

# Pharmaceutical Cataract Surgical Waste: The Facts, Costs and Environmental Impact of Multi-Use Ophthalmic Drops & Ophthalmic Ointments

(USP 797: United States Pharmacopeia Chapter 797 entitled “Pharmaceutical Compounding-  
Sterile Preparations”)

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We are *all* guilty of it. Following orders that is! We are trained from infancy to listen to our parents. Then, we are told that our teachers are correct, so, we did what they told us. If we didn't, we were/are labeled as... troublemakers!

*(Urban dictionary, (2011): **Troublemaker**-someone who expresses a view on a forum that differs from those of the Administrator and/or, a moderator of a forum. The person deemed to be a troublemaker will usually be 100% correct in their statements, but the moderator will object, making statements that could be classified as speaking balderdash. As a result, the Troublemaker is told to go form their own forum, even though everything they said was correct).*

We eventually grow up, and respect authority. When we become medical professionals, we trust the guidelines which are there for both our and our patients' safety. When we work, we follow the rules (Policies) of our Institutions which are based on guidelines from The Joint Commission, CDC, and other Medical Organizations.

We never really question whether the guidelines are based on evidence or opinion. Should we? (AKA: Troublemaker)

Have you ever thought about the multi-use eye drop bottles/ophthalmic ointments we use during the peri-operative period, as well as in the operating rooms? Some say you must only use them on one patient, some say at the end of the day you should throw them out, and some say you have to throw them out at the end of the 28-day period....so what are the facts?

**Misinformation** spread by word of mouth or *electronic media* is common. Nowadays, with rapid access to information, there is often well-intentioned misinformation:

**One electronic example of Misinformation is:** (see link below)

<https://members.ufs.com.au/health/advice/eyedrops>

**Quote from the MISINFORMATION**

*“Eye drops have preservatives in them to ensure the sealed product remains sterile until the expiration date. After opening however, the preservative can only ensure the drops are safe for the eye for a period of 28 days. After this, using the drops can cause serious damage to the eye as bacteria may have been introduced”. The ingredients themselves will also not be as effective and could be dangerous.”*

All of us are faced with volumes of Regulations from Hospitals and Hospital Policies, ASCs, the Joint Commission (TJC), Center for Medicaid & Medicare (CMS), Individual State Pharmacy Acts and State Inspections.

At times, it feels like buying a home or car: volumes of information that really is of minimal interest, but, regrettably, you are responsible for all the details!

When faced with all this information, your normal response may just be “yes sir” or “yes mam” and you find yourself complying with your Institution's check lists of instructions.

But have you ever wondered the basis for some of the Regulations? What is the factual *evidence* that is the driving force behind the Regulations & Policies? (Enter: Troublemakers)

### **So, why should we even be interested???**

The Aravind Eye Care System (13 locations) in Southern India is the largest eye care system in the world. This Institution sees close to 5 million patients annually and does over 500,000 surgeries a year!

The average surgeon does approximately 48-64 phacoemulsification's in a morning with an endophthalmitis rate of 0.006% including residents, fellows, and foreign guests. The fully burdened cost of a cataract operation at Aravind (their complication rate is far lower than it is here in the US) averages about \$22.00 per case excluding the actual cost of the IOL.

When it comes to operating room waste, being green and saving money are one and the same thing! An eye drop bottle or ophthalmic ointment tube, tossed in the medical waste receptacle after 28-days, means the plastic is staying there forever and the medication within the bottle, will be in my landfill, and may get into my drinking water.

Why so inexpensive? They don't skimp on quality because complications are far more costly and they are bad for social marketing and counter to physician duties and values. They just don't throw out the things we do. Every eye drop bottle is used until it is empty.

You may think.... "That must be horrible!"

We all know that when patients instill drops into their own eyes, the tip has potential to get contaminated. Of course, this will lead to endophthalmitis and endanger your patients... Or will it? (By the way, when we videotaped over 1800 preoperative eye drop instillations, there was no bottle tip-eye touch. Also, each bottle was cultured...all cultured negative. (Wu, A.M.).

So, putting a drop in a patient's eye is different than a patient putting a drop in their own eyes.

**Reference: American Society of Ophthalmic Registered Nurses (ASORN) Instillations of Eye Drops/Ointments (2021 July)**

<https://asorn.org/assets/PDF-Documents/Instillation-of-Eye-Drops-and-Ointments-2021.pdf>

**Reference: American Academy of Ophthalmology (2021 July)**

<https://www.aao.org/eye-health/ask-ophthalmologist-q/how-long-after-opening-is-it-safe-to-use-eye-drops>

**So, do you have to toss out this eye drop bottle(s)?**

*\*In US Institutions, clinical practice is driven by Institutional Policy. Make sure you know and follow your Institutions Policy.*

***What are the Regulations?***

The ASCRS OICS Surgical Pharmaceutical Waste Subcommittee (SPWS) of which we are members first went **to the FDA**.

**When asked, we received the following reply:**

*In summary, **the FDA** determines as part of the review leading to the approval of topical ophthalmic new drug products, an expiration date which is included on each bottle. This expiration date is based on extensive formal testing of the drug product in the marketed container closure system and includes sterility assurance. The antimicrobial preservative included in multidose topical ophthalmic drug products is intended to minimize the hazard of injury that might result from contamination of the bottle during use. The FDA expects that the strength, quality, and purity of the topical ophthalmic drug product will be maintained during the entire period of its use if stored as described in the labeling and used by the date listed on the bottle as the expiration date. Topical ophthalmic drug products are not limited to use by a single individual or a duration of use shorter than the expiration date included on the bottle unless specific statements to that effect are included in the labeling of the product.<sup>1</sup>*

The SPSW next contacted **The Joint Commission** which is an Accrediting Agency focused on improvement strategies which help health care organizations continually improve patient's safety and their quality of care.

We reached **Dr. Robert Campbell PharmD, BCSCP, Director, Clinical Standards Interpretation Group and Director, Medication Management of the Joint Commission**.

On June 3, 2021, **Dr. Campbell confirmed that the 28-day expiration dating used for multi-dose infusible & injectable medications does not apply to topical agents such as ophthalmic drops and ophthalmic ointments.**

The manufacturers package insert provides expiration dates for the particular product.<sup>2</sup>

**What about the AAAHC?**

Spokesperson Anna Figy stated in a 6/3/21 email to the SPWS,

“Multidose eyedrops on multiple patients are allowed provided that the medication is labeled, handled, administered and stored according to Policies, Manufacturer's Instructions for Use (IFU), and best practice recommendations.”

**What about the AAAASF?**

**liana Wolfe RN, Director of Clinical Compliance at AAAASF** stated in a letter dated September 30, 2021:

Per the AAAASF Standards Committee, when using multi-dose eye drops in a surgical facility, it is acceptable for expiration dates to follow the manufacturer's recommendations if multi-dose eye drops are labeled, handled per CDC guidelines, and administered and stored according to policies, manufacturer instructions, and best practice recommendations. These facilities must monitor and perform surveillance of the administration of multi-dose eye drops as part of their infection control program. Facility staff must be trained and have ongoing competencies documented specific to multi-dose eye drops.<sup>3</sup>

So, we **can** keep using topical ophthalmic medications, if stored properly, until the expiration date on the bottle!

**This now leads us (Task Force, AKA “Troublemakers”)** to ambitiously pursue Institutional (Hospital) Policy to change their practice. The change would support the scientific evidence (Evidence Based Practice) that the SPWS and Accrediting Agencies has brought to light and agreed upon.

Institutional Policy change must be inclusive and supported by all of the Institutions top Leadership, Pharmaceutical & Therapeutics Committee, and Infection Prevention & Epidemiology. ***This is an organization problem that has to be solved locally.***

#### **“Why” is all of this important?**

Cataract surgery is the most common performed surgery in the world, with over 29 million cases performed in 2019, of which 4.3 million were performed in the USA. The ophthalmology specialty has an opportunity to make meaningful reductions in its waste production.

Without meaningful advances, climate change will become a [public health emergency](#) with the potential to disrupt billions of lives and destroy the world as we know it. Leaders within each area of our country’s economy, including healthcare, must examine their industry’s contributions to climate change. The American healthcare sector [is responsible for 10%](#) of the nation’s greenhouse gas emissions; if our healthcare sector were its own country, it would be the 13<sup>th</sup> largest producer of greenhouse gases worldwide!

A primary, and under-studied, inefficiency within our healthcare sector is the physical waste produced in hospitals and health centers. In hospitals, 20-33% of this waste is generated by the operating rooms. (Reference; Kagoma, et.al.) Data on how much waste is produced, per patient, is limited, though one study from 2010 estimated that each staffed bed in a hospital results in [33.8 pounds of waste per day](#), ranging from gloves and gowns to surgical supplies and medicine containers. Each cataract surgery in Western countries, as an example, is estimated to generate the same amount of greenhouse gas emissions [as driving a car \(310https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5728421/miles\)](#).

And our own research indicates that in the United States, almost all of this waste is either incinerated or [ends up in landfills](#), where it will remain for decades. It is no surprise then that life

cycle assessments have found that [a significant portion](#) of the carbon footprint of the healthcare sector arises from the production and disposal of medical waste.

### What about the cost?

Spending for healthcare in the US is approximately \$3.5 trillion, or almost 18% of the GDP. Prescription drugs account for approximately 10% of this spending. A recent study by Tauber and associates [reference] evaluated wasted topical medications following uneventful and uncomplicated phacoemulsification in both an ambulatory care center, medical care center for veterans, outpatient care setting, and tertiary care center.

- Cataract surgery patients' inability to take home their medication after discharge has a negative impact on the Cost of Healthcare, for both the patient and the facility.
- The inability of the patient to take home their medications after discharge **may potentially** negatively impact the quality of their care.
- **Wasting their eye drops/eye ointment directly causes an increase in healthcare costs.**
- We need to help change existing Hospital Policy efforts to curb Topical Drug Waste.
- **Discarding multi-use ophthalmic drops/ophthalmic ointment before the manufacturers expiration date (28-day rule, and most likely the facility Policy) creates ARTIFICIAL DRUG SHORTAGES**, because the medication is tossed out prior to the true expiration date that is recommended by the Manufacturer.
- We need to educate individuals, organizations, States and Feds to move towards Standardization & Consistency of:
- Procedures, Safety/Protocols and Guidelines/Policies.

The ambulatory care center disposed of approximately 2/3 of all pharmaceuticals used in cataract surgery with a resulting monetary cost of \$217/per patient case for the unused drops. The potential greenhouse gas emissions (GHG) per month were equivalent to driving an average passenger car 1025 to 6120 miles per month or burning 47 to 281 gallons of gas per month.

In summary, being green will save your patient/families and facility money!

Look around you and start to notice all of the waste.

Start to investigate whether it can be saved, reused, or was it even needed! Look at facts, cost, drug shortages, and environmental impact. Be a change agent for your ophthalmic institution.

“Choosing wisely among possible courses requires knowledge about the effects of those actions. Public Health and medical decision makers therefore need some sound casual inferences to know what works and what harms people. We cannot conduct enough...trials to answer causal questions about all treatment strategies and outcomes...If an appropriate target trial does not exist when a decision must be made, casual inference may need to rely on . observational population data.” (Hernan, MA).



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