VA | U.S. Department of Veterans Affairs

Department of Veterans Affairs Technology Transfer

Bringing Research Advancements for Veterans to Everyone!

TECHNOLOGY TRANSFER PROGRAM

Agenda

TECHNOLOGY TRANSFER PROGRAM

Bringing Research Advancements for Veterans to Everyone!

- Technology Transfer
- Business at the VA
- Scope of VA Portfolio
- Our business process
  - Invention Disclosure
  - Determination of Rights
  - Assessment of Technology
  - Marketing
  - Licensing
  - Royalty Distribution
- Questions & Answer

Andrew Schally
Miami VAMC

Technology Transfer

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- The commercialization of inventions and discoveries made by Government and academic researchers
- Most often it involves licensing a patent to a company which will develop the invention into a product that benefits the public
- Could involve a collaboration with the inventor(s) through a license or a Cooperative Research And Development Agreement (CRADA)

At the VA…

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- The mission of the VA Technology Transfer Program (TTP) is to facilitate the commercialization of VA inventions to benefit Veterans and the American public
  - Manage Inventions of VA employees
  - Review CRADAs
  - Consultations
  - Collaborate with partners
- Bringing Research Advancements for Veterans to Everyone (BRAVE)

TTP Org

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- 10 FTE
- 1 - Director, Dr. John Kaplan PhD, JD, MBA, PE
- 5 - Technology Transfer Specialists (PhD, JD, MBA, MPP)
- 5 - Staff Assistants (JD, MBA)

  - Experience - Government, Private Industry, Consulting

Snapshot

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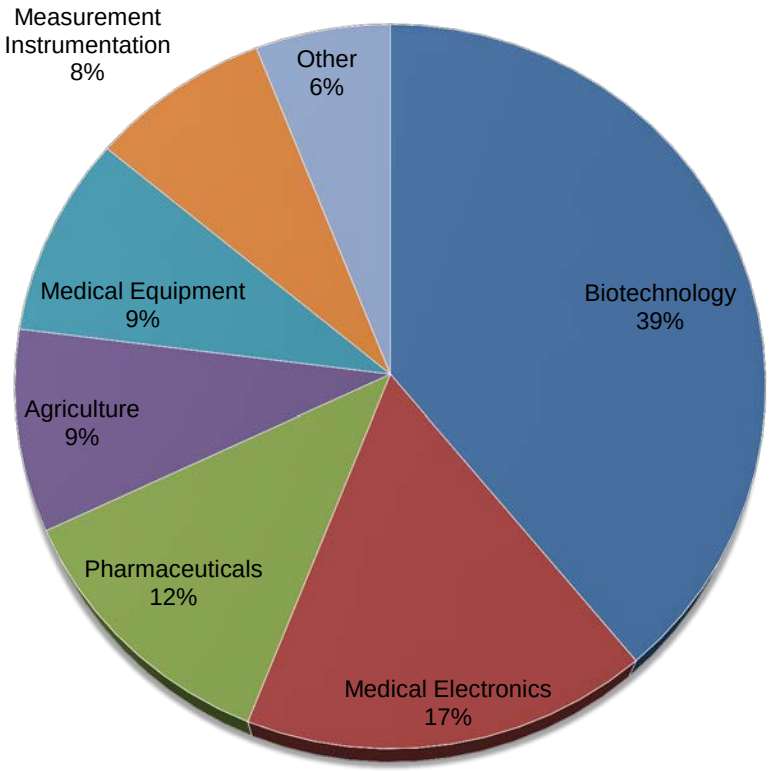
- Intramural Research Program ($600MM/ $1.8BB)
- Hundreds of CRADAs reviewed each year
- Over 100 partnerships with academia
- 325 IDs/ yr.
- 15 active license agreements (VA only)
  - Est. 100 plus VA & Affiliate license agreements
- $300-500K annual license revenue (VA only)
  - Est. $2.5MM annual VA & Affiliate license revenue
- FY 16
  - 63 patents filed
  - 30 patents issued



Aspirational Goals

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- FTEs
  - Current 10
  - Goal 22
- Disclosures
  - Current average 215
  - Goal 700 plus
- Patents
  - Patent applications 63
  - Goal 400 plus
- Licenses
  - Current 15
  - Goal 150 plus

Representative VA Affiliates

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University of Washington

University of Florida

East Tennessee State University

University of Tennessee

Loma Linda University

Saint Louis University

Stanford University

Arizona State University

Louisiana State University

Tulane University

University Missouri

Washington University in St Louis

University of New Mexico

University of Oklahoma

Alaska

University of Nevada

University of Arizona

Wright State University

Rensselaer Polytechnic Institute

Medical College of Georgia

Duke University

University of South Carolina

University of Arkansas

Wayne State University

University of Minnesota

Iowa State University

University of Iowa

NY State University of New York (Buffalo)

Yale University

UCLA

Massachusetts Eye and Ear Infirmary (MEEI)

University of Maryland

New York University

NY State University of New York System

University of Mississippi

Cleveland Clinic Foundation

Hawaii

University of Utah

University of Illinois, Chicago

University of Notre Dame

University of Michigan

University of Louisville

Case Western Reserve University EST. 1826

University of Cincinnati

KU The University of Kansas

Wisconsin Alumni Research Foundation

Wisconsin, Medical College

University of Nebraska Medical Center

Louisiana Tech University

Virginia Commonwealth University

Baylor College of Medicine

University Alabama Birmingham

Georgia State University

Emory University, Atlanta

University of Pittsburgh

Harvard Medical School

University of South Florida

Texas A&M University System

Oregon Health & Science University

University of Maryland

The University of Texas Medical System

University of Colorado

Vanderbilt University

Loyola University Chicago

Boston University

University of Pennsylvania

Brown University

University of Miami

Our Process

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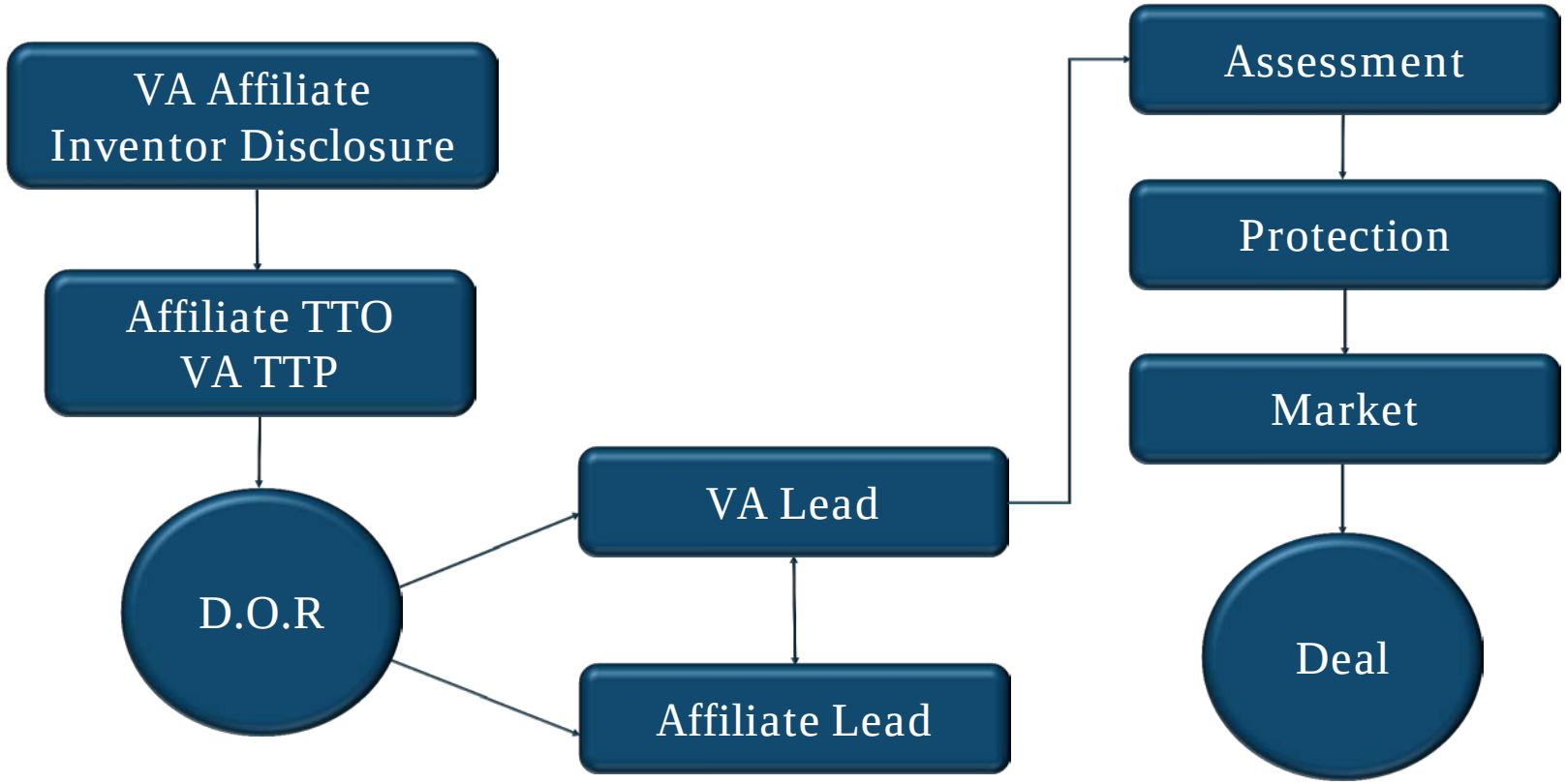

Disclosure

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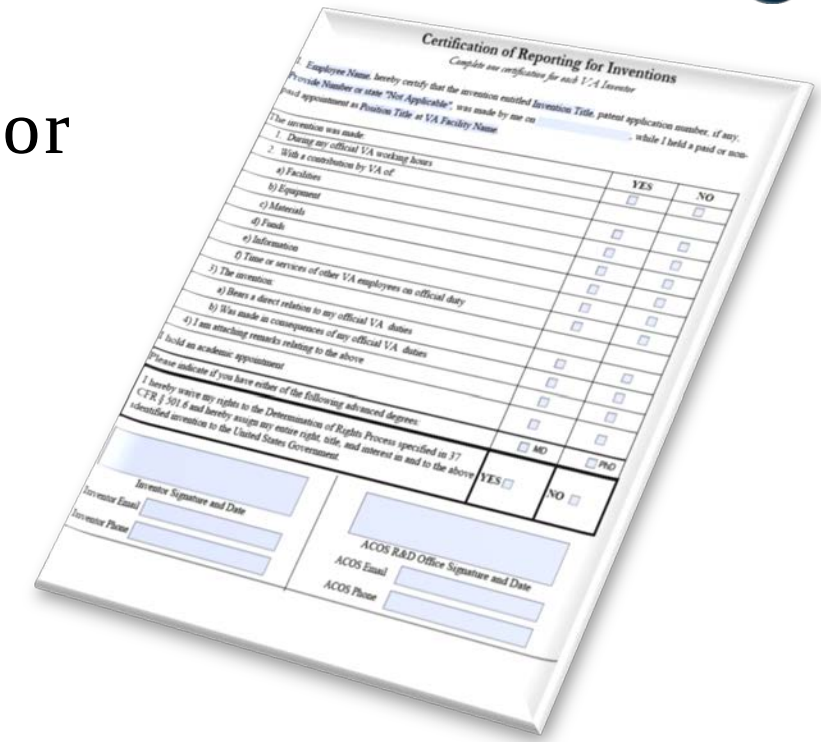
- 38 CFR 1.656
- VA Certification Form
- 1 per each VA affiliated inventor
  - Full-Time
  - Part-Time
  - WOC
  - IPA



Certification of Reporting for Inventions

Complete one certification for each VA Inventor

I, Employee Name, hereby certify that the invention entitled Invention Title, patent application number, if any, Provide Number or state "Not Applicable", was made by me on _____, while I held a paid or non-paid appointment as Position Title at VA Facility Name

The invention was made:

1. During my official VA working hours
2. With a contribution by VA of:

	YES	NO
a) Facilities	☐	☐
b) Equipment	☐	☐
c) Materials	☐	☐
d) Funds	☐	☐
e) Information	☐	☐
f) Time or services of other VA employees on official duty	☐	☐
3) The invention:		
a) Bears a direct relation to my official VA duties	☐	☐
b) Was made as consequences of my official VA duties	☐	☐
4) I am attaching remarks relating to the above	☐	☐
I hold an academic appointment	☐	☐
Please indicate if you have either of the following advanced degrees:	☐ MD	☐ PhD
I hereby waive my rights to the Determination of Rights Process specified in 37 CFR § 501.6 and hereby assign my entire right, title, and interest in and to the above identified invention to the United States Government	YES ☐	NO ☐

Inventor Signature and Date

Inventor Email

Inventor Phone

ACOS R&D Office Signature and Date

ACOS Email

ACOS Phone

Determination of Rights

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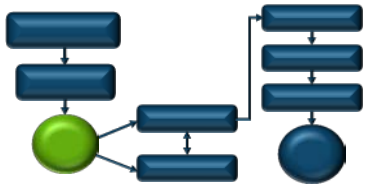
- **Assessment of Government Rights**
  - Assert Government ownership of the invention
  - Leave ownership of the invention with the inventor
  - Leave ownership of the invention with the inventor subject to the VA retaining a non-exclusive, Govt. use license
- **VA Asserts Rights**
  - Managed by VA; or
  - Obligations through CTAA/IMA/IIA if jointly owned



What happens next?

Machelle Pardue
Atlanta VAMC

Assessment

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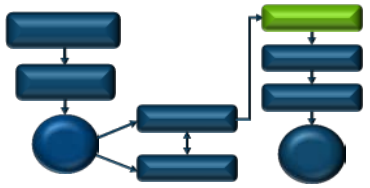
- Brief Technical Description
- Brief Market Analysis
- Competitive Position
- Barriers to Entry
- Recommendations



Inventor: Dr. X
VAMC: VA Medical Center

VA COMMERCIALIZATION ASSESSMENT

VA Ref. #: xx-xx
Disclosure Date: March 2016
Protection Status: Disclosure

A Combined Inhibition of EGFR and TNFR or EGFR and JNK in the treatment of Cancer

Despite the success of EGFR-targeted therapies for NSCLC, resistance to treatment commonly occurs as a result of secondary EGFR mutations and other acquired resistance mechanisms resulting in a low 5-year survival for advanced disease. This technology suggests that resistance to EGFR inhibition may be partially due to increased levels of TNF-a and subsequent JNK activation, which is protective against tumor cell death. Use of TNF-a with inhibitors such as Erlotinib may eliminate EGFR resistance and improve treatment responses.

- ***Market for technology*** – For use in the treatment of NSCLC, glioma, or any human cancer overexpressing EGFR.
- ***Market dynamics*** – NSCLC accounts for 1.4 million deaths annually, with 1.6 million new cases diagnosed each year.
- ***Market need addressed*** – Despite the success of EGFR-targeted therapies in NSCLC, secondary mutations in EGFR and/or acquired resistance mechanisms inevitably occurs, significantly influencing patient survival with advanced disease.
- ***Closest competition*** – NF-κB has been described as a critical adaptive survival mechanism induced by EGFR inhibition. A combined treatment approach using erlotinib and a direct NF-κB inhibitor may eliminate residual disease and enhance patient responses.
- ***Reduction to Practice/Stage of Development*** – The technology utilizes inhibitors currently used in clinical practice. However, the technology as a combined therapy is currently in the preclinical stages of development and awaiting further *in vivo* testing.

I. Brief Technical Description

Non-small cell lung carcinoma (NSCLC) is the most common cause of cancer death with

Patent Protection

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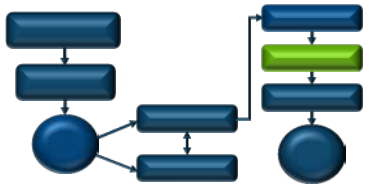
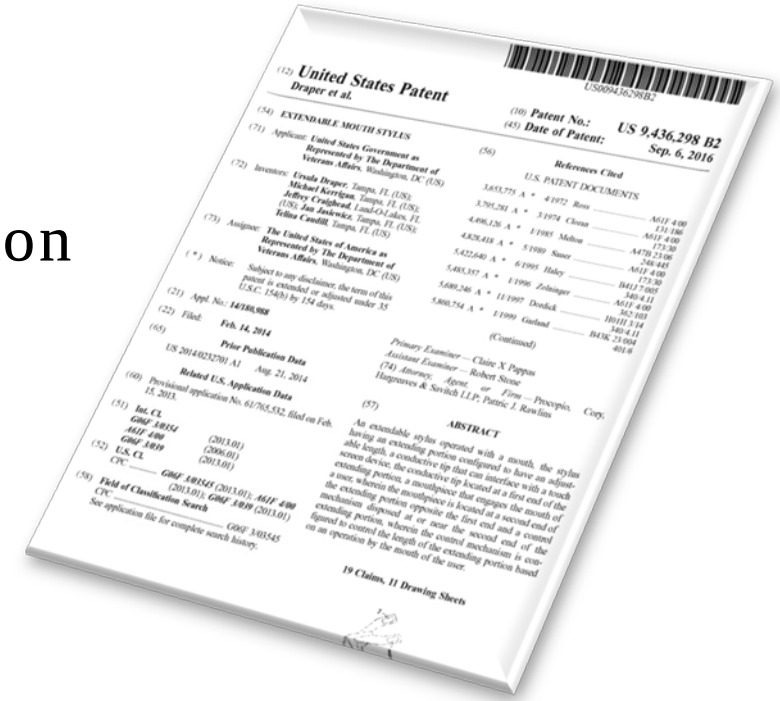


- **Provisional Patent Application**
  - VA contracted patent firm
  - Collaborative process between attorney and inventor(s)
  - Managed by TTS
  - Active marketing during first year informs decision on conversion to a utility patent application
- **Utility Patent Application**
  - In the absence of a license or strong licensing prospect, only U.S. patent is sought



(12) United States Patent
Draper et al.

US009436298B2

(10) Patent No.: US 9,436,298 B2
(45) Date of Patent: Sep. 6, 2016

(54) EXTENDABLE MOUTH STYLUS

(71) Applicant: United States Government as Represented by The Department of Veterans Affairs, Washington, DC (US)

(72) Inventors: Ursula Draper, Tampa, FL (US); Michael Kerrigan, Tampa, FL (US); Jeffrey Craighead, Tampa, FL (US); Jan Andrejko, Land O'Lakes, FL (US); Yelina Cordill, Tampa, FL (US)

(73) Assignee: The United States of America as Represented by The Department of Veterans Affairs, Washington, DC (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 154 days.

(21) Appl. No.: 14/180,988

(22) Filed: Feb. 14, 2014

(65) Prior Publication Data
US 2014/0232701 A1 Aug. 21, 2014

Related U.S. Application Data
(60) Provisional application No. 61/765,532, filed on Feb. 15, 2013.

(51) Int. Cl.
G06F 3/0354 (2013.01)
A61F 4/00 (2006.01)
G06F 3/039 (2013.01)

(52) U.S. Cl.
CPC G06F 3/03545 (2013.01); A61F 4/00 (2013.01); G06F 3/039 (2013.01)

(58) Field of Classification Search
CPC G06F 3/03545
See application file for complete search history.

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(Continued)

Primary Examiner — Claire X Pappas
Assistant Examiner — Robert Stone
(74) Attorney, Agent, or Firm — Procopio, Cory, Hargreaves & Savitch LLP; Patric J. Rawlins

(57) ABSTRACT

An extendable stylus operated with a mouth, the stylus having an extending portion configured to have an adjustable length, a conductive tip that can interface with a touch screen device, the conductive tip located at a first end of the extending portion, a mouthpiece that engages the mouth of a user, wherein the mouthpiece is located at a second end of the extending portion, opposite the first end and a control mechanism disposed at or near the second end of the extending portion, wherein the control mechanism is configured to control the length of the extending portion based on an operation by the mouth of the user.

19 Claims, 11 Drawing Sheets

Marketing

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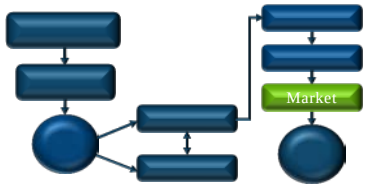
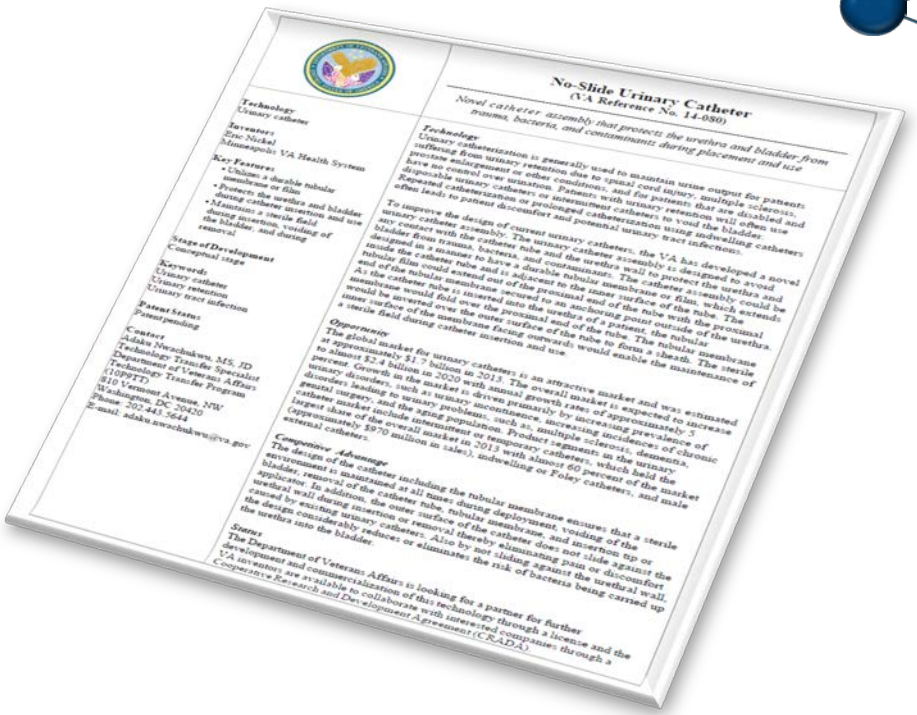
- Passive
  - Posted to Web site
- Marketing Briefs
- Active Marketing
- Media Outlets
- Inventor Suggestions





No-Slide Urinary Catheter
(VA Reference No. 14-080)

Novel catheter assembly that protects the urethra and bladder from trauma, bacteria, and contaminants during placement and use

Technology
Urinary catheter

Inventors
Eric Nickel
Minneapolis VA Health System

Key Features
- Utilizes a durable tubular membrane or film
- Protects the urethra and bladder during catheter insertion and use
- Maintains a sterile field during insertion, voiding of the bladder, and during removal

Stage of Development
Conceptual stage

Keywords
Urinary catheter
Urinary retention
Urinary tract infection

Patent Status
Patent pending

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Technology
Urinary catheterization is generally used to maintain urine output for patients suffering from urinary retention due to spinal cord injury, multiple sclerosis, prostate enlargement or other conditions, and for patients that are disabled and have no control over urination. Patients with urinary retention will often use disposable urinary catheters or intermittent catheterization to void the bladder. Repeated urinary catheterization or prolonged catheters to void the bladder often lead to patient discomfort and potential urinary tract infections.

To improve the design of current urinary catheters, the VA has developed a novel urinary catheter assembly. The urinary catheter assembly is designed to protect the urethra and bladder from trauma, bacteria, and contaminants. The catheter assembly could be designed in a manner to have a durable tubular membrane or film, which extends inside the catheter tube and is adjacent to the inner surface of the tube. The tubular film could extend out of the proximal end of a patient, the tubular membrane would be inverted into the urethra of a patient, the tubular membrane would be inverted over the proximal end of the tube. The tubular membrane would fold or inverted secured to an anchoring point outside the proximal end of the tube with the proximal end of the tube to form a sheath. The sterile inner surface of the membrane facing outwards would enable the maintenance of a sterile field during catheter insertion and use.

Opportunity
The global market for urinary catheters is an attractive market and was estimated at approximately $1.7 billion in 2013. The overall market is expected to increase to almost $2.4 billion in 2020 with annual growth rates of approximately 5 percent. Growth in the market is driven primarily by increasing prevalence of urinary disorder, such as urinary incontinence, increasing prevalence of chronic genital injury, and the aging population, such as, multiple sclerosis, dementia, catheter injury, and the aging population. Product segment is the urinary largest share of the overall market in 2013 with almost 60 percent of the market (approximately $970 million in sales), indwelling or Foley catheters, and male external catheters.

Competitive Advantage
The design of the catheter including the tubular membrane ensures that a sterile environment is maintained at all times during deployment, voiding of the bladder, removal of the catheter tube, tubular membrane, and insertion tip or applicator. In addition, the outer surface of the membrane, the catheter does not slide against the urethral wall. Also by not sliding against the urethral wall, caused by sliding urinary catheter or removal thereby eliminating pain or discomfort the design considerably reduces or eliminates the risk of bacteria being carried up the urethra into the bladder.

Status
The Department of Veterans Affairs is looking for a partner for further development and commercialization of this technology through a license and the VA inventors are available to collaborate with interested companies through a Cooperative Research and Development Agreement (CRADA).

Marketing Report

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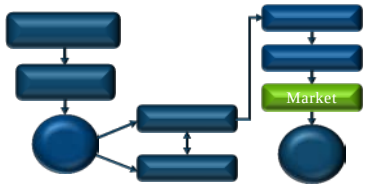
Active Marketing



Company	Contact	Action	Response After Review	Response After Review of Confidential Information
Adroit Medical Systems 1146 Carding Machine Rd. Loudon, TN 37774 http://www.adroitmedical.com /company-description.php	Gene Gammons President Phone: 1-800-267-6077 Email: geneadroit@aol.com	2/27/13 – Called and spoke with G. Gammons. He is interested and would like to see the NCD. Introductory e-mail and NCD were sent. 3/13/13 – Sent follow up e- mail to G. Gammons. Received reply, "Yes , I would be interested in reviewing your device, As you may or may not know, This technology is what my life has been dedicated to manage Hypo/Hyperthermia, The art of heating and Cooling patients." Replied asking if the information had been received on the 27th. Also explained that the technology was intended to be used for the management of hypo/hyperthermia. Received second e-mail reply to my original message, "Yes I would be very interested in discussing your device"	3/14/13 – Called and spoke with Gene. He is interested in speaking with the inventors and would be happy to sign an NDA. TreMonti will arrange the call and coordinate any necessary paperwork. 3/18/13–E-mailed G. Gammons requesting contact information at Adroit in order to move forward with the NDA. 4/9/13 – Resent NCD to G. Gammons. 4/23/13 – Followed up with G. Gammons regarding interest.	

Licensing

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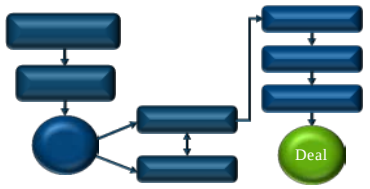

- To Further Commercialize
- Application Process is Codified (37 CFR 404)
  - Commercial Development Plan
- Negotiate an exclusive, partially exclusive, or nonexclusive license agreement
  - Fees
  - Royalties
  - Reimbursement of Costs

No Inventor Involvement During Financial Negotiations

Royalty Distribution

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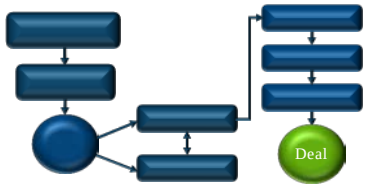

- First $2,000 to each inventor, then:
- 50% to inventor(s)
- 50% to VAMC where invention was made

Contact

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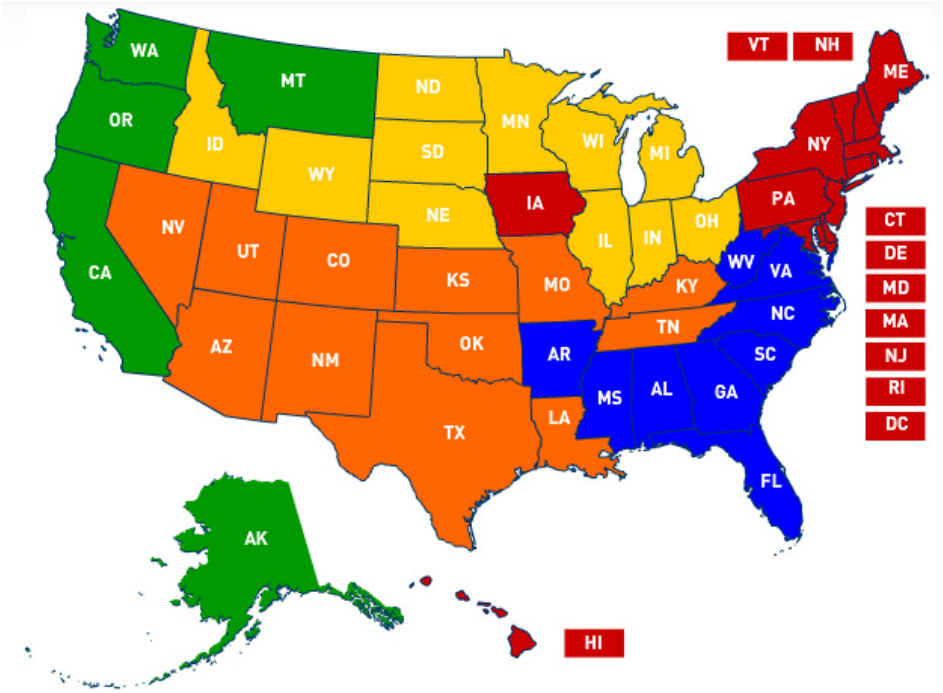

Helpful Links

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- Intranet: http://vaww.research.va.gov/programs/tech_transfer/
- Internet: http://www.research.va.gov/programs/tech_transfer/
- VHA Directive 1200.18

Questions & Answers

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Thank you!