUTIONS

Conception and design: Francis C. Staskon, Heather S. Kirkham, Richard T. Miller Financial support: Richard T. Miller Administrative support: Richard T. Miller Provision of study materials or patients: Richard T. Miller Collection and assembly of data: Francis C. Staskon, Richard T. Miller Data analysis and interpretation: All authors Manuscript writing: All authors Final approval of manuscript: All authors Accountable for all aspects of the work: All authors

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AUTHORS' DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST

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Amy Pfeifer

Employment: AllianceRx Walgreens Prime, Walgreens Stock and Other Ownership Interests: Walgreens Boots Alliance Consulting or Advisory Role: Penumbra (I)

Richard T. Miller

Employment: AllianceRx Walgreens Prime, McKesson (I) Patents, Royalties, Other Intellectual Property: Miller, Richard; Pfeifer, Amy; Letwin, Rhonda. 2017. Facilitating Patient Communication Using Branching Logic in an Outpatient Oncology Treatment Regimen. United States Patent No. 9,779,631, filed February 27, 2013, and issued October 3, 2017. Travel, Accommodations, Expenses: AllianceRx Walgreens Prime, McKesson (I)

No other potential conflicts of interest were reported.