GRANT PROPOSAL: Precision Medication Delivery System Using PAW Technology

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1. ABSTRACT

This proposal presents the development of a novel medical device: the **Piezo-Generated Aerosol Wand (PAW)**. PAW is a **hand-held**, non-contact applicator designed for precision delivery of liquid medications to sensitive surfaces, including eyes, wounds, oral mucosa, and surgical sites. Traditional methods (drops, sprays, pads) often result in overdosing, patient discomfort, and contamination risk. PAW overcomes these limitations through a focused aerosol micro-cloud generated by a **micro piezoelectric system**.

An integrated **Composite Spherical Piezo-Lens (CSPL)** component enhances this precision by focusing aerosol streams to a user-adjustable convergence point, ensuring consistent dosing across varying anatomical targets. The project proposes a four-phase development plan, culminating in clinical adaptation and regulatory preparation.

2. BACKGROUND AND OBJECTIVES

Status and Challenges

Medication delivery to delicate tissues is challenged by:

- Imprecise dosing
- Systemic drug absorption
- Physical discomfort
- Cross-contamination
- Patient noncompliance (especially in pediatrics and geriatrics)

Conventional sprays and drops lack precision and control over dose geometry, contributing to reduced efficacy and increased side effects.

Technology Summary

The **PAW platform** integrates:

- A micro piezo-driven actuator generating aerosolized droplets
- A **Composite Spherical Piezo-Lens (CSPL)** for focal stream convergence
- Manual controls for dosage modulation
- Optional sensor-guided or electrostatic targeting

The system will utilize **off-the-shelf piezo components**, potentially adapted from acoustic levitator assemblies, and be enclosed in lightweight, ergonomically optimized hand-held housing. The CSPL nozzle configuration will allow modulation of droplet diameter, stream velocity, and focal distance.

An embedded microcontroller will regulate piezo pulse parameters, drive feedback mechanisms for dose consistency, and allow future integration with smartphone-based tracking interfaces for usage logging and prescription compliance.

Objective
Develop, prototype, and validate a **hand-held, non-contact medication delivery platform** suitable for sensitive applications such as ophthalmology, ENT, dermatology, and wound care, using acoustic fluid manipulation principles and droplet convergence geometry.

3. PROJECT TEAM AND ROLES

Team Member	**Specialty/Role**
Lev Neymotin, PhD	Principal Investigator, Systems Integration, Device Modeling
Mechanical Engineer	Device CAD Design, Fabrication Oversight
Fluid Dynamics Specialist	CFD Simulation, Droplet Behavior Analysis
Electrical Engineer	Circuit Design, Embedded Control System
Industrial Designer	Ergonomic Housing, Component Packaging
Clinical Consultant	Medical Application Testing, Use-Case Validation
Regulatory Advisor	FDA Classification, Submission Preparation

This multidisciplinary team integrates core competencies required for the PAW platform:
- Engineering (mechanical, fluidic, electrical) for hardware development
- Applied physics for modeling aerosol propagation
- Clinical expertise for relevance and testing
- Regulatory oversight to ensure path-to-market readiness

4. DEVELOPMENT TIMELINE AND BUDGET

Development Phases

Phase	Description	Duration (months)	Labor Cost ($k)	Materials & Equipment ($k)	Total Cost ($k)
Phase 1	Feasibility & Simulation	3	75	25	100
Phase 2	Prototype Fabrication	4	120	60	180
Phase 3	Application Testing	4	100	40	140
Phase 4	Clinical Integration	6	150	70	220
Total		**17 months**	**445**	**195**	**640**

Detailed Tasks by Phase

Phase 1: Feasibility & Simulation

- Simulate piezo-based droplet generation under varying electrical pulse conditions
- Model CSPL droplet convergence geometry using Boundary Element Methods (BEM)
- Use CFD for aerosol flow shaping and focused deposition on curved surfaces

Phase 2: Prototype Fabrication

- Procure and adapt piezo components (atomizers, micro-actuators)
- Manufacture and assemble CSPL nozzle with embedded micro-droplet ports
- Develop embedded control PCB and software
- Construct first-generation ergonomic shell and control interface

Phase 3: Application Testing

- Perform benchtop testing with artificial tissue and wound models
- Test repeatability and uniformity of droplet cloud delivery
- Integrate clinical feedback for ergonomic and precision refinements

Phase 4: Clinical Integration & Regulatory Prep

- Conduct IRB-approved usability study with ophthalmology and wound care professionals
- Gather dosing accuracy and patient feedback
- Prepare 510(k) documentation and pre-submission with FDA consultant

Each task will be assigned to relevant technical and clinical leads, with Lev Neymotin overseeing technical integration and milestone coordination.

5. TEST CASE: OPHTHALMIC APPLICATION

The initial proof-of-concept application will focus on **ophthalmology**, a use case where conventional drops often lead to overdosing, poor retention, and discomfort. With the PAW system:

- Micro-droplet clouds are gently directed to the eye surface without contact
- Volumes are reduced by 80–90%, minimizing drug waste and systemic absorption
- Delivery is easier for elderly, children, and self-administering patients

This test case also allows quantitative evaluation of coverage pattern, stream targeting precision, and user experience, making it ideal for early demonstration and FDA pathway classification.

6. FUNDING STRATEGY AND COLLABORATION OPPORTUNITIES

Potential Public and Private Funding Sources:

- **NIH SBIR/STTR** (NEI for eye-related use cases, NIBIB for bioengineering)
- **NSF Partnerships for Innovation**
- **BARDA** (advanced wound care and post-operative solutions)
- **Michael J. Fox Foundation** (if adapted for Parkinson's-related medication delivery)
- **Gates Foundation** (for global medication access improvement)

Potential Collaborators:

- **Bascom Palmer Eye Institute** – Ophthalmic use-case testing
- **Cleveland Clinic Innovations** – Device co-development
- **Academic Departments** at Northwestern, UChicago, or similar (fluid mechanics & bioengineering)
- **Piezo-component vendors** (e.g., Steminc, APC International) for sourcing and integration

This broad base of institutional and commercial stakeholders ensures both short-term validation and long-term path to scale and market.

7. CONCLUSION

The PAW system, built around a compact piezo-driven delivery engine and CSPL nozzle design, aims to transform how medications are delivered to the most delicate parts of the human body. By combining deep engineering innovation with insights from fluid dynamics and medicine, this hand-held system will enable accurate, waste-free, and non-invasive delivery.

With a technically robust team, off-the-shelf components, and a clearly defined four-phase roadmap, the project is ready for funding and execution. Its first milestone—ophthalmic validation—offers a powerful platform to expand to broader clinical fields.