Analysis of the Economic Impacts of Dropless Cataract Therapy on Medicare, Medicaid, State Governments, and Patient Costs

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About Cataract Surgeons for Improved Eyecare:

Cataract Surgeons for Improved Eyecare (CSIE) is a nonprofit educational organization of cataract surgeons and ophthalmologists from across the United States. Members of CSIE are prominent in the leading medical societies devoted to ophthalmology and cataract surgery. The organization is dedicated to public education concerning improvements in the care of patients requiring cataract surgery.

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Key Findings

- Based on U.S. Bureau of the Census data of population projections and National Eye Institute data regarding the prevalence of cataracts among age groups, Medicare and Medicaid will fund more than 38 million cataract surgeries over the next ten years. Medicare is expected to pay for the great majority of these surgeries – 96% of the total, or an average of 3.7 million surgeries each year. Medicaid is expected to fund the remaining 4%, or an average of 150,000 surgeries per year. The number of Medicare and Medicaid-funded cataract surgeries is expected to grow at a compounded average annual growth rate of approximately 3%.
- The cost of drop therapy – that is, multiple prescription drugs applied topically to the eye for a period of weeks both before and after surgery – is an additional expense of cataract surgery. Most of this expense is currently borne by Medicare, Medicaid, state governments, and patients. Based on CMS data and our survey of physicians currently using the dropless therapy, within Medicare, the cost of the drug combination used for drop therapy ranges from a low of $175 to a high of $431 per eye, with a weighted average of $323. Within Medicaid, the cost of the prescription drugs used in drop therapy ranges from a low of $174 to a high of $431 per eye, with a median of $337. The confidence level established for our survey is 95%, meaning that we can be 95% confident that our survey would produce the same results if we were to conduct it again.
- Priced at $100 per prescription, dropless therapy is significantly less expensive than the traditional drop therapy alternative for cataract surgery.
- Current Medicare and Medicaid policy is to neither reimburse for dropless therapy nor to allow the patient to pay. Rather, the current policy requires that the incremental cost of dropless therapy be absorbed by the surgical facility or the physician performing the surgery. This puts dropless therapy at a disadvantage compared to drop therapy, for which Medicare and Medicaid do provide reimbursement.

- Changing the current federal policy and allowing patients to choose and pay for dropless therapy for cataract surgeries would save cataract patients approximately $1.4 billion for out-of-pocket co-payments between 2016 and 2025, under the most likely scenario. Currently, out-of-pocket co-payments can reach as much as $650 per eye for individual patients.
- Changing the current federal policy and allowing patients to choose and pay for dropless therapy for cataract surgeries would save Medicare, Medicaid, and patients between $2.1 billion and $13.0 billion, with a most likely savings estimate of $8.7 billion, between 2016 and 2025, based on our survey of physicians. Under the most likely scenario, Medicare and Medicaid would save approximately $7.1 billion over the same period. The confidence level for our survey was established at 95%, meaning that we can be 95% confident in our results.
- U.S. state governments would save $124 million in Medicaid payments during this ten year time frame, under the most likely scenario.
- Cumulative savings for individual state governments ranged from $200,000 to $19 million per year. California would save approximately $19 million over the next ten years. New York and Florida would save $9.5 million and $8.4 million, which account for the states positioned to benefit the most, respectively.
- Dropless therapy would produce additional recurring cost savings to the health care system overall, for an indefinite period, as a result of averted administrative costs for care providers.

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1. Background

Currently, most cataract patients are required to self-administer multiple drugs to their eyes several times a day for a period of weeks both before and after cataract surgery. This typically involves the use of three different prescription eye drops: an antibiotic, a steroid, and a non-steroidal anti-inflammatory drug (NSAID). The purpose of the drop therapy is to prevent inflammation and infection after cataract surgery. The benefits of utilizing antibiotics and anti-inflammatories for prophylaxis against infection and inflammation are well documented. Appendix A sets forth a summary of some of the existing literature.

In contrast to drop therapy, dropless therapy is performed by the physician immediately following cataract surgery, and requires only a single administration. When the patient is discharged after surgery, she does not have to purchase and self-administer drugs for prophylaxis against infection and inflammation. This minimizes patient compliance issues. By ensuring that 100% of the prescribed medication is applied to the desired area of the eye at the time of surgery, health outcomes are improved. Since dropless therapy was introduced for use in the United States, approximately 80,000 cataract surgeries have been performed in this way.

The most common approach to dropless therapy entails a single injection of anti-infective and anti-inflammatory drugs. A compound solution of three U.S. Food and Drug Administration approved drugs has been optimized for isotonicity at a pH most compatible with the eye. The compound consists of triamcinolone acetonide injectable suspension,[1] moxifloxacin hydrochloride ophthalmic solution,[2] and vancomycin hydrochloride.[3] The

[1] Approved by the U.S. Food and Drug Administration in 1957.
[2] Approved by the U.S. Food and Drug Administration in 1999.

compound solution obviates the need for separate administrations of three different drugs via eye drops. It also eliminates the need for repetitive administrations over a period of weeks, as is required with drop therapy. Other approaches to dropless therapy involve separate injections of the three drugs. As in the case of the compound solution, these separate injections are administered only once, immediately following surgery.

Although it is not the subject of our analysis, as a threshold matter we ascertained that a number of studies have documented the safety and efficacy of currently available dropless therapies.[4] In addition, approximately 40 trade articles regarding the efficacy of dropless therapy have been published. A partial list of these publications is provided in Appendix B. These studies and articles compare dropless therapy to traditional drop therapy across a number of parameters. The general conclusions set forth are as follows:

- **Prescription cost**: The cost of dropless therapy currently is approximately $100 per prescription. This compares to a cost of approximately $350 for the most commonly prescribed drop therapy alternatives. It should further be noted that costs in the range of $650 was not uncommon as exemplified in our case study.
- **Patient compliance issues**: Traditional drop therapy requires the patient or a third party to administer eye drops for a period of approximately four weeks both pre- and post-operatively. Administering drops is often difficult for those recovering from cataract surgery. This is particularly so because the vast majority of cataract surgeries are performed on older patients. Many elderly people cannot independently administer the required eye drops and require assistance from caregivers to administer the drops properly. Unlike saline eye drops with which most patients are

[3] Approved by the U.S. Food and Drug Administration in 1986.
[4] J. Liegner, *Better surgery through chemicals*, presentation at the American Society for Cataract and Refractive Surgeons Annual Meeting, April 25-29, 2014, Boston, MA; Galloway, S., *Intravitreal placement of antibiotic/steroid as a substitute for post-operative drops following cataract surgery,* presentation at the American Society for Cataract and Refractive Surgeons Annual Meeting, April 25-29, 2014, Boston, MA.

familiar, antibiotic and steroid drops require accurate placement on the surface of the eye for effectiveness, and touching the surface of the eye with the bottle can lead to contamination and infection. This careful regimen must be repeated, often more than a dozen times a day, for a period of a month or more. In addition to the physical difficulties many patients experience with self-administration, patient compliance is negatively affected by memory issues that are common among the cohort of the population eligible for cataract surgery. When patients forget to administer their drugs, or cannot do so, surgical outcomes are poorer, and complications result. The patient's difficulty in remembering the specifics of their regimen is increased by the fact that the frequency of application for each of the three drugs typically changes during the course of the prescription. (In this analysis, we do not undertake to estimate the costs of complications from patient noncompliance, but they are likely significant). Table 1-1 summarizes some of the literature regarding the difficulty patients experience in properly administering drops:

Table 1-1
Survey of Current Literature
Regarding Drop Administration

Study	Key Findings
Dreer, L., C. Girkin C, and S.L. Mansberger, "Determinants of medication adherence to topical glaucoma therapy."[5]	This prospective study was conducted to determine the associations between medical, demographic, socioeconomic, and ocular factors and adherence to topical glaucoma ocular hypotensive therapy. 116 patients participated. It was found that 64% administered the prescribed dosage within 3 hours of dosing time (Definition 1) with race being a significant predictor at 11%. 75% administered some drops within 3 hours of dosage time, again with race as a significant predictor at 15% (Definition 2). 80% administered some drops within 6 hours, with race and income being significant predictors of partial treatment compliance (19%).
Hennessy, A.L., et al. "Videotaped evaluation of eyedrop instillation in glaucoma patients with visual impairment or moderate to severe visual field loss."[6]	This analysis of glaucoma patients instilling their eye drops showed that of 204 subjects, 71% were able to get the drop into the eye. Only 39% administered the drop without touching the ocular surface, instilling an average of 1.4 ± 1.0 drops, requiring 1.2 ± 0.6 attempts. Age (< 70 vs ≥ 70 years)
Mansouri, K., et. al., "Compliance and knowledge about glaucoma in patients at tertiary glaucoma units."[7]	This observational study of 200 consecutive patients already under glaucoma medication in two Swiss tertiary glaucoma clinics (Geneva and Bern) was conducted to determine the rate of compliance and glaucoma-related knowledge in Swiss patients and to identify any risk factors for poor compliance. 81% (n = 162) of patients were reported to be compliant. Forgetfulness was cited as the most common cause of non-compliance with the dosing regimen (63%). Positively associated factors with compliance include better knowledge of glaucoma and receiving help in administering the drops. The findings indicate that a better knowledge of the disease could improve the compliance rate.
Tsai, T., et. al., "An evaluation of how glaucoma patients use topical medications: A pilot study."[8] Transactions of the American Ophthalmological Society. 2007;105: 29-35.	The authors surveyed 253 sequential glaucoma patients, having them complete a questionnaire about their use of eye drops, most specifically regarding the administration and storage of the drops. It was found that 17% relied on others to help administer their drops. They concluded that better instruction in administration and storage could help overcome patient frustration and non-compliance, and improve efficacy.

[5] L. Dreer, et. al., "Determinants of medication adherence to topical glaucoma therapy," *Journal of Glaucoma*, 2012, Issue 21, pp. 234-40.
[6] A.L. Hennessy, et al. "Videotaped evaluation of eyedrop instillation in glaucoma patients with visual impairment or moderate to severe visual field loss." *Ophthalmology*, 2010, Issue 117.
[7] K. Mansouri, K.. "Compliance and knowledge about glaucoma in patients at tertiary glaucoma units." *International Journal of Ophthalmology*, 2011, Issue 31 pp. 369-76.
[8] T. Tsai, et. al., "An evaluation of how glaucoma patients use topical medications: A pilot study." Transactions of the American Ophthalmological Society, 2007, Issue 105, pp 29-35.

- **Medical efficacy:** Many prescribers believe the use of dropless therapy produces superior medical results for cataract patients. The direct injection of the medication to the desired area eliminates the variability in application and outcomes that results when drugs must be individually administered over a prolonged period, outside the purview of the physician, as is the case in drop therapy.
- **Patients with disabilities:** Dropless therapy enables the provision of cataract surgery to a large population of cataract patients for whom traditional drop therapy would not be practical. This includes patients who are physically and/or mentally challenged, such as those with osteoarthritis, rheumatoid arthritis, scoliosis, Parkinson's, kyphosis, Alzheimer's, and dementia.

Given that the one-time administration of medication in dropless therapy is significantly less expensive than the multiple drugs and doses required by traditional drop therapy, this analysis was undertaken to quantify the economic impacts on Medicare, Medicaid, U.S. state governments, and patients that could be expected if dropless therapy were adopted more widely for use in connection with cataract surgeries. In addition to estimating and documenting the potential savings to the federal government and state governments through the Medicare and Medicaid programs from the use of dropless therapy in cataract surgeries covered by these programs, we have estimated the potential patient savings resulting from reduced pharmaceutical co-payments.

The analysis of economic impacts herein is limited to cataract surgery and does not include other conditions that may be treated using dropless therapy, such as retina procedures. It also excludes quantification of the likely significant additional patient savings resulting from averted costs for care provision during the post-surgery stage. The general magnitude of these indirect costs that result from drop therapy is alluded to anecdotally in the case studies, but savings from elimination or mitigation of these costs are not included in the overall savings

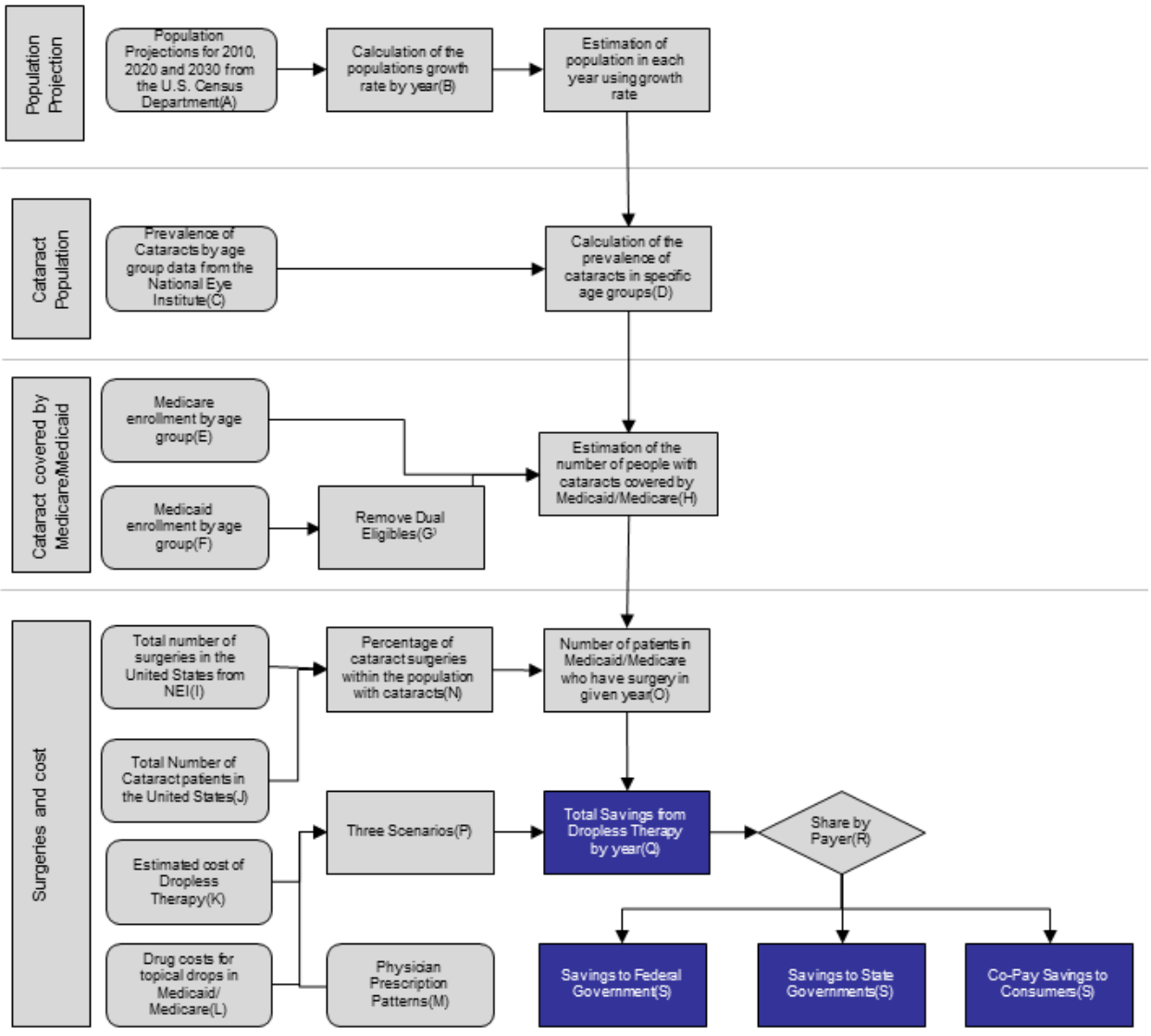
estimates. In addition, the overall cost savings do not include any estimate of the likely reductions in physician costs resulting from lower administration costs in connection with dropless therapy, as compared to drop therapy. These costs include the cost of instructing patients in the techniques of self-administration, the cost of follow-up necessary to ensure patient compliance, and the cost of dealing with complications (including infection) that result from imperfect self-administration, incomplete compliance, and noncompliance, all of which are associated with the traditional drop therapy alternative.

2. Methodology

Cash Flow Model:

In order to calculate the economic benefits, we constructed a cash flow model to estimate the potential savings to the federal government, state governments, and patients. The model utilizes generally accepted principles of mathematics, statistics, business administration, public finance, and policy analysis. The architecture of the cash flow model is shown in Figure 2-1.

Figure 2-1
Architecture of Cash Flow Model



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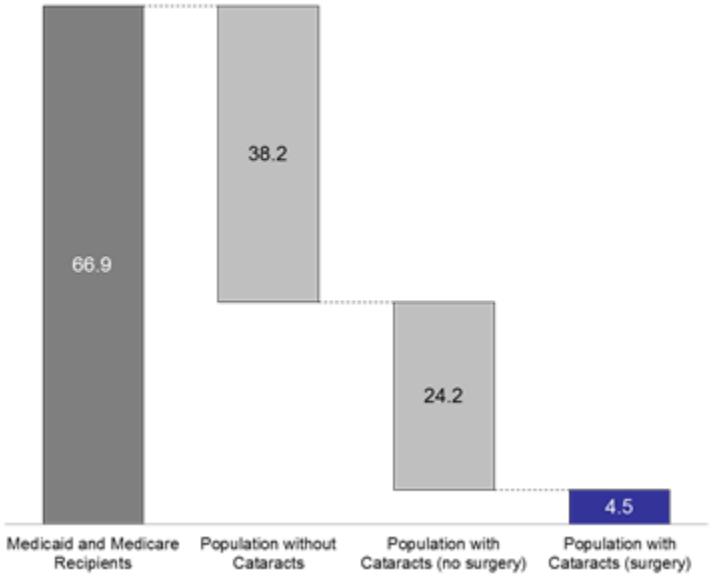
(A) U.S. Bureau of the Census, “2014 National Population Projections: Summary Tables,” http://www.census.gov/population/projections/data/national/2014/summarytables.html.
(B) Assumes linear growth.
(C) National Eye Institute, “Cataracts,” https://nei.nih.gov/eyedata/cataract.
(D) Ibid.
(E) Center for Medicare & Medicaid Services, “Medicare Enrollment – Aged Beneficiaries: as of July 1, 2012,” https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareEnrpts/Downloads/12Aged.pdf.
(F) The Henry J. Kaiser Family Foundation, “Federal and State Share of Medicaid Spending,” http://kff.org/medicaid/state-indicator/federalstate-share-of-spending/.
(G) K. Young, et. al., “Issue Brief: Medicaid’s Role for Dual Eligible Beneficiaries,” The Henry J. Kaiser Family Foundation, August 2013, https://kaiserfamilyfoundation.files.wordpress.com/2013/08/7846-04-medicaids-role-for-dual-eligible-beneficiaries.pdf.
(H) Center for Medicare & Medicaid Services, “Medicare Enrollment – Aged Beneficiaries.
(I) National Eye Institute.
(J) Ibid.
(K) Assumed: $100 per surgery.
(L) Center for Medicare & Medicaid Services, “Medicare Provider Utilization and Payment Data: Part D Prescriber,” last modified September 10, 2015, http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Provider-Charge-Data/Part-D-Prescriber.html.
(M) Andrew Chang & Company, Survey of Physicians Using Dropless Therapy, 2015.
(N) Number of Surgeries / Number of Population with Cataracts.
(O) Covered Patients with Cataracts * Surgery Rate.
(P) Weighted Average, High Cost, Low Cost.
(Q) Scenario Total Pharma Cost per Surgery * Covered Surgeries – Dropless Therapy Cost – Share of Dropless Patients Received NSAID * Cost of NSAID.
(R) The Henry J. Kaiser Family Foundation, “Federal and State Share of Medicaid Spending,” http://kff.org/medicaid/state-indicator/federalstate-share-of-spending/. P. Barry, “What Does Medicare Cost?” AARP Bulletin, last modified July 29, 2015, http://www.aarp.org/health/medicare-insurance/info-04-2011/medicare-cost.html.
(S) Share by Payer * Total Cost.

In order to estimate the number of Medicare and Medicaid-funded cataract surgeries, we first estimated the population that is at risk of cataracts. The prevalence of cataracts by age group is based on recent National Eye Institute (NEI) data.[9] We factored the prevalence rates with current and projected population by age cohort, using data developed by the U.S. Bureau of the Census to estimate the risk of cataracts by age cohort.[10] We assumed this risk for cataracts by age cohort to be fixed in future years. We then combined this data with enrollment in Medicare and Medicaid by age, assuming that prevalence of cataracts, within age groups, is evenly distributed across payers. We then removed dual eligible from the Medicaid population.[11] This permitted us to calculate the number of Medicare and Medicaid beneficiaries with cataracts by year.[12]

[9] National Eye Institute, "Cataracts," https://nei.nih.gov/eyedata/cataract.
[10] United States Bureau of the Census, "2014 National Population Projections: Summary Tables," http://www.census.gov/population/projections/data/national/2014/summarytables.html.
[11] Katherine Young, et. al,. "Issue Brief: Medicaid's Role for Dual Eligible Beneficiaries," *The Henry J. Kaiser Family Foundation*, August 2013. https://kaiserfamilyfoundation.files.wordpress.com/2013/08/7846-04-medicaids-role-for-dual-eligible-beneficiaries.pdf.
[12] Center for Medicare & Medicaid Services, "Medicare Enrollment – Aged Beneficiaries: as of July 1, 2012," https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareEnrpts/Downloads/12Aged.pdf ; The Henry J. Kaiser Family Foundation, "Medicaid Enrollment by Age," http://kff.org/medicaid/state-indicator/medicaid-enrollment-by-age/.

Figure 2-2 shows the means by which we estimated the portion of Medicare and Medicaid beneficiaries with cataract that receives cataract surgery. Using NEI data regarding the number of cataracts and surgeries by year, we estimated the portion of cataract patients that receive surgery.[13] We assumed this rate is fixed in future years. We combined this rate with the number of Medicare and Medicaid beneficiaries with cataract by year to estimate the total number of Medicare and Medicaid-funded cataract surgeries by year.

Figure 2-2
Medicaid and Medicare Funded Cataract Surgeries – 2025
(Millions)



We next factored pharmaceutical data from the Centers for Medicare and Medicaid Services (CMS) with prescription patterns defined by the scenarios described above to estimate the average cost of drops per case using drop therapy.[14] We compared this with the cost per case of dropless therapy, determined as follows.

In a minority of cases, physicians choose to prescribe not only dropless therapy, but also patient-administered NSAID drops (one of the three pharmaceutical drops typically used in drop

[13] National Eye Institute, loc. cit.
[14] Centers for Medicare & Medicaid Services, "Medicare Provider Utilization and Payment Data: Part D Prescriber," last modified September 10, 2015, http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Provider-Charge-Data/Part-D-Prescriber.html.

therapy). We therefore estimated the proportion of cases in which both dropless therapy and NSAID drops will be used, based on extrapolation from the current practice pattern of physicians. To determine the overall cost of dropless therapy, we added to the actual cost of the dropless therapy itself an additional amount representing the cost of the NSAID drops used in those cases in which physicians choose to prescribe them alongside dropless therapy. In this way, we arrived at a per-case estimate of the cost of dropless therapy.

We then subtracted the overall cost of dropless therapy, so determined, from the cost of prescription drops used in drop therapy to estimate the savings per surgery. We multiplied this average by the number of surgeries funded by Medicare and Medicaid each year to estimate the total cost savings to Medicare and Medicaid, respectively.

Using Kaiser Family Foundation data[15] and AARP data[16] we estimated the share of both costs and savings within Medicare and Medicaid that is covered by the federal government (Medicare total minus copays, plus Medicaid federal share), by state governments (Medicaid state share), and by patients (Medicare copays).

[15] The Henry J. Kaiser Family Foundation, "Federal and State Share of Medicaid Spending," http://kff.org/medicaid/state-indicator/federalstate-share-of-spending/.
[16] Patricia Barry, "What Does Medicare Cost?" *AARP Bulletin*, last modified July 29, 2015, http://www.aarp.org/health/medicare-insurance/info-04-2011/medicare-cost.html.

As shown in Table 2-1, under drop therapy, patients are typically given a prescription for three different pharmaceuticals in drop form. These include an antibiotic, a steroid, and an NSAID. The particular NSAID, steroid, and antibiotic that are prescribed vary among prescribing physicians, and accordingly, costs can vary significantly. Under Medicare, the cost of the drug combination ranges from a low of $175 to a high of $431, with a weighted average of $323. Under Medicaid, the cost of the three different drops ranges from a low of $174 to a high of $431, with a median of $337. The Medicare co-pay for pharmaceuticals is 20% of the total drug cost, and the Medicaid co-pay is $1.[17]

In order to account for this variability in the cost of prescription drops used in drop therapy, we created three scenarios to establish an upper and lower bound, and to identify a most likely estimate. Each scenario is based on the cost of drops that are currently being prescribed in connection with drop therapy, and each includes an estimate of the cost differential compared to dropless therapy.

Table 2-1
Prescription Scenarios

	Medicare			Medicaid		
	Weighted Average	Low	High	Weighted Average	Low	High
NSAID	$165	$139 (Bromfenac Sodium)	$207 (Bromday)	$168	$137 (Bromfenac Sodium)	$206 (Bromday)
Antibiotic	$89	$12 (Tobramycin)	$109 (Besivance)	$89	$12 (Tobramycin)	$109 (Besivance)
Steroid	$70	$24 (Prednisolone Acetate)	$114 (Durezol)	$80	$25 (Prednisolone Acetate)	$115 (Durezol)
Total	$323	$175	$431	$337	$174	$431

[17] Center for Medicare & Medicaid Services, unpublished information provided on June 12, 2015.

The Low Scenario assumes that all physicians are prescribing the lowest cost drop combination among drops that are currently commonly prescribed. The High Scenario assumes that all physicians are prescribing the highest cost combination of drops. The Weighted Average assumes that, on average, physicians are prescribing drops in the pattern shown by surveyed physicians (see "Survey of Dropless Therapy Prescribers," below).

Our analysis incorporates a number of key assumptions that we believe to be both well founded and reasonable. Table 2-2 below summarizes our major assumptions:

Table 2-2
Key Assumptions

Category	Assumption
Dropless Therapy Cost	▪ The dropless therapy is priced at $100 per prescription.
Traditional Drop Therapy Pricing	▪ Drop therapy pricing will remain consistent with historical pricing. Pricing information was obtained from 2013 Medicaid and Medicare data. ▪ Each patient fills their prescription only one time and each prescription lasts two weeks. Based on interviews with subject matter experts, we believe this assumption is conservative, and will tend to understate the comparative economic benefits of dropless therapy.
Medicare and Medicaid Cataract Surgery Caseload	▪ Population growth and demographic characteristic assumptions based on US Census projections. ▪ Prevalence of cataracts by age group based on NIH data. ▪ Cataract surgery rate based on NIH data. ▪ Patient has only one cataract surgery per eye in their lifetime. Based on interviews with subject matter experts, we believe this assumption is conservative, and will tend to understate the comparative economic benefits of dropless therapy.

Survey of Dropless Therapy Prescribers:

In order to better understand how physicians currently utilize dropless therapy, we developed a survey for current active prescribers of dropless therapy. We contacted 209 physicians who actively prescribe dropless therapy in the U.S. (ordered within previous 3 months), asking them to complete an online survey. The survey administration began on July 22, 2015 and ended on September 11, 2015.

Given the raw number of existing dropless therapy prescribers, a high survey response rate was required to achieve statistical significance as shown in Table 2-3 below:

Table 2-3
Population of Current Dropless Therapy Prescribers:
Sampling Requirements

Population Size	Confidence Level	Confidence Interval	Sample Requirement	Response Rate
209	99%	+/- 2.5%	194	93%
	99%	+/- 5%	160	77%
	99%	+/- 10%	93	44%
	95%	+/- 2.5%	185	89%
	95%	+/- 5%	136	65%
	95%	+/- 10%	67	32%
	90%	+/- 2.5%	176	84%
	90%	+/- 5%	119	57%
	90%	+/- 10%	52	25%

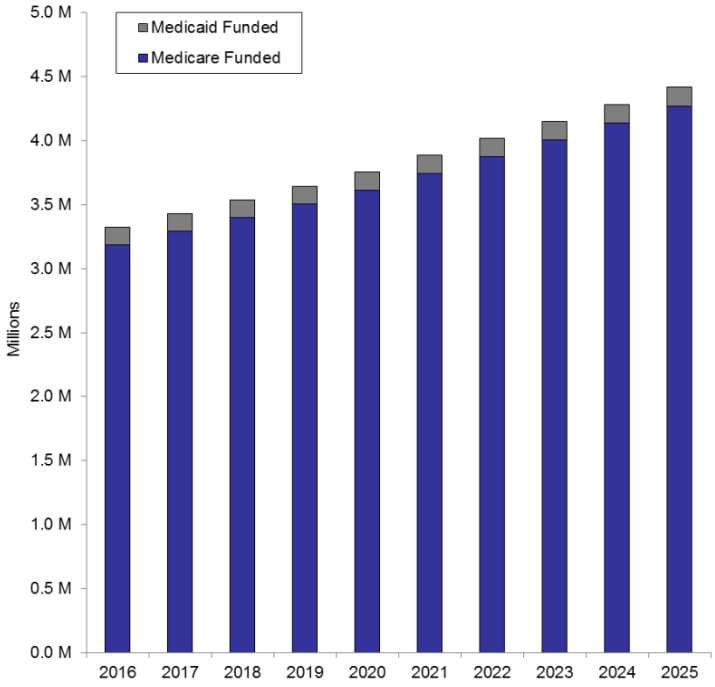
Generally accepted confidence levels for policy and business research are 90% and 95%. Prior to the release of the survey, we selected a 95% confidence level for this analysis. To achieve this confidence level given the size of the population of dropless therapy providers,

necessitated a response rate ranging from 32% to 93% depending on the desired confidence interval. The final result was 142 responses to the survey, representing a response rate of 68%. Of the total surveys returned, 125 were complete (that is, all questions were fully answered) and 17 were partially complete (some questions were not answered). The resulting confidence interval on each question ranged from +/- 1.2% to 6.7%, with a median confidence interval of 4.3%. Given the exceptionally high response rate, we believe that the data can be used reliably and are the best available data for the purposes of this study.

3. Findings

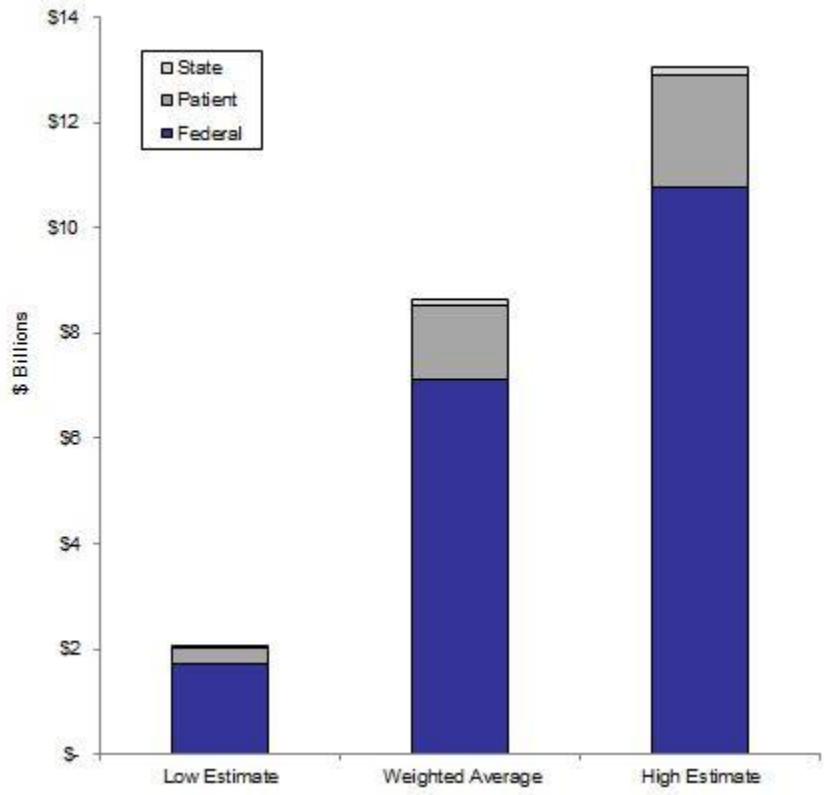
As shown in Figure 3-1, we estimate there will be 38 million cataract surgeries over the next ten years. Medicare is expected to fund the great majority – 96% of the total, or an average of 3.7 million surgeries each year. Medicaid is expected to fund the remaining 4%, or an average of 150,000 surgeries per year. The number of Medicare and Medicaid-funded cataract surgeries is expected to grow at a compound average annual growth rate of approximately 3%.

Figure 3-1
Estimated Medicare and Medicaid Funded Cataract Surgeries
(2016 – 2025)



As shown in Figure 3-2, utilization of dropless therapy for cataract surgeries could save Medicare, Medicaid and patients between $2.1 billion and $13.0 billion, with a most likely savings estimate of $8.7 billion, between 2016 and 2025. Our most likely Weighted Average estimate produces federal Medicare and Medicaid savings of approximately $7.1 billion, and patients are projected to save approximately $1.4 billion.

Figure 3-2
Estimated Cumulative Savings
(2016 – 2025)



Our High Estimate, which is based on higher-cost alternative prescription combinations, produces federal Medicare and Medicaid savings of approximately $10.8 billion during the ten-year period. Furthermore, U.S. state governments would save approximately $677 million in their share of Medicaid payments. Patients would save approximately $2.1 billion in averted pharmaceutical copayments.

The Low Estimate produces federal Medicare and Medicaid savings of approximately $1.7 billion and total state Medicaid savings of over $27 million. Patients would save approximately $334 million from averted prescription co-payments.

As shown in Figure 3-3, under our most likely scenario, we estimate that federal, state and patient savings would average approximately $865 million per year. Total potential savings are expected to increase from $748 million in 2016 to $994 million in 2025, reflecting a compound average annual growth rate of approximately 3%. This growth rate should be considered conservative, predominantly reflecting the rate of growth in the U.S. cataract surgery caseload, and not factoring in other contributors to growth in costs.

Figure 3-3
Estimated Annual Savings
(Weighted Average Estimate)

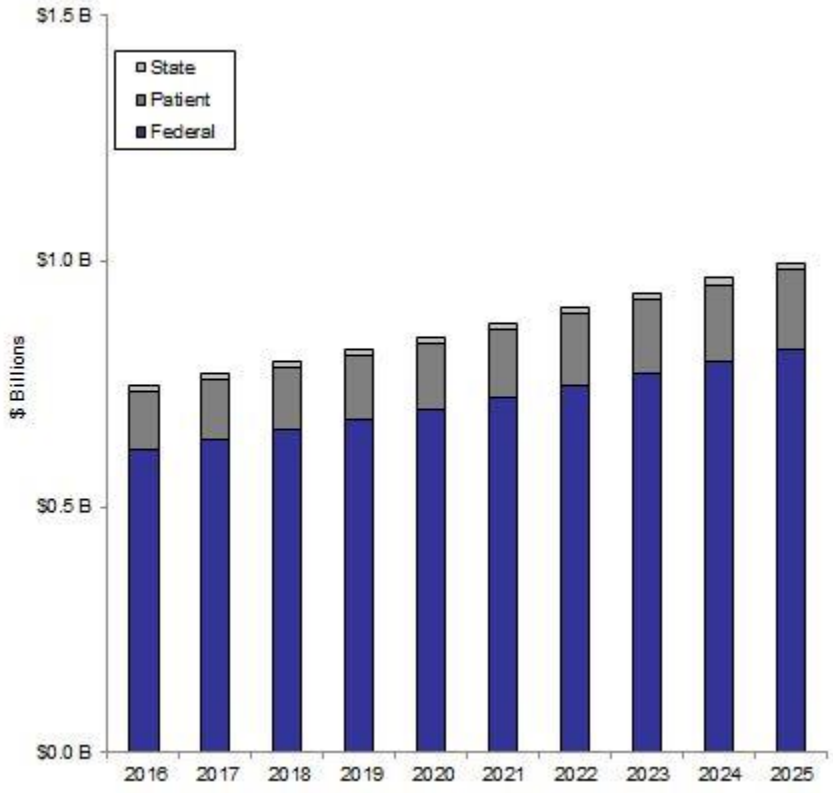
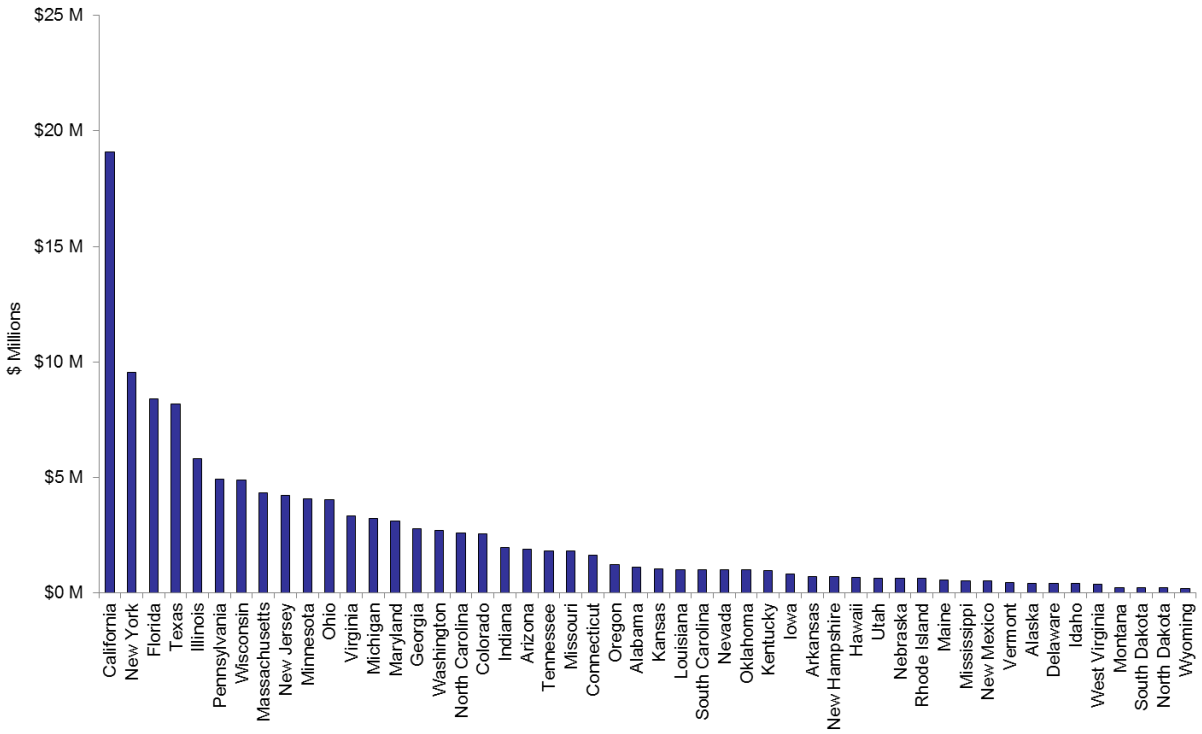


Figure 3-4 exhibits the cumulative savings to states between 2016 and 2025. During that time period, state governments are expected to save approximately $124 million cumulatively.

Figure 3-4
Cumulative Estimated State Savings
(Weighted Average Estimate)



Cumulative savings for U.S. state governments ranged from $0.2 million to $19 million, and are generally correlated to population size of the respective state. California is positioned to benefit the most from dropless therapy (it accounts for approximately 15% of the total state savings). California would save approximately $19 million dollars over the next ten years. New York, with $9.5 million in savings, has the second greatest savings potential. Florida ranks third with a potential $8.4 million in savings.

4. Conclusion

Despite significant advantages for patients and the health care system, adoption of dropless therapy has lagged because of federal reimbursement policy. With over 38 million cataract surgeries projected to be funded by Medicare and Medicaid over the next ten years, changing the current policy to permit broader adoption (for example, by giving patients the option to choose and pay for dropless therapy) would produce significant cost savings for patients and for the Medicare and Medicaid programs, at both the federal and state level. It would significantly reduce costs for patients because, even if they paid for the therapy themselves, they would be relieved of paying the high co-payments for drops under the current policy. The cost per prescription of dropless therapy is as much as 77% lower than the drop therapy alternative. Overall savings could be as high as $13.0 billion by 2025.

Were dropless therapy to be more broadly adopted, then under the most likely scenario, the federal government could expect savings for Medicare and Medicaid of approximately $7.1 billion during the ten-year period of 2015-25. State governments would save approximately $124 million in their share of Medicaid payments during the same ten year time frame. In addition, individual patients – whose out-of-pocket co-payments can be as much as $650 – are projected to save approximately $1.4 billion. The cumulative savings for U.S. state governments range from $0.2 million to $19.0 million. California would save approximately $19 million dollars over the next ten years. New York and Florida would save $10 million and $8 million respectively.

These economic benefits should be considered conservative estimates. Because of averted administrative health care provider costs, the broader use of dropless therapy could be expected to produce an indefinite stream of additional cost savings to the health care system.

Appendix A-1
Survey of Current Literature
Regarding Prophylactic Use of Antibiotics and Anti-Inflammatories

Study	Key Findings
Amer, S.A.K., et al., "Safety of prophylactic moxifloxacin during phacoemulsification."[18]	The authors studied 60 eyes to evaluate the safety of intracameral moxifloxacin during standard coaxial phacoemulsification. The eyes were divided into two groups, with one group receiving an injection of 0.1cc moxifloxacin at the end of standard coaxial phacoemulsification with foldable IOL. Intracameral 0.1 ml of 0.5% moxifloxacin (Vigamox, Alcon) was found to be safe for the visual rehabilitation and corneal endothelium.
Anijeet, D.R., et. al., "Intracameral vancomycin following cataract surgery: An eleven-year study."[19]	This is a retrospective analysis of 16,606 cataract surgeries that were performed between January 1, 1998 and December 31, 2008. The incidences of presumed or culture-proven endophthalmitis during Period A (prior to January 2001 when the use of intracameral vancomycin was introduced) and Period B (after introduction) were compared. There was a significant risk reduction after the introduction of intracameral vancomycin, with an absolute risk reduction of 292 cases of endophthalmitis per 100,000 cataract surgeries.
Chang, D.F., et. al., "Prophylaxis of postoperative endophthalmitis after cataract surgery: results of the 2007 ASCRS member survey."[20]	This online survey of members of the American Society of Cataract and Refractive Surgery revealed many surgeons still have a strong preference for preoperative and postoperative topical antibiotic prophylaxis, with most favoring latest generation topical fluoroquinolones. It was found that 77% of respondents were not injecting intracameral antibiotics, but 82% would strongly consider it if a reasonably priced commercial preparation were available.
Espiritu, C.R., et. al., "Safety of prophylactic intracameral moxifloxacin 0.5% ophthalmic solution in cataract surgery patients."[21]	A study of 65 eyes conducted at the American Eye Center in Manila, Philippines determined the safety of prophylactic intracameral moxifloxacin 0.5% ophthalmic solution (Vigamox) in patients having cataract surgery. All eyes received a 0.1 mL intracameral moxifloxacin 0.5% ophthalmic solution containing 500 mug of moxifloxacin as the last step of phacoemulsification. It was concluded that intracameral Vigamox 0.5 mg/mL appeared to be nontoxic.
Gao, H. et. al., "Intravitreal moxifloxacin: Retinal safety study with electroretinography and histopathology in animal models."[22]	This study demonstrated that moxifloxacin is a safe intravitreal antibiotic in mouse and rabbit animal models. Electroretinography (ERG) and histologic examinations showed no difference was found between control groups of mice and rabbits and groups that were injected with different concentrations of moxifloxacin. Authors concluded intravitreal injections of moxifloxacin could be considered as an alternative to currently used antibiotics if human studies prove it safe and efficient.

[18] S.A.K. Amer, et al., "Safety of prophylactic moxifloxacin during phacoemulsification," *Journal of American Science*, 2013, Issue 9, pp.14-27.
[19] D.R. Anijeet, et. al., "Intracameral vancomycin following cataract surgery: An eleven-year study," *Journal of Clinical Ophthalmology*, 2010, Issue 4, pp. 321-326.
[20] D. Chang, et. al., "Prophylaxis of postoperative endophthalmitis after cataract surgery: results of the 2007 ASCRS member survey," *Journal of Cataract & Refractive Surgery*, 2007, Issue 33, pp. 1801-1805.
[21] C.R. Espiritu, et. al., "Safety of prophylactic intracameral *moxifloxacin 0.5% ophthalmic solution in cataract surgery patients," Journal of Cataract & Refractive Surgery*, 2007, Issue 33, pp. 63-68.
[22] H. Gao, et. al., "Intravitreal moxifloxacin: Retinal safety study with electroretinography and histopathology in animal models," *Investigative Ophthalmology and Visual Science*, 2006, Issue 47, pp.1606-1611.

Appendix A-2
Survey of Current Literature
Regarding Prophylactic Use of Antibiotics and Anti-Inflammatories

Study	Key Findings
Jonas, J.B., et. al., "Cataract surgery combined with intravitreal injection of triamcinolone acetonide."[23]	The authors evaluated a study group of 60 eyes (56 patients) to determine whether the addition of cataract surgery to an intravitreal injection of triamcinolone acetonide would markedly increase the frequency and range of complications. The study group and triamcinolone control group did not vary significantly in visual acuities and ocular pressures and instances of postoperative infectious endophthalmitis and other complications were not observed. It was concluded the addition of cataract surgery to an intravitreal injection of triamcinolone acetonide may not noticeably increase the amount and frequency of side effects and complications of intravitreal triamcinolone acetonide. However, no safe conclusions could be reached regarding differences in frequency of postoperative infectious endophthalmitis.
Jonas, J.B., et. al., "Intravitreal triamcinolone acetonide for the treatment of intraocular edematous and neovascular diseases."[24]	The authors explored the best response to intravitreal triamcinolone acetonide injection in terms of gain in visual acuity for eyes with intraretinal edematous diseases. The article discusses different instances when intravitreal triamcinolone may be useful, concluding that while it may offer a possibility for adjunctive treatment of intraocular oedematous and neovascular disorders, side effects and long-term follow-up observations need to be taken into account.
Lane, S.S., et. al., "Evaluation of the safety of prophylactic intracameral moxifloxacin in cataract surgery."[25]	The authors evaluated the safety of an intracameral injection of moxifloxacin 0.5% ophthalmic solution as prophylaxis for endophthalmitis in patients having cataract surgery. They found no statistical differences between the two treatment groups studied and no adverse events occurred. Therefore, it was concluded that a 250 mg/0.050 mL intracameral injection of moxifloxacin was safe in the prophylaxis of endophthalmitis after cataract surgery.
Rudnisky, C.J., et. al., "Antibiotic choice for the prophylaxis of post-cataract extraction endophthalmitis."[26]	The authors performed a review of 75,318 cataract surgeries performed over 8 years by 26 different surgeons at 4 public hospitals and 5 nonhospital surgical facilities in the United States. They found an overall 8-year incidence of 0.03%. Univariate analysis showed that the rate was not influenced by use of intracameral or subconjunctival antibiotics, whereas the use of moxifloxacin was associated with a lower rate of endophthalmitis (P= 0.029).

[23] J.B. Jonas, et. al., "Cataract surgery combined with intravitreal injection of triamcinolone acetonide," *European Journal of Ophthalmology*, 2005, Issue 15, pp.329-335.
[24] J.B. Jonas, et. al., "Intravitreal triamcinolone acetonide for the treatment of intraocular edematous and neovascular diseases," *Ophthalmology*, 2004, Issue 101, pp.113-120.
[25] S.S. Lane, et. al., "Evaluation of the safety of prophylactic intracameral moxifloxacin in cataract surgery," *Journal of Cataract & Refractive Surgery,* 2008, Issue 34, pp.1451-1459.
[26] C.J. Rudnisky, et. al., "Antibiotic choice for the prophylaxis of post-cataract extraction endophthalmitis." *Ophthalmology,* 2014, Issue 121 (April), pp. 835-841.

Appendix B
Trade Journal Articles Regarding Dropless Therapy
(Partial List)

Anonymous, "Debating the Merits of Dropless Cataract Surgery; Keith A. Walter, MD, and Alice T. Epitropoulos, MD, FACS, discuss compounded antibiotic and steroid injections," *Ocular Surgery News* (U.S. Edition), December 2014.

Anonymous, "Premium Cataract Surgery Finds Its Place; A sizeable number of patients are paying out of pocket for upgrades, but cost is a limiting factor, facility managers say," *Outpatient Surgery*, August 2014.

Scripture, Kevin T., and Sydney L. Tyson, "The Last Hurdle – Taking Cataract Surgery Dropless; Surgeons' staff will tell you drops are the bane of their existence; *Cataract & Refractive Surgery Today*, June 2014, pp. 52 – 53.

Bethke, Walter, "Can Surgeons Stop the Drops? A look at recent attempts to replace postop eye drops with injections and the pros and cons of this approach," *Review of Ophthalmology*, April 2014.

Caceres, Vanessa, "'Dropless' Approach to Cataract Surgery Expands," *EyeWorld*, November 2014.

Charters, Lynda, "Dropless Cataract Surgery Yields Postoperative Prophylaxis for Patients, Practices," *Ophthalmology Times*, June 2015.

Chu, Y. Ralph, "Dropless Procedure Redefines Cataract Surgery; Intraoperative injection of compounded formulation improves compliance," *Advanced Ocular Care*, January/February 2015.

Dalton, Michelle, "Dropless Cataract Surgery Offers 'Significant Benefit;' Using an intravitreal transzonular injection improves patient compliance while maintaining good outcomes," *Ophthalmology Times*, January 2015.

Epitropoulos, Alice T., "Dropless Cataract Surgery," *MillennialEye*, September – October 2014.

Fisher, Bret, "Creating a Premium Practice; Using the most advanced technologies available allows physicians to provide the best results for their patients, *Cataract & Refractive Surgery Today*, September 2015, pp. 79 – 80.

Goldberg, Damien F.,"Generic Versus Branded Drops; A face-off of cost, compliance, and convenience," *MillennialEye*, July – August 2014.

Helzner, Jerry, "A Care for Dropless Cataract Surgery; A single prophylactic injection is gaining growing support," *Ophthalmology Management*, May 2014.

Kekevian, Bill, "Cataract Surgery: Going Dropless; How a single injection may redefine roles for the ophthalmic staff," *Ophthalmic Professional*, November 2014.

Kekevian, Bill, "Drug Quality and Security Act Addresses Compounding Pharmacies; A year after an outbreak killed dozens, the FDA is taking steps to update oversight," *Retinal Physician*, March 2014.

Kent, Christopher, “Antibiotics & Cataract Surgery: New Frontiers; Alternatives to topical drops appear to be effective – and they’re becoming more popular,” *Review of Ophthalmology*, April 2015.

Krader, Cheryl Guttman, “Intravitreal Antibiotic + Steroid Makes Dropless Cataract Surgery Possible,” *Ophthalmology Times*, May 2014.

Krader, Cheryl Guttman, “News on Cataract Surgery Medications Centers on Intraocular Preparations; Phenylephrine-ketorolac combination and ‘dropless’ procedures top of mind,” *Ophthalmology Times*, December 2014.

Lewis, James S., “Advantage Plentiful with Dropless Cataract Surgery; The technique is effective, saves time and money, and has good results,” *Ocular Surgery News* (U.S. Edition), May 2014.

Liegner, Jeffrey T., “Innovations in Ophthalmology: Dropless Cataract Surgery; A steroid-antibiotic combination can replace expensive eye drops, save money, and ensure compliance,” *Cataract & Refractive Surgery Today*, January 2015, pp. 70 – 71.

Lindstrom, Robert L., “Access to Compounded Medications Critical for Ophthalmologists, Patients,” *Ocular Surgery News* (U.S. Edition), May 2015.

Lipuma, Laura, “Intracameral Antibiotics; Which intracameral antibiotic is best,” *EyeWorld*, January 2015.

Loden, James C., “Dropless Cataract Surgery; Better for the patient, better for the surgeon,” *The OphthalmicASC*, October 2014

Mangan, Richard B., “Why I Am Glad That My Cataract Surgeon Offers Dropless Cataract Surgery; Benefits for the patient and the practice,” *Advanced Ocular Care*, October 2014, pp. 76 – 78.

Mangan, Richard B. Mangan, edited by Derek N. Cunningham and Walter O. Whitley, “No Drops Required; Transzonular drug delivery during cataract surgery is a safe, convenient way to quash concerns about postoperative drug compliance,” *Review of Optometry*, August 2014.

Mahootchi, Ahad, “Going Dropless; Why I opted out of the retail pharmacy games,” *MillennialEye*, July – August 2014.

Matossian, Cynthia, “The Economics of Going ‘Dropless;’ Prophylactic injections can save hassle and money for both you and your patients,” *Ophthalmology Management*, September 2014.

Newsom, T. Hunter, “New Options for Ophthalmic Surgery,” *Outpatient Surgery*, July 2014.

O’Connor, Dan, “Products to Power Up Your Cataract Services; The latest advances in technology can contribute to optimal patient outcomes,” *Outpatient Surgery*, May 2015.

Radcliffe, Nathan, “Minimalism in Eye Care,” *MillennialEye*, November 2014.

Schanzer, Cathy, M. Stewart Galloway, “No More Drops for Patients in the Real World?” *Ophthalmologist*, November 2014.

Schweitzer, Justin, “Dropless Cataract Surgery Offers Benefits for Patients, Providers; Convenience and improved compliance are among the advantages,” *Advanced Ocular Care*, April 2015, pp. 28 – 29.

Schimmel, Daniel, “’Dropless’ Cataract Surgery Enhances Prophylaxis, Patient Satisfaction; Patients are beginning to request this method, which may be the catalyst for more doctors to add it to their repertoire,” *Primary Care Optometry* News, May 2015.

Thompson, Vance, “Post-Cataract Surgery Intraocular Injections Offer Alternative to Traditional Drop Therapy; Injections of Tri-Moxi-Vanc can benefit patients, surgeons and staff,” *Ocular Surgery News* (U.S. Edition), September 2015.

Weinstock, Robert J., “Cataract Surgeon Describes Early Experience with Transzonular Delivery of Medication; An investigator-initiated clinical trial of a compounded formula of medications injected during cataract surgery is underway,” *Ocular Surgery News* (U.S. Edition), August 2014.

Appendix C
Dropless Therapy Prescriber Survey

A survey of current active prescribers was administered in order to better understand how physicians utilize dropless therapy. Specifically, this survey provided information regarding the prescription practices of physicians using dropless therapy and their alternative prescription practices when not using dropless therapy.

The survey was conducted over approximately six weeks. It was released on July 22, 2015 and closed on September 11, 2015. The population of the survey was 209 physicians identified as active dropless therapy prescribers. The survey was administered online and was delivered via email.

Given the sampled population size of dropless therapy prescribers, a high survey response rate was required to achieve statistical significance, as shown in Table C-1 below.

Table C-1
Population of Current Dropless Therapy Prescribers:
Sampling Requirements

Population Size	Confidence Level	Confidence Interval	Sample Requirement	Response Rate
209	99%	+/- 2.5%	194	93%
	99%	+/- 5%	160	77%
	99%	+/- 10%	93	44%
	95%	+/- 2.5%	185	89%
	95%	+/- 5%	136	65%
	95%	+/- 10%	67	32%
	90%	+/- 2.5%	176	84%
	90%	+/- 5%	119	57%
	90%	+/- 10%	52	25%

Generally accepted confidence levels for policy and business research are 90% and 95%. Prior to the release of the survey, we selected a 95% confidence level for this analysis. To achieve this confidence level, given the sampled population of dropless therapy providers, necessitated a response rate ranging from 32% to 93% depending on the desired confidence interval. The final result was 142 responses to the survey, representing a response rate of 68%. Of the total surveys returned, 125 were complete (that is, all questions were fully answered) and 17 were partially complete (some questions were not answered). The resulting confidence interval on each question ranged from +/- 1.2% to 6.7%, with a median confidence interval of 4.3%. Given the exceptionally high response rate, we believe that the data can be used reliably and are the best available data for the purposes of this study.

In order to help achieve the necessary response rate, we offered prescribers a participation incentive. Each was offered a $50 Amazon gift card to take the survey. It is our understanding it is customary for physicians to receive similar gift incentives to participate in similar types of studies. We do not believe that this incentive would produce sample biases that could alter our findings. In addition, we conducted extensive follow-up with prescribers in order to increase response rates. This included a total of up to 15 emails and two phone calls per physician.

Appendix D:
Cataract Surgery Estimate
(2016)

	40-49	50-54	55-59	60-64	65-69	70-74	75-79	80+
Estimated Medicare Enrolled Population in Age Groups (Census[27]/CMS[28])	Omitted				17M	12M	9M	12M
Risk of Cataracts (NEI[29]/Census[30])					25%	36%	49%	68%
Total Cataracts (A x B)					4M	4M	4M	9M
Prevalence of Surgery (NEI[31])					15%			
Number of Surgeries (C x D)					3M			
Population in Age Groups (Census[32])	42M	21M	21M	19M	16M	12M	9M	11M
Risk of Cataracts (NEI[33]/Census[34])	3%	5%	9%	15%	25%	36%	49%	68%
Total Cataracts (F x G)	1M	1M	2M	3M	4M	4M	4M	8M
Medicaid Enrollment in Age Groups (KFF[35])	10%				14%			
Non-Dual Eligibles (KFF[36])	NA				9%			
Medicaid Covered Cataracts (∑ H x I x J)	650K				250K			
Prevalence of Surgery (NEI[37])	15%							
Number of Surgeries (K x L)	140K							

[27] United States Bureau of the Census, loc. cit.
[28] Center for Medicare & Medicaid Services, "Medicare Enrollment – Aged Beneficiaries: as of July 1, 2012," loc. cit.
[29] National Eye Institute, loc. cit.
[30] United States Bureau of the Census, loc. cit.
[31] National Eye Institute, loc. cit.
[32] United States Bureau of the Census, loc. cit.
[33] National Eye Institute, loc. cit.
[34] United States Bureau of the Census, loc. cit.
[35] Center for Medicare & Medicaid Services, "Medicaid Enrollment by Age," loc. cit.
[36] Young, loc. cit.
[37] National Eye Institute, loc. cit.

Appendix E
Case Studies

In conjunction with this economic analysis, the authors conducted interviews with a number of prominent cataract surgeons who utilize dropless therapy, and several of their patients. The three representative case studies below summarize highlights from these interviews and are included to provide context and additional insight regarding the economic impact of dropless therapy in cataract surgery.

Joanna Fisher, MD[38]
Valley Eye Professionals
Huntingdon Valley, PA

Background

Joanna Fisher, MD, is Chief of Ophthalmology and Attending Surgeon at Holy Redeemer Hospital in Meadowbrook, PA. In addition, she is Associate Surgeon in the Cataract and Primary Eye Care Department at Wills Eye Hospital, where she is a member of the teaching staff, and a Clinical Associate Professor at Thomas Jefferson University. She is a private practice physician with over 25 years' experience performing ophthalmic surgery, and has been practicing in Huntingdon Valley for the past 25 years.

Dr. Fisher likens the impact of dropless therapy on cataract surgery to the breakthrough she experienced when she first incorporated sutureless surgery. What these two share in common, she said, is that they make cataract surgery easier, safer, and less expensive to perform.

[38] Based on telephone interviews with Dr. Joanna Fisher on July 30, 2015 and Mr. Frank Johnson on August 10, 2015.

Comparison to Drop Therapy

One of the primary concerns with traditional drop therapy, Dr. Fisher said, is that patients frequently have difficulty understanding — and therefore complying with — the post-operative care protocol. The current post-operative treatment of cataract surgery patients requires them to take several different drops of antibiotics, steroids, and non-steroidal anti-inflammatory drugs (NSAIDs). These different drugs must be administered multiple times throughout the day during the recovery period. Directions pertaining to the application of the drops are complicated and difficult for many patients to follow. The resulting confusion, Dr. Fisher said, consumes several hours of time in answering questions for each patient.

“A lot of patients tell me the surgery was easy; it’s the recovery that is challenging,” Dr. Fisher said. “There have been occasions where my staff have added hours to their already busy schedules to educate patients about the care instructions and to follow up with pharmacy phone calls. In fact, we have two full-time coordinators who spend most of their time dealing with patient drop administration issues. It is not unusual to receive multiple phone calls from the same patient regarding the number of drops to be taken and when to take them.”

Dr. Fisher further explained that in addition to the administrative burden of helping patients understand and comply with their postoperative care, the actual administration of the drops is often problematic for the patient. Because many cataract patients are elderly, applying an adequate amount of solution to the surface of the eye can be challenging. Many patients, Dr. Fisher said, will seek the help of family members and caretakers to administer the drops, and this can add significant cost that the patient must bear. Patients who cannot afford such expenses may delay their surgery until someone becomes available to assist them, she said.

“Roughly 60% to 70% of patients in my practice require assistance to instill their drops. I recall one patient who admitted herself to an assisted living facility for three weeks so someone could administer the drops. That cost alone was overwhelming,” Dr. Fisher said.

Many patients who fail to administer the drops correctly, or at all, do so because of their confusion over the prescribed steps and the physical difficulty of applying the drops. Such cases of misuse, overuse, or a complete lack of use, Dr. Fisher explained, can have several negative potential outcomes. These include contamination, infection, and inflammation, all of which may permanently harm the patient’s final vision.

According to Dr. Fisher, the costs associated with drop therapy, including typically unaccounted-for costs in the use of caretakers for assistance with drop instillation, lead some patients to delay or forgo cataract surgery. “Some patients delay surgery because they cannot afford the drops, which is really unfortunate,” she said. She noted that one complete prescription for one eye can cost as much as $650, and twice that much for surgery on both eyes. These costs can grow even higher, Dr. Fisher pointed out, when patients waste large amounts of the prescription drops in failed attempts to instill them. She also noted that the less expensive generic drops that are available come with an associated risk of decreased benefit in the healing and recovery process.

Patient Experience

Dr. Fisher highlighted the experience of one of her patients who is a military veteran. When the patient went to the pharmacy and discovered that his prescription medications would cost $650 “just for the first eye,” he became greatly concerned about whether he could afford not only this surgery but the second eye surgery that he knew he also needed. After consulting with her patient, Dr. Fisher suggested dropless therapy. The patient readily agreed. After the surgery, the patient reported that dropless therapy saved him time as well as money and

substantially improved his recovery. “I would have had to cut back my schedule,” he said, “if I had not been able to use dropless therapy. But because I did, I did not have to take any time off, either before or after the injection therapy. I could see the day of surgery without glasses, with a tremendous increase in distance vision in terms of both clarity and sharpness.”

“He was really, really excited,” Dr. Fisher told us. “It was quite moving. Since then he’s had his other eye done, and he’s very grateful.”

Dr. Fisher said this patient’s experience is not unique. “I have been amazed at how much more quickly my patients are healing after using dropless therapy. Typically I would see patients one day and then three weeks after [the surgery]. But now that I started offering dropless therapy, I am amazed how quiet the eyes are and how much healing occurs after just one week.”

Bernard Spier, MD, FAOO[39]
Northern New Jersey Eye Institute
South Orange, NJ

Background

Bernard Spier, MD, an ophthalmologist at the Northern New Jersey Eye Institute, has practiced for 26 years. Over the course of his career, which includes training at the Yale-New Haven Hospital, Boston City Hospital, Thomas Jefferson University Hospital, Brigham and Women's Hospital, and Harvard's Massachusetts Eye and Ear Infirmary, Dr. Spier has performed over 10,000 cataract and implant procedures.

Dr. Spier stated that dropless therapy can make cataract surgery possible for patients who previously were not candidates. “The list is long,” he said, of medical conditions that make it difficult to use drop therapy. “I couldn’t even begin to tell you. There are many different

[39] Based on telephone interview with Dr. Bernard Spier on July 30, 2015.

neurological and congenital problems people can have.… Of this population, I'm guessing a third has psychiatric problems. The majority have other problems including neurological. It's just a long list.… Then we have patients who are paraplegic, quadriplegic. Then we have people with arthritis so they can't hold a bottle of eye drops." Overall, Dr. Spier said, for "disabled patients, either mentally or physically incapable of putting in drops … it's a lot simpler and safer."

Comparison to Drop Therapy

According to Dr. Spier, the greatest beneficiaries of dropless therapy have been the large number of patients in his practice who were unable to undergo cataract surgery due to their inability to administer drops for the post-operative recovery. Among those in this category are patients who have a significant fear of allowing anything near their eye.

"There is a not insignificant number of patients out there who have cataracts, but for whom we are unable to perform surgery because the associated drop protocols are not an option. If patients cannot administer the drops, we know they are not going to do well after surgery, and, as a result, we just do not perform the operation," Dr. Spier said.

"It borders on an ethical mandate for us in the medical community to have an option to deliver the cataract care patients need and deserve. Fundamentally, that is what dropless therapy adds. It is not an uncommon problem to have patients who will not or cannot get the bottle close to the eye."

Dr. Spier explained that in addition to people who have to forgo surgery because of a phobia of touching the eye, patients with a prior history of glaucoma – especially those who have undergone surgery for the procedure – also benefit greatly from the availability of dropless therapy. "Cataract surgery can be risky for patients who have had previous glaucoma surgery, as the surgery can cause increased inflammation," Dr. Spier said. "Using the normal drop

therapy, the only option to decrease the inflammation is to increase the steroid dose by as much as two to three times. However, as most patients are already applying drops every two hours, such an increase in dosage would mean applying a drop every hour – and this may be even more difficult." With dropless therapy, however, patients can easily increase their dosage and decrease inflammation by combining the therapy with a regular regimen of drops. For such patients, Dr. Spier stated, dropless therapy "significantly reduces the chance that the glaucoma surgery will fail."

In his practice, Dr. Spier has noted that drop therapy has a high propensity of causing confusion with patients due to the high number of drops needed and the complexity in the often tapered schedule. Patients may also have difficulty applying the drops and can spill or use them improperly, leading to many patients going through their drops far too quickly. In these instances, patients face added financial burdens in refilling the prescription. When patients run out of their prescriptions early, many insurance companies will not cover the cost of additional drops. As a result, Dr. Spier said, these become additional out-of-pocket expenses for patients.

Patient Experience

Dr. Spier recalled a case involving an elderly patient with severe Down syndrome who had advanced cataracts. Although the patient required cataract surgery, it was put off for several years because Dr. Spier and the patient's caretakers were unsure about the patient's ability to comply with a drop regimen.

"It was difficult enough to examine this patient in the office. He would squeeze his eyes shut and make it impossible to get near him. This gave me great pause about the ability of his caretakers to safely and effectively administer drop therapy," Dr. Spier said. "However, when dropless therapy became available, cataract surgery became a viable option."

Dr. Spier said he has already performed surgery on the patient's first eye and plans are underway for the second procedure. "His cataract was pretty severe, so just allowing him to see with one eye was enough to change his life. He used to walk into walls and had trouble feeding himself. After the surgery, his caretakers noticed a definite change in his behavior…. He's happy as a lark."

Vance Thompson, MD[40]
Director of Refractive Surgery
Vance Thompson Vision, Sioux Falls, SD

Background

Vance Thompson, MD, is the Director of Refractive Surgery for Vance Thompson Vision in Sioux Falls, South Dakota. He also serves as Assistant Professor of Ophthalmology at the University of South Dakota Sanford School of Medicine, where he is an internationally recognized researcher and lecturer. Dr. Thompson is a specialist in laser vision correction and advanced cataract surgery. He has performed more than 500 cataract surgeries using dropless therapy. He has shared this experience in educational presentations at a number of ophthalmic conferences. During his interview, Dr. Thompson stressed that patients readily accept the rationale for dropless surgery and that most patients ask for it once it is introduced as an option during their surgery.

Comparison to Drop Therapy

According to Dr. Thompson, while traditional drop therapy has been a mainstay of the postoperative care of cataract patients for years, the approach has certain limitations. Notably, the complexity of the dosing requirements can negatively affect patient compliance. The drop therapy regimen, Dr. Thompson stated, is only effective if patients follow through with the prescribed plan.

[40] Based on telephone interview with Dr. Vance Thompson on August 10, 2015.

“Antibiotic drops are typically used four to five drops a day for a week to ten days; the steroid drops are usually prescribed four times a day on a tapering dose over the next month,” Dr. Thompson said. “All told, patients may have to take up to 150 drops from different bottles. This is not even considering the fact that the dosage may have to be adjusted in some cases, thus adding to the complexity. Patient compliance is a major concern with drop therapy.”

An additional concern that Dr. Thompson often hears from patients is that even if they are able to understand the complicated regimen, actual installation of the drops may be less than optimal.

“Many of my patients have told me they do not like touching their eye, or that they have difficulty squeezing the bottle. Others feel they cannot hold their eye open and simultaneously negotiate the instillation. In the past, patients have told me they depend on family members or visiting nurses to help take the drops, and that just adds cost, complexity, and hassle that a lot of patients are unwilling to bear,” Dr. Thompson said.

According to Dr. Thompson, because many cataract patients are older individuals with concomitant medical issues, they may be dealing with several chronic ailments, and may be taking a wide range of medications. The many patients who face these other age-related medical issues may have difficulty properly complying with drop therapy. According to Dr. Thompson, this can have negative consequences, including an increased risk of infection that can lead to permanent vision loss and an increased risk of inflammation that can undermine the quality of the outcome.

Patient Experience

During his interview, Dr. Thompson discussed how dropless therapy was particularly beneficial to a patient with Parkinson’s Disease. This woman was concerned she would not be able to undergo cataract surgery due to her condition.

“During the initial consultation, the patient expressed a lot of concern about undergoing surgery, and her anxiety grew much worse when we began to discuss postoperative care and the drops she would have to use,” Dr. Thompson said. “However, when we discussed the opportunity for her to use dropless therapy, it relieved a lot of tension and we were able to move forward with her case.”

According to Dr. Thompson, in this case, surgery may not have been an option without dropless therapy; at a minimum, it would have commenced under very stressful circumstances. He explained that this case is representative of the fact that dropless therapy can enhance patients’ experiences with their surgery and improve overall patient satisfaction.

Dr. Thompson said that because of the superior outcomes and improved patient experience, “When I present the option of dropless to my patients, nobody wants drops.” As a result, “I use dropless for almost all of my cataract patients.”

Appendix F
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