POLICY BRIEF

Modernizing Cataract Surgery

Real-World Evidence Supports FDA Approval of Intracameral Moxifloxacin

Each year over **4 million Americans** — primarily Medicare beneficiaries — undergo cataract surgery, the most common surgical procedure in the United States. Preventing post-operative infection (endophthalmitis) is paramount and currently relies on complex multi-week topical antibiotic eyedrop regimens, which are expensive, difficult for elderly patients to administer, and less effective than modern alternatives.

Surgeons worldwide have adopted **intracameral moxifloxacin**, an antibiotic injection delivered once at the end of surgery, yet **no FDA-approved intracameral formulation currently exists in the United States**. As a result, U.S. surgeons must rely on off-label compounding and dilution, introducing unnecessary safety risks, regulatory barriers, and unjustified excessive costs.

ANNUAL PROCEDURES
4M+
Americans receive cataract surgery each year

INFECTION RISK
−73%
Reduction in endophthalmitis vs. standard care

10-YEAR SAVINGS
$8.7B
Projected federal savings if adopted

§ 01 · CLINICAL EVIDENCE

The Evidence

Extensive real-world evidence demonstrates that intracameral moxifloxacin significantly improves patient safety.

- A meta-analysis of **3,566,022 eyes** found that intracameral moxifloxacin reduced the odds of endophthalmitis by **73%** compared to standard care.
- Large datasets from global surgical registries and integrated health systems confirm similar reductions in infection risk.
- Studies consistently report **no adverse events** directly attributable to moxifloxacin at appropriate doses.

> *Because endophthalmitis is rare, a traditional Phase III clinical trial would require at least 70,000 patients to demonstrate statistical significance — prohibitively expensive and time-consuming, despite millions of existing real-world cases already confirming safety and effectiveness.*

Recent FDA policy updates explicitly allow approval pathways using large real-world evidence datasets, making this an appropriate and efficient regulatory approach.

§ 02 · FISCAL IMPACT

Fiscal Impact for Medicare and the VA

Modernizing Cataract Surgery

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The current postoperative eyedrop regimen is costly and inefficient. A standardized intracameral injection delivers comparable or better outcomes at a fraction of the cost.

APPROACH	AVERAGE COST PER EYE	ANNUAL FEDERAL IMPACT
Traditional postoperative eyedrops	**$103–$228**	Current baseline
Intracameral "dropless" injection	**~$16–$22**	Up to **$450M** in annual savings

Potential federal savings include:

- Up to **$450 million annually** in reduced drug costs across the U.S. healthcare system.
- Up to **$8.7 billion over 10 years** for Medicare, Medicaid, and patients.
- Reduced pharmacy burden and improved adherence for Veterans Health Administration patients and elderly patients, many of whom face challenges administering complex drop regimens.

§ 03 · PUBLIC HEALTH & SAFETY

Public Health & Safety Benefits

FDA approval of a standardized intracameral formulation would:

- Eliminate risks associated with **compounding and dilution errors**.
- Ensure consistent **sterile unit-dose formulations**.
- Improve outcomes by eliminating patient **non-compliance with eyedrops**.
- Align U.S. surgical practice with **global standards of care**.

Currently, the lack of FDA approval leads to inconsistent usage and safety risks both within the Veterans Health Administration and U.S. healthcare systems.

§ 04 · RECOMMENDATIONS

Requested Congressional Support

Three coordinated actions would unlock the safety and savings benefits documented above.

1

FDA ACTION

Evaluate under the modern RWE framework

Encourage the FDA to evaluate intracameral moxifloxacin using existing real-world evidence datasets under its modern RWE framework.

2

CMS CONSIDERATION

Open reimbursement pathways for dropless protocols

Direct CMS to evaluate reimbursement pathways that allow adoption of dropless cataract surgery protocols, generating significant federal savings.

3

VHA IMPLEMENTATION

Standardize intracameral antibiotic access for veterans

Support policy enabling standardized intracameral antibiotic access across the Veterans Health Administration to improve patient safety and reduce costs.

THE BOTTOM LINE

Real-world evidence from **millions of surgeries** demonstrates that intracameral moxifloxacin is **safer, more effective, and far less expensive** than the current eyedrop-based system.

Approving a standardized formulation would **protect patients, modernize surgical practice, and save billions in federal healthcare spending**.