



One Time Therapy For Nasal Allergy Symptoms



Vahid Saadat
President & CEO

Our Business

Arrinex technology provides lasting relief from the symptoms of chronic nasal allergies by targeting the source of autonomic control of congestion and nasal discharge. Arrinex's procedure mimics the action of gold standard pharmaceuticals.

Business

First company offering durable relief from symptoms of nasal allergy through a painless in-office procedure

Market

- 24M patients in U.S. , 2.5M qualified pool of patients
- Launch in Q3 / 2016

Regulatory & Clinical

- 510(k) with predicates
- Clinical study under way

Technical/IP

- Disposable single use – no capital equipment
- Solid IP

Funding

- \$5M series “A” to achieve milestones of: 510(k), pivotal clinical study and limited market release

-Large market
-Pent up demand



24 million patient pool in the U.S.
2.5 million patients fail medical therapy
\$11 billion cost to the healthcare system
50%+ overlap of sinusitis and rhinitis symptoms

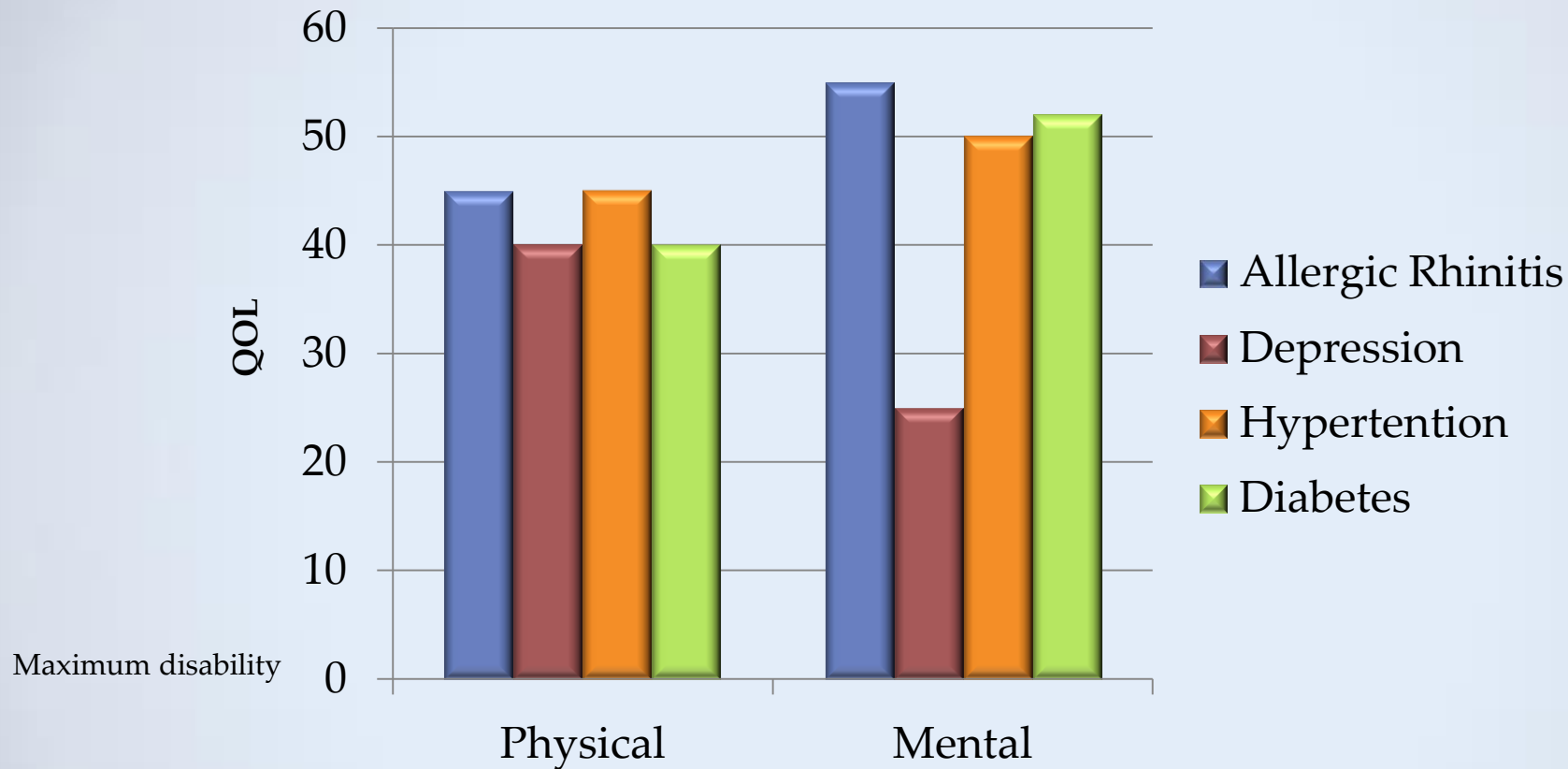
1-Source: 1 CDC

2-Source: 2 Schulman/SRBI landmark study of 15000 households, conducted by: Michael Blaiss M.D., Jennifer Derebery M.D., James hadley M.D., Robert Naclerio M.D. et. al. (14% diagnosed with rhinitis)

3-Source: 2 MEPS Statistical Report #204, Allergic Rhinitis: Trends in Use and Expenditures, 2000 and 2005. Soni, A., May 2008.

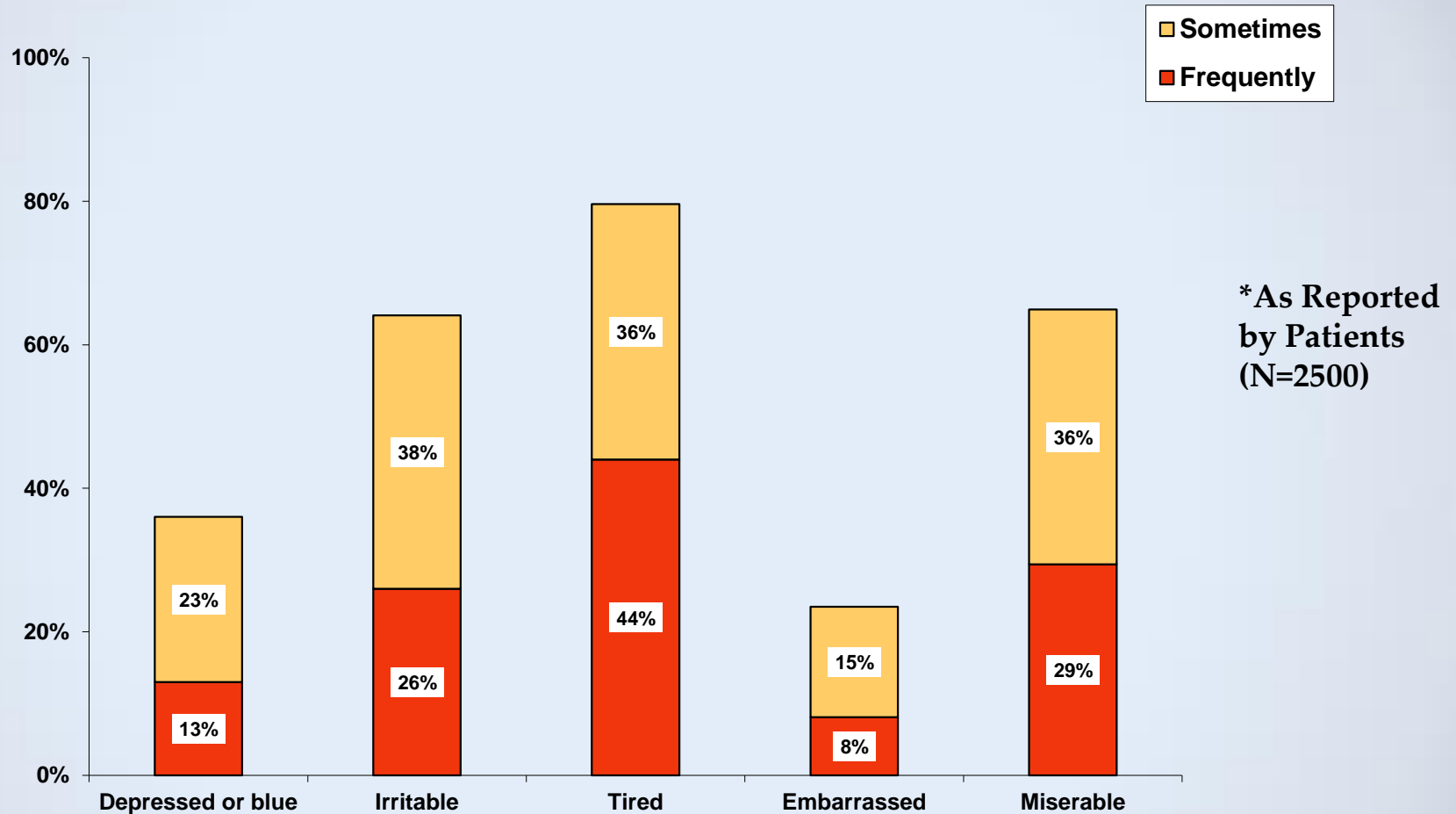
4-World Allergy Organization

Quality of Life Impact

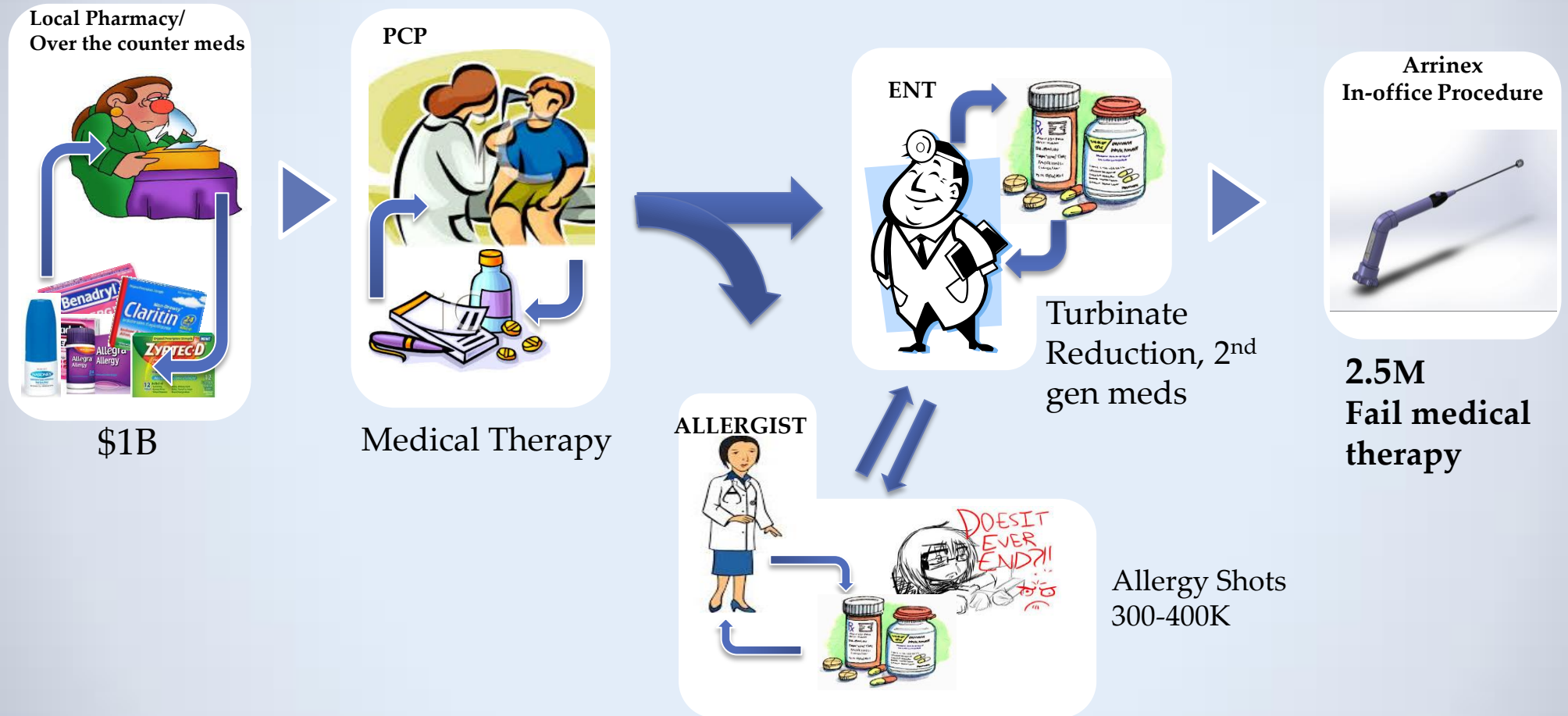


SF36 validated QOL questionnaire: SF-36

Impact of Symptoms on Daily Life*



Typical Patient Journey



Various sources:

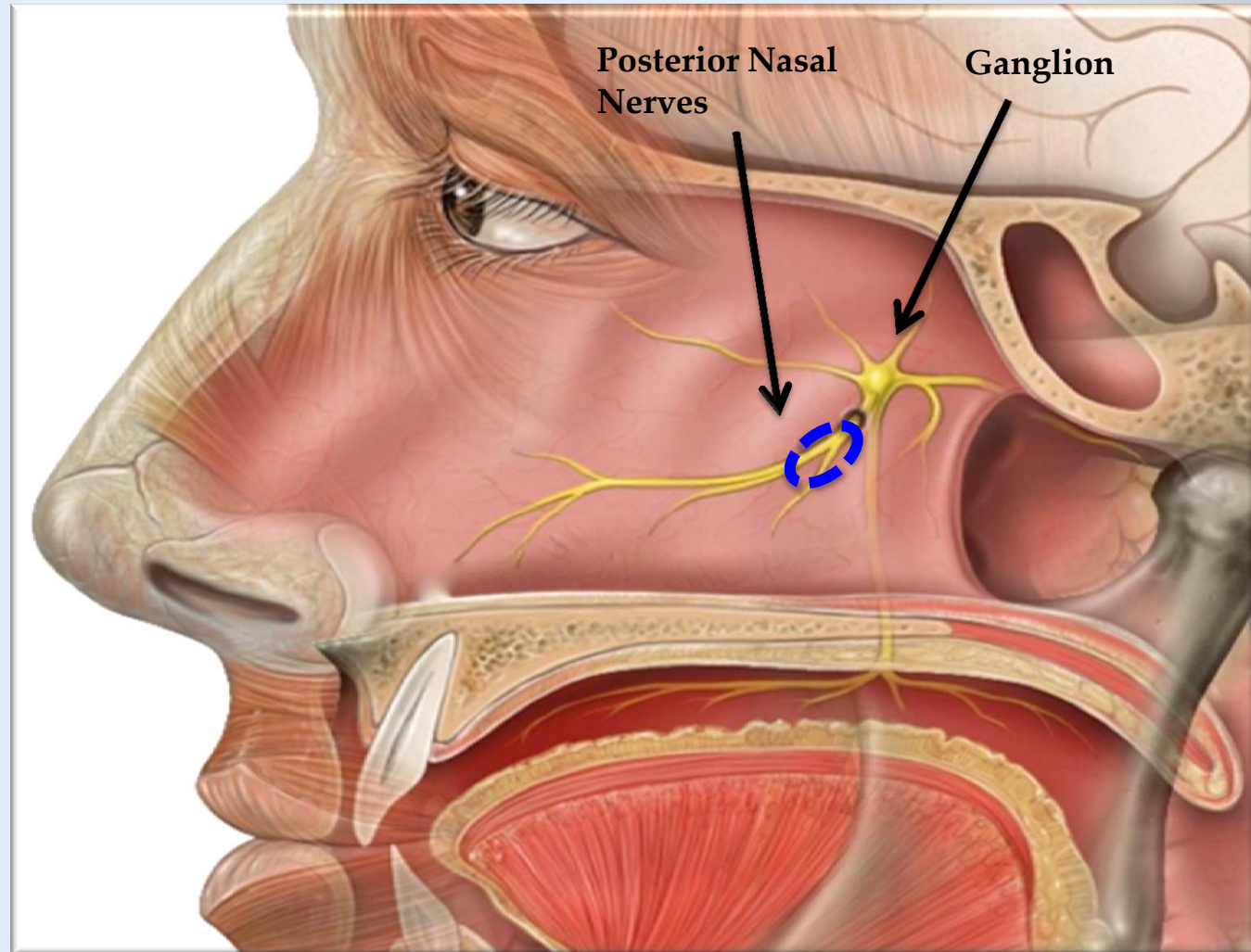
CDC, Arrinex Notes, Average from Mularkey chart in Arrinex White Paper. MEPS Statistical Report #204, Allergic Rhinitis: Trends in Use and Expenditures, 2000 and 2005. Soni, A., May 2008.



Arrinex Non-Invasive Solution

Innervation of Nasal Mucosa & Rhinitis

Suppression of the posterior nasal nerves to mitigate nasal discharge and congestion.



Clinical Evidence

Surgery

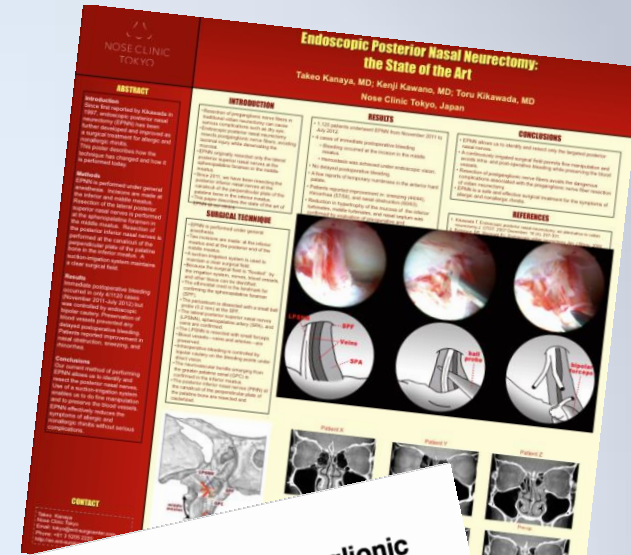
(Kikawada, 2012)

- 1056 patients
- 95% success at one month
- 80% success at 2 years

Ablation

(Strome, 1994)

- 154 patients treated
- 93% success at one month
- 75% success at 2 years



An Assessment of Postganglionic Cryoneurolysis for Managing Vasomotor Rhinitis

Harsha Girdhar-Gopal, M.D., Lee Okunowski, B.A., and Marshall Strome, M.D., M.S., F.A.C.S.

ABSTRACT

Vasomotor rhinitis has been treated with multiple regimens with varied success. We have used perinasal cryoneurolysis to freeze the postganglionic parasympathetics as a definitive therapeutic procedure. A total of 154 cryoneurolysis procedures were performed in a 2-year period. Complete data was available for 144 patients. Concomitant endonasal surgery was performed in 144 patients. Surveys were sent to all patients, with 93% of patients treated had significant improvement in their inferior turbinates. On a scale of 1-10, nasal breathing improved from a mean of 2.9 preoperatively to 8.0 at 10% responding. Of the responders, 80% would recommend the procedure to others. On a scale of 1-10, nasal breathing scores improved from a mean of 2.9 preoperatively to 8.0 at 10% responding. Data from this patient cohort revealed cryoneurolysis to be an effective alternative to inferior turbinectomy and turbinate reduction, with a high rate of patient satisfaction and a low recurrence rate (Am J Rhinology 8:157-164, 1994).

Chronic rhinitis of a non-allergic cause is among the most common disorders seen by the general otolaryngologist. Most often, such rhinitis is caused by

idiopathic vasomotor instability and hence is called "vasomotor rhinitis." The mechanism for its development is felt to be from an increased parasympathetic output and subsequent increase in the level of acetylcholine in the nasal cavity. Some feel that vasomotor rhinitis is a disease but an exaggerated physiologic process.¹ Vasomotor rhinitis characteristically presents with episodic nasal pruritus and sneezing. The obstruction often worsens in recumbency and during exercise or cold weather. Several studies have suggested that cryoneurolysis of the turbinates is effective in reducing nasal obstruction, although less so for rhinorrhea in vasomotor and allergic rhinitis.²⁻⁴ However, long-term follow-up is lacking. In a 15-year retrospective of extensive cryoneurolysis, it was noted that a variable duration of relief and the need for repeat surgery occurred in 6% of patients.⁵ In another prospective randomized comparison of partial inferior turbinectomy, laser turbinectomy, cryoneurolysis, and cryoturbinatectomy, cryoneurolysis was found to have comparable results 2 months postoperatively, with 78% and 75% of patients, respectively, reporting good or fair results.⁶ It is the experience of the authors, however, that turbinate cryoneurolysis and submucosal diathermy give immediate relief of obstructive symptoms, but have high rates of recurrence. Although no study to our knowledge has adequately addressed the worsened nasal obstruction during recumbency often associated with vasomotor instability.

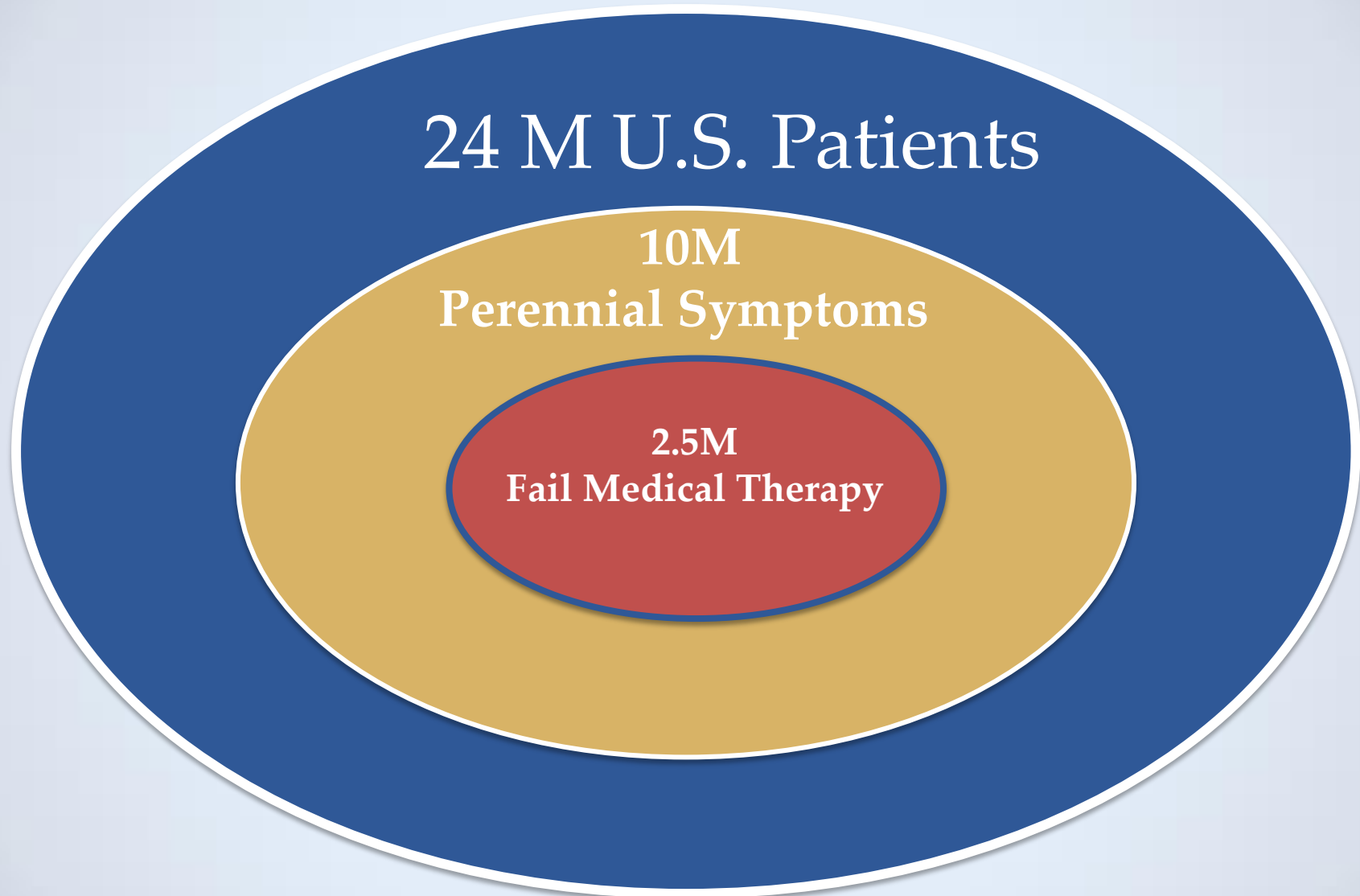
From the Joint Center for Otolaryngology, Beth Israel Hospital and Brigham & Women's Hospital, Department of Otolaryngology, Harvard Medical School, Boston, Massachusetts (Presented at the American Rhinological Society Meeting in Los Angeles, California, April, 1993). Supported in part by Brigham Surgical Group Foundation, Inc., 110 Cypress St., Brookline, MA 02146. Address correspondence and reprint requests to Dr. Harsha Girdhar-Gopal, 333 Longwood Ave., Boston, MA 02115.

Am J Rhinology



Market size and segmentation

Market



Source: 1 CDC

Source: 2 Schulman/SRBI landmark study of 15000 households, conducted by: Michael Blaiss M.D., Jennifer Derebery M.D., James hadley M.D., Robert Naclerio M.D. et. al. (14% diagnosed with rhinitis)



Clinical & Regulatory Plan

Clinical Plan

30 patient U.S. pilot study started

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graph TD; A[30 patient U.S. pilot study started] --> B[• Pilot Study<br/>➤ Follow up: 7, 30, and 90 days<br/>➤ Endpoints: Symptom ratings using standard tests, patient satisfaction, safety]; B --> C[• Pivotal study<br/>➤ 100 patients<br/>➤ Symptom ratings using standard tests, quality of life questionnaire.<br/>➤ Data will support marketing and publications];
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- **Pilot Study**

- Follow up: 7, 30, and 90 days
- Endpoints: Symptom ratings using standard tests, patient satisfaction, safety

- **Pivotal study**

- 100 patients
- Symptom ratings using standard tests, quality of life questionnaire.
- Data will support marketing and publications

U.S. Regulatory Plan

- **Initial clearance:**
 - Traditional 510(k) without clinical data
 - Indication: to destroy tissue during endoscopic surgical procedures by applying freezing cold.
 - Multiple predicates with same intended use & technological characteristics



Milestones and Financial Overview

Commercial Rollout Plan

PRE-COMMERCIAL CLINICAL

- Prove safety & efficacy
- Develop champions
- Generate data

SOFT LAUNCH

- Optimize & refine procedure
- Expand awareness

FULL LAUNCH

- Grow customer base
- Broaden patient population by expanding indications
- Increase awareness among referring physicians

Intellectual Property

- Multiple patent applications
- Freedom to operate confirmed
- Solid IP given our first entrant position in the field

Clinical Advisors

Peter Hwang, M.D., Chief, Division of Rhinology, Stanford School of Medicine

William Bolger, M.D., Chief of Rhinology at the Mayo Clinic, Florida

Richard Goode, M.D., Professor Emeritus, Stanford School of Medicine

Lionel Nelson, M.D., Private Practitioner, San Jose, CA

Marshall Strome, M.D., Chairman Emeritus, Cleveland Clinic H&N Institute

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