



**NEW DIRECTIONS**  
**Technology Consulting**

Innovation  
in Healthcare

**CONNECTED  
COMBINATION  
PRODUCTS**

**BREAKING  
NEWS**



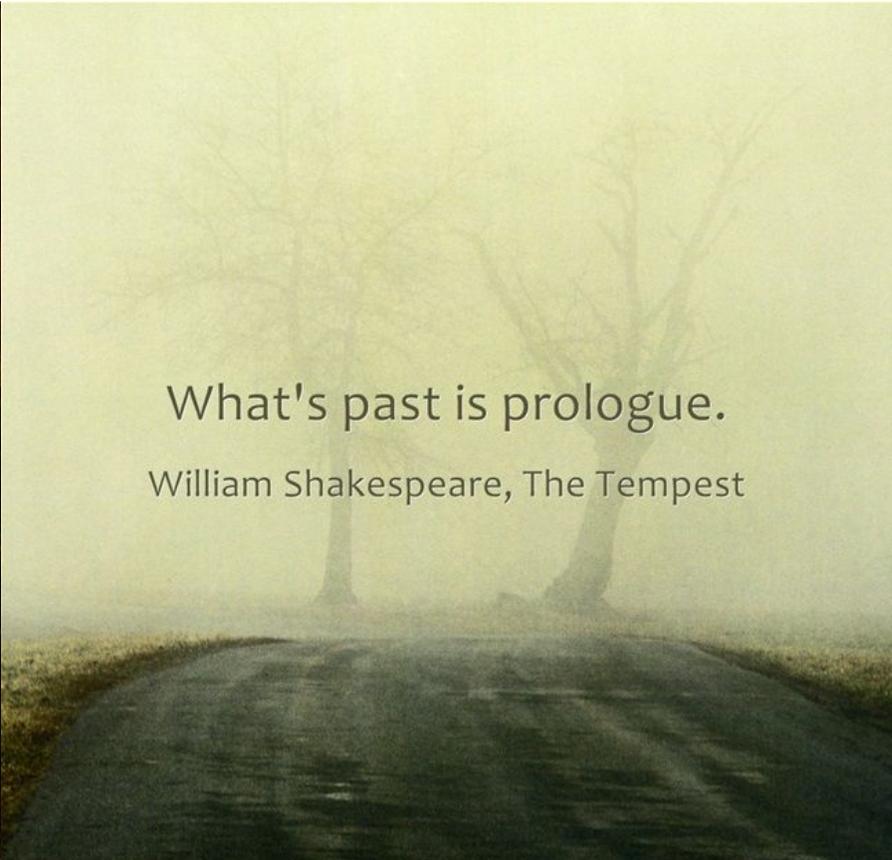
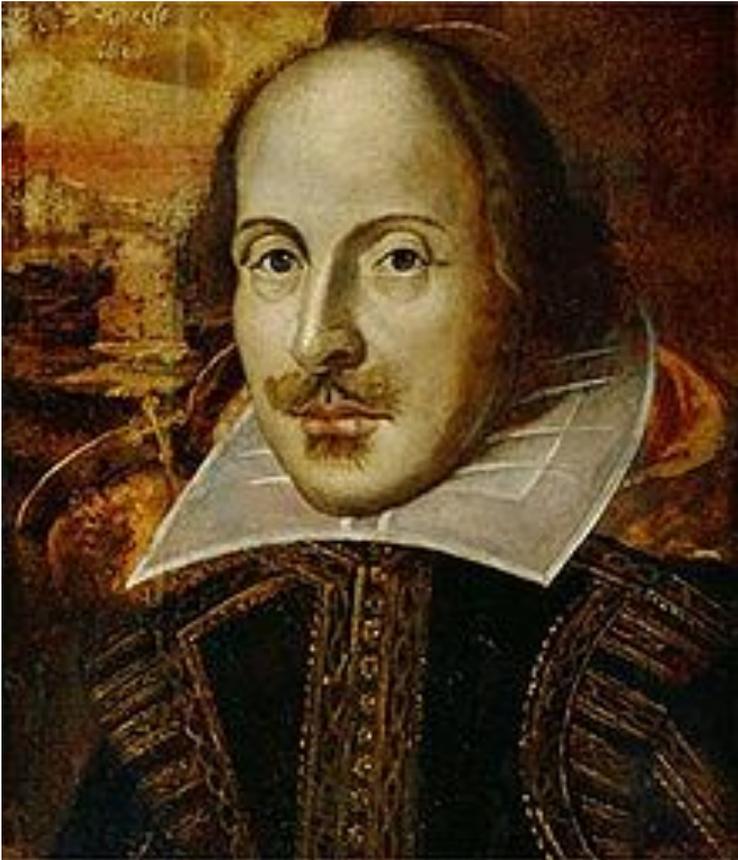
**Drug Development Partnerships 2018**

January 22-24, 2018

# Presenter Intro

- Pharma and medical device industry executive, helping to develop self-injection devices; including the original EpiPen and nerve agent antidote delivery systems.
- Inventor of commercially successful products to improve patient outcomes.
- A former employer, filed and was subsequently granted 7 patents essential to drug delivery telemanagement. These are known as the mMed Patent Portfolio, with the patents based on presenter's inventions. Priority dates are 2006.
- New Directions Technology Consulting LLC (New Directions), was contracted to monetize the mMed Patent Portfolio.
- I've had the good fortune to work with many creative, trusted partners and colleagues.
- I AM NOT A LAWYER. Also, not a regulatory expert. I'm sure you all have your own good counsel.
- Any opinions I state are my own.

# Development of Connected Combination Products

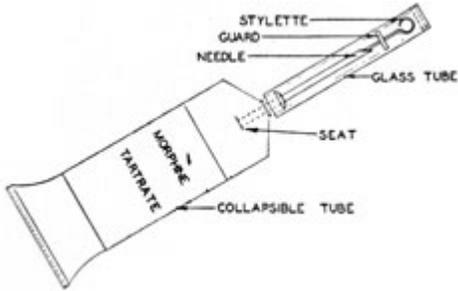


# Drug Delivery Platforms

## *Some Success Factors*

- **Identified needs**
  - Improving adherence and outcomes, reducing healthcare costs
- **Enablers**
  - Smartphones, sensors, data capabilities, biotech revolution, device/system development & other applicable
- **Defined task**
- **Trusted, ethical partners**
- **Creativity, support and good advice (business, legal, regulatory)**
- **Timing**
- **Persistence, adaptivity**
- **Appropriate agreements, adequate rewards, acceptable risks**
- **IP to add and maintain value**
- **Other?**

# Defined Task - Improvements over Syrettes



  
**MERIDIAN** Columbia, MD 21046, U.S.A. 0001280  
 MEDICAL TECHNOLOGISTS - A subsidiary of King Pharmaceuticals<sup>®</sup>, Inc.  
 Store at 25° C (77° F); Excursions permitted to 15 - 30° C (59 - 86° F). Rx Only  
 [See USP Controlled Room Temperature]. Avoid freezing.

**MORPHINE SULFATE INJECTION, 10 mg** **CII**

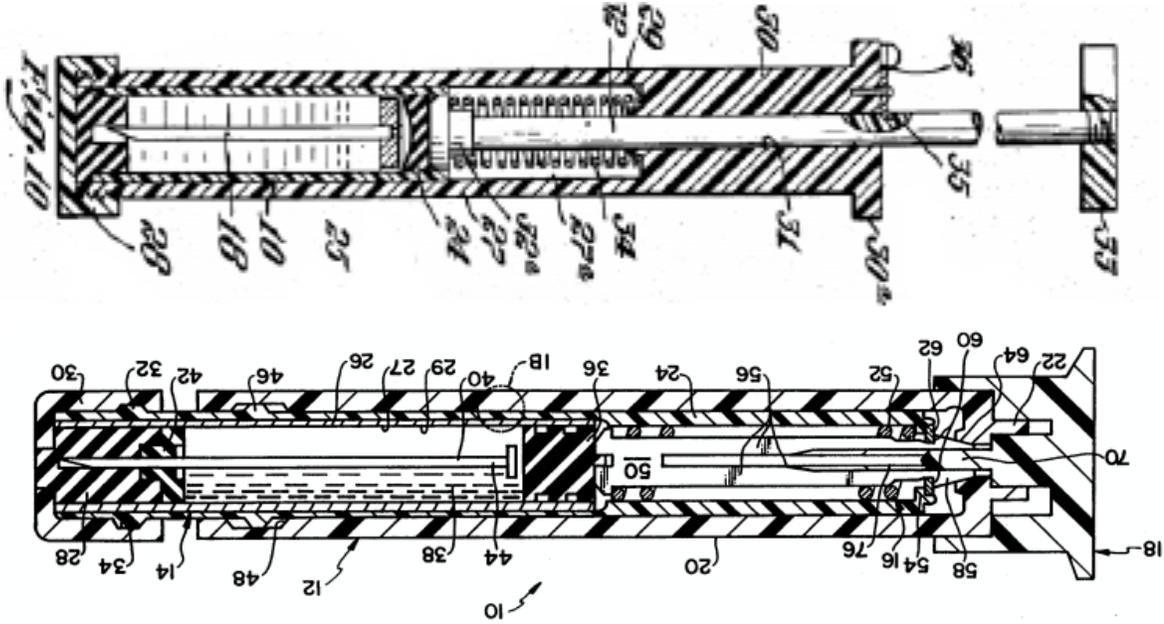
**1 REMOVE RED SAFETY CAP**  
**2 PLACE PURPLE END ON OUTER THIGH AND PUSH FIRMLY**

**MORPHINE AUTO-INJECTOR**

3 NDC 11704 23501 9  


NSN 6505-01-302-5530

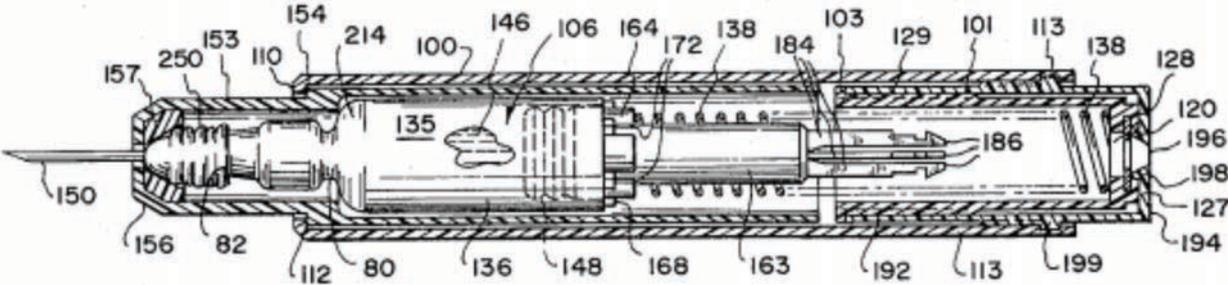
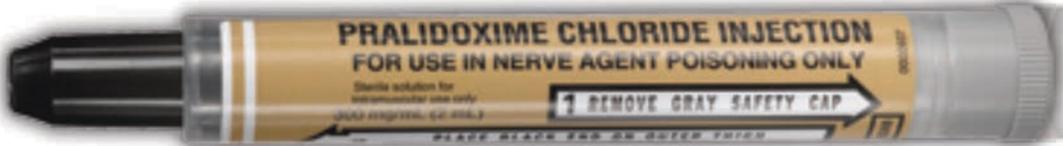
# Autoinjectors/Atropen Platform



Sarnoff **1955** '072 Means for Hypodermic Injector

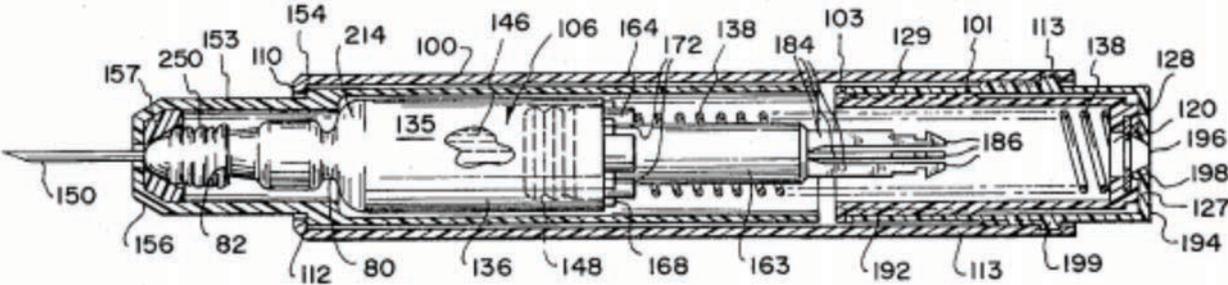
Monroe, Mesa et. al. 1994 '286 Polyparaxylene coated container

# Autoinjectors/ComboPen Platform and EpiPens



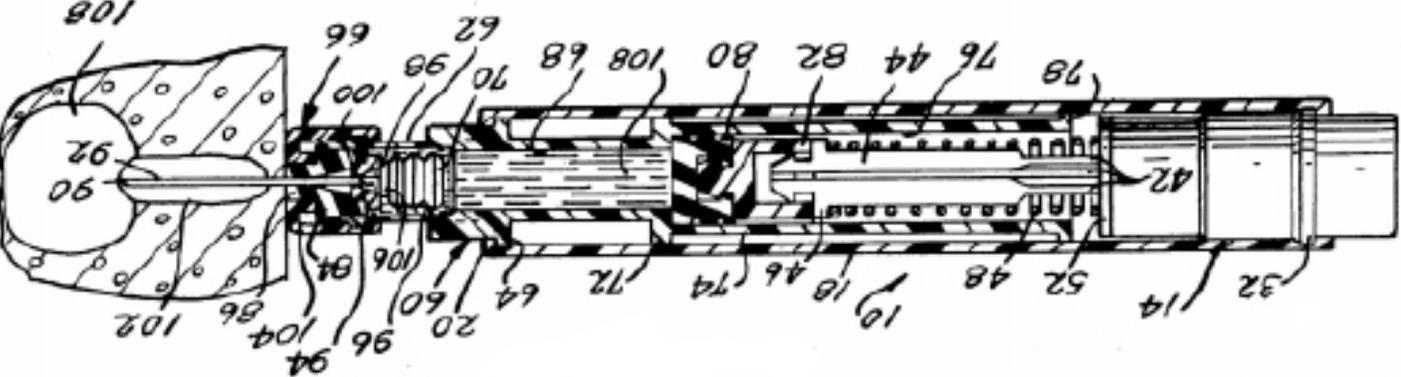
*Sarnoff and Calkins 1975 '863 Hypodermic having cannula covered with resilient sheath*

# Autoinjectors/ComboPen Platform-Anticonvulsant



*Sarnoff and Calkins 1975 '863  
Hypodermic having cannula  
covered with resilient sheath*

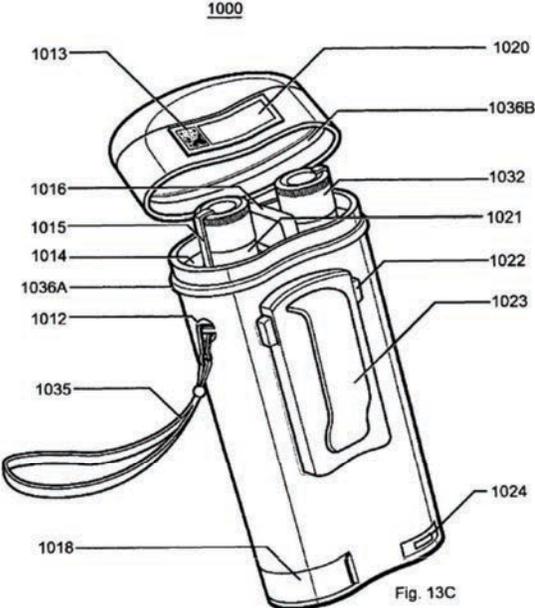
# Autoinjectors/Antidote Treatment Nerve Agent *Combines multiple platforms*



Monroe, Dalling, Mesa 1992  
'843 Dispersion  
multichamber autoinjector

# Case with Reporting Ability

## Another platform



*Monroe 2011 '778  
Injection device and  
case with reporting  
ability*

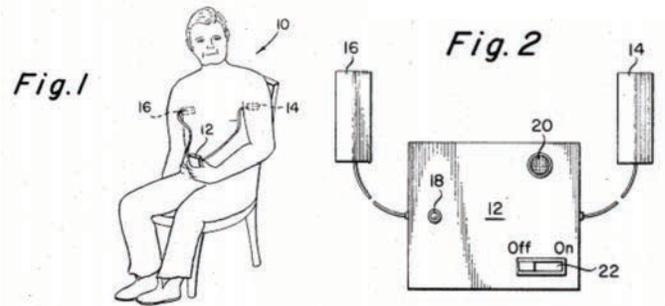
# Cardiac Diagnostics



## KardiaMobile and KardiaBand

KardiaMobile is well known. In December 2017, U.S. FDA cleared AliveCor's KardiaBand, a watch band accessory for the Apple Watch. This is the first medical device accessory for the Apple Watch.

Dave Albert, who founded AliveCor, credits his early inspiration to a conversation at Dr. Stan Sarnoff's home tennis court. Dr. Albert calls Stan "the grandfather of remote cardiac monitoring."



*Sarnoff and Reinhold 1974 '700 Monitoring Electrical Activity of the Heart*

# Other Connected Biopharma Delivery and Related Diagnostic Products

Recently cleared by FDA



## Asthma Treatment:

Adherium's SmartTouch for AZ Symbicort inhaler [510(k)]

**Multiple Sclerosis Treatment:** Bayer's BETACONNECT system



# Other Connected Biopharma Delivery and Related Diagnostic Products (cont'd.)

## Recently cleared by FDA

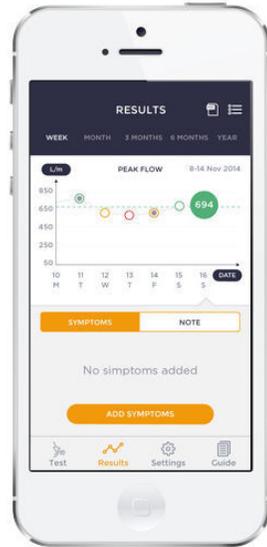


**Glucose monitoring systems:** clearance of several connected systems, Tandem t:slim X2 (shown), Ascensia's CONTOUR NEXT ONE, Smart Meter's iGlucose & Abbott's FreeStyle Libre



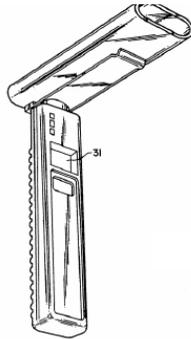
**Antipsychotic drug:**  
Otsuka & Proteus  
Abilify

# Respiratory Diagnostics



**MIR Smartone Peak Flow and FEV1 Monitor (*shown*) and others.**

To assist those with asthma and COPD



*Reinhold, Valentine and Monroe. 1993 '851 Specialized Peak Flow Meter*

# Drug Delivery by Inhalation

- The inhalation segment of the Pharma industry is growing.
- The expiration of GSK's patent on Advair is encouraging new product entrants to treat asthma and COPD. Both are significant populations.
- There is significant work on inhaled small molecule treatment of pain, migraine, opioid overdose and some cardiac conditions. Work continues on inhaled large molecule (insulin) treatments.
- Inhalation is technique sensitive. Managing the related human factors is difficult.
- The rise of connected inhalation devices is leading to new partnerships.
- Inhalation magazine, now in its 12th year, continues to grow and will be expanding its educational Webinar program in 2018.



# Combination Product Connectivity

## *A platform*



### Potential System Elements

Capabilities for communications of medication and related data through a smartphone or other device with short-and long-range communications capabilities, and delivery of information to caregivers and/or a central monitoring facility operated by medical professionals.

1. Medication container with embedded sensors and AIDC capability
2. Communication device with integrated applications
3. Central facility

# mMed Patent Portfolio – A Platform for Connectivity



## **Monroe 2010 '085**

### **Product Information Management System:**

Method of processing product-related shipment and usage information after the product has been distributed. This allows a flow of information to and from patients. Claims use of a “product tag,” such as a barcode.

## **Monroe 2011 '393**

### **Injection Device with Reporting Ability:**

Means for showing that a drug-containing injector is not being carried by the designated person.

## **Monroe 2011 '778**

### **Injection Device and Case with Reporting Ability:**

Means for including one or multiple medications and dosage forms in cases and communicating added information.

# mMed Patent Portfolio – A Platform for Connectivity (*cont'd.*)

## Monroe 2012 '111 and '658

### Central Facility that Communicates with Portable Container via Mobile Device:

A central monitoring facility staffed with medical professionals can facilitate medical treatment. FDA does not regulate practice.

### Product Container for Use with Communications Device Capable of Long-Range and Short-Range Communications



# FDA Approvals for Complex Generics



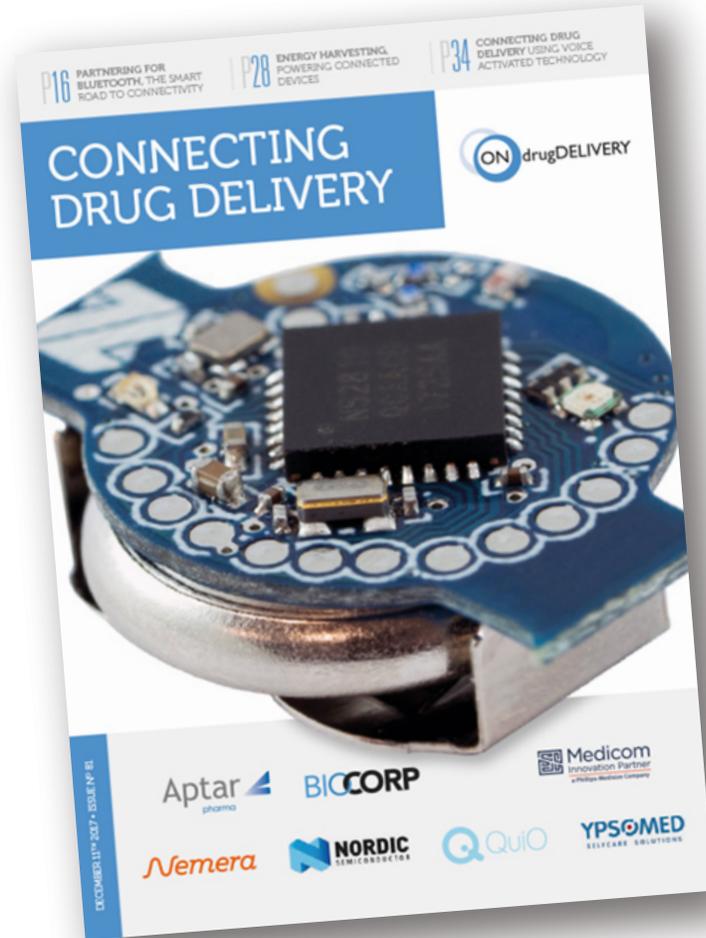
FDA Commissioner Gottlieb announced on Nov. 28, 2017 (Generic Drug Science Day) guidance on regulatory simplification. If it materializes, adding value through connectivity could well be easier and even more strategically important than ever.

## Some of Dr. Gottlieb's key points:

- The hurdles to FDA approval can be high for complex generics delivered through a device, such as a metered dose inhaler, or an autoinjector.
- The branded drug maker may still hold IP on certain features of the device, which can be hard to copy since patents protect key features.
- A generic competitor may propose a different device, which may raise scientific and regulatory questions as to same clinical effect and safety profile.

**Analysis: If a branded product has elected to provide connectivity to support the branded product, the generic might have to provide equivalent features (connectivity) to support the generic.**

# Connectivity



**ONdrugDELIVERY**, a DDP Media Sponsor, has historically been a leader in providing focused coverage of connectivity. ODD is now publishing **connectivity issues twice per year**. Our article, on page 42, reports on **connectivity highlights from two recent conferences**.



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# Serialization Articles

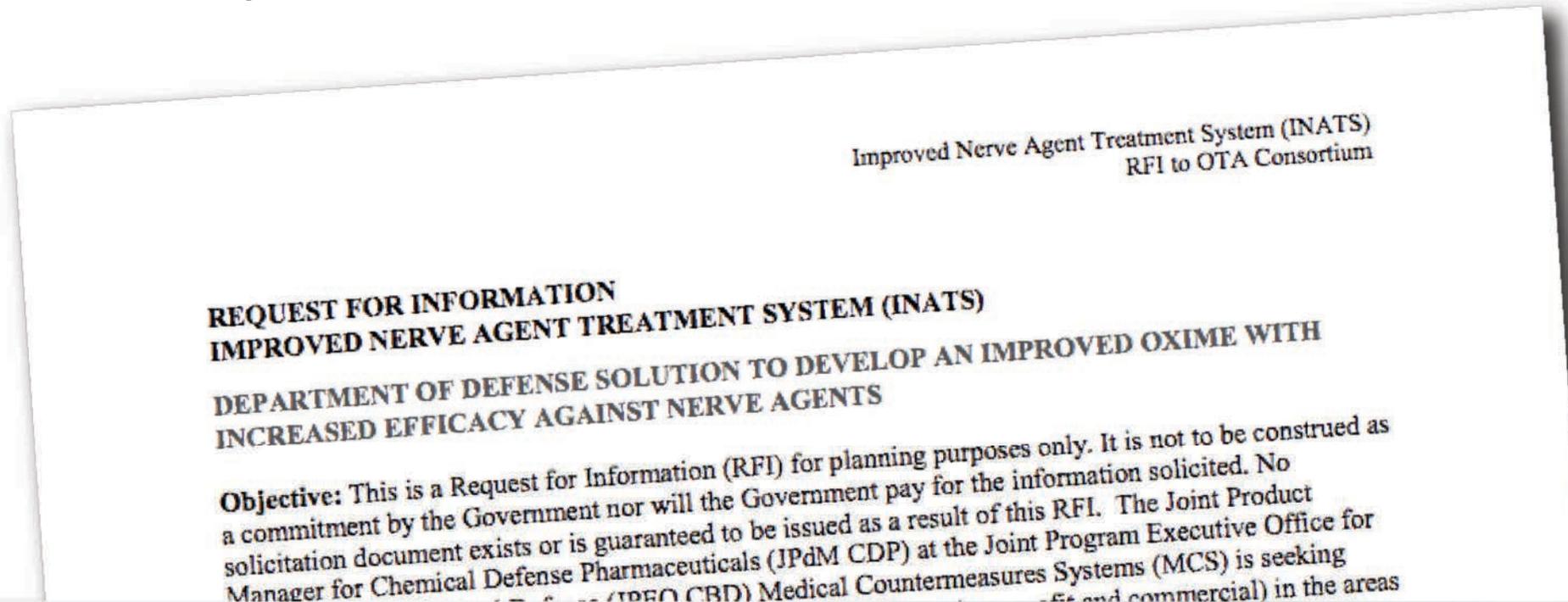


Two-part article showing the rationale and importance of serialization for combination products. October 2017/Web and December/January 2017/print.

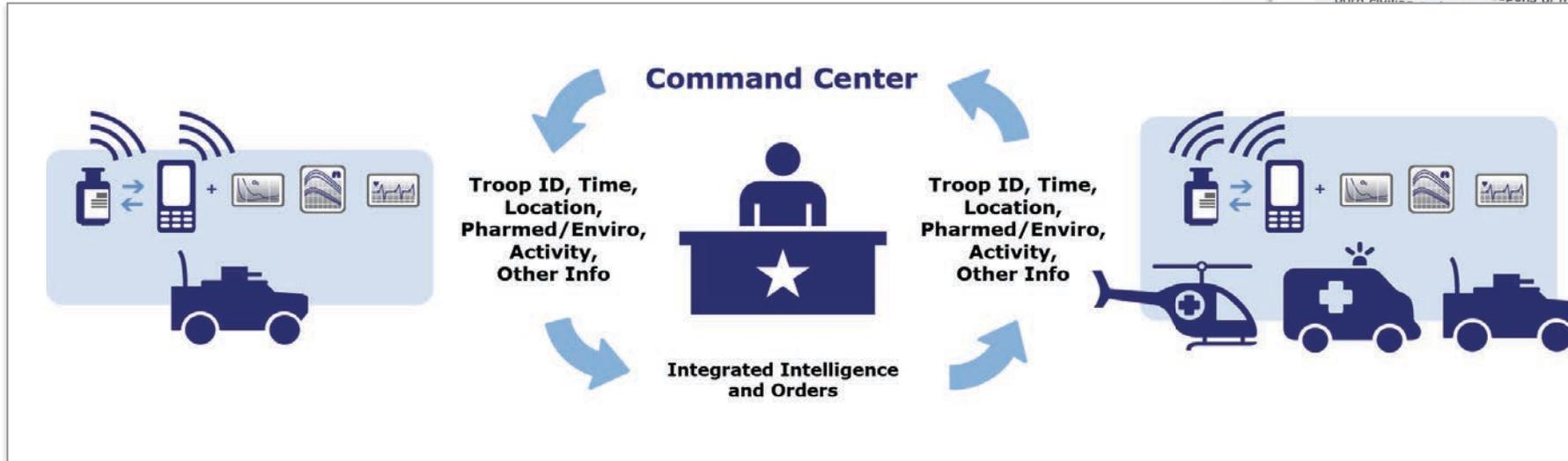
# Request for Information

## Improved Nerve Agent Treatment System (INATS)

Joint Product and Executive Managers for chemical countermeasures issued a request for information. Responses were due Dec. 1, 2017. Connectivity should be considered.



# Improved Threat Responses



**New Directions**  
Technology Consulting, LLC

**mMed™ Patent Portfolio**  
for mobile medication management

Licensing exclusively through New Directions Technology Consulting, LLC

### Improve Threat Responses and Casualty Outcomes Using Pharmacomedical Telemanagement

**BENEFITS:**

- Response plans that include real-time pharmacomedical telemanagement can improve casualty care and outcomes, while lowering risks and reducing costs:
- Monitoring of drug location, operability, storage, use, misuse and non-use; specifics about each use and expiration info based on cumulative temperature exposure; automatic replacement of used or expired product
- Assistance and instruction, and informed intervention that avoids unnecessary, disabling treatments
- Better pharmaceutical resource management. (Many emergency pharma treatments are injectables, which often require environmental control. Some are subject to diversion and abuse.)
- Better management of human factors, REMS and CAPA, as well as better clinical study management and faster regulatory approvals
- Pharma data collection for integration with other healthcare-related information, entry into electronic medical records and population health analyses
- Improved communications and relationships between and among stakeholders, as well as improved real-time and perceived readiness, reducing stress and improving quality of life and performance

The United States, NATO and others have awakened to the chemical, biological, radiological, nuclear, explosives (CBRNE), threats, threats from weapons of mass destruction (WMDs) to threats come from their surrogates, and paint an alarming picture of the threats from extremists to WMDs. WMDs are sometimes essential. WMDs are essential. WMDs are essential.

Emergency medical require even more devices and equipment\* are as fatal. Without medical intervention, use.

mission-critical operations, the need in remote locations, the U.S. w.

information and other

pharmacomedical and medical-resource logistics deployed in remote locations.

# Big Data and Economies of Scale

## Mergers and Acquisitions

Pharmacy buys insurer



Buying providers' practices



Pharma and distributors  
M&A



# New CDC Grand Rounds Report

“...nonadherence is associated with higher rates of hospital admissions, suboptimal health outcomes, increased morbidity and mortality, and increased health care costs.”

“Medication adherence is critical to improving chronic disease outcomes and reducing health care costs. Successful strategies to improve medication adherence include...use of health information technology tools to improve decision-making and communication during and after office visits.”

**Analysis: The “office visit” might be a telephonic MTM consult.**

The screenshot shows the CDC website interface for the Morbidity and Mortality Weekly Report (MMWR). The article title is "CDC Grand Rounds: Improving Medication Adherence for Chronic Disease Management — Innovations and Opportunities", dated November 17, 2017. The authors listed are Andrea B. Neiman, Todd Ruppap, Michael Ho, Larry Garber, Paul J. Weidle, Yuling Hong, Mary G. George, and Phoebe G. Thorpe. The article abstract discusses the association between medication adherence and clinical outcomes, noting that nonadherence leads to higher hospital admissions and costs. It also mentions that approximately one in five new prescriptions are never filled, and that direct health care costs associated with nonadherence have grown to approximately \$100-\$300 billion annually. The article is categorized under "Article Metrics" with 33 total views, including 1 news item, 1 blog, 25 tweets, and 2 Mendeley citations. The page also features a "View suggested citation" link and a "Metric Details" link.

“What's past is prologue”...Going Forward

**mMed Patent Portfolio  
licensed to**



# "What's past is prologue"...Going Forward

## Why Aterica?

- My trust in their ethics
- Our desire to work with practicing entities
- Aterica's commitment to product, vision and advancing quality of life through innovative digital health solutions, very much like my vision for the mMed platform
- Our ability to enable creative and meaningful solutions for patients through mMed patents and Aterica IP and product development expertise
- Our timing (external and internal developments)
- Aterica's willingness to contract appropriately



# Going Forward

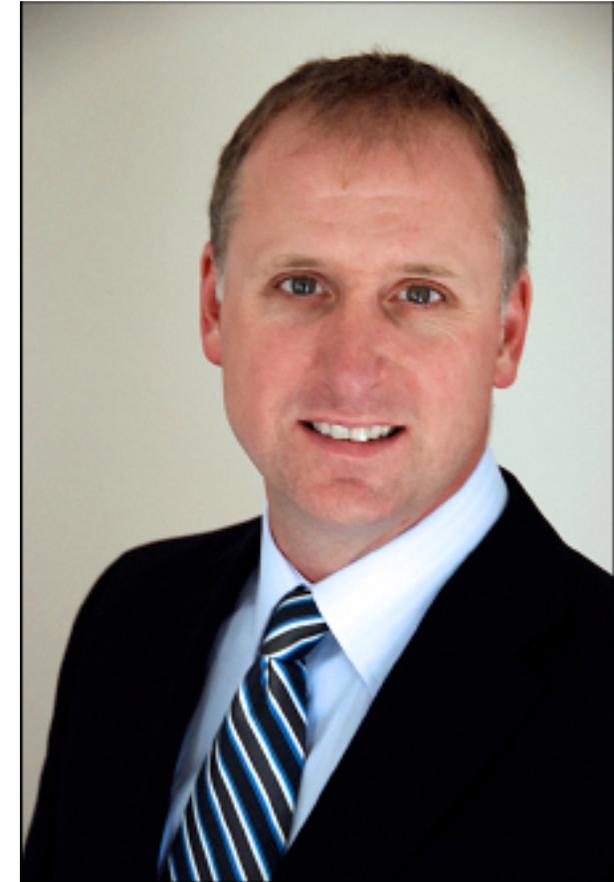


**Presenter: Mike Fisher**

*VP Marketing & Business Development  
Aterica Digital Health*

Entrepreneurs in Health Innovation

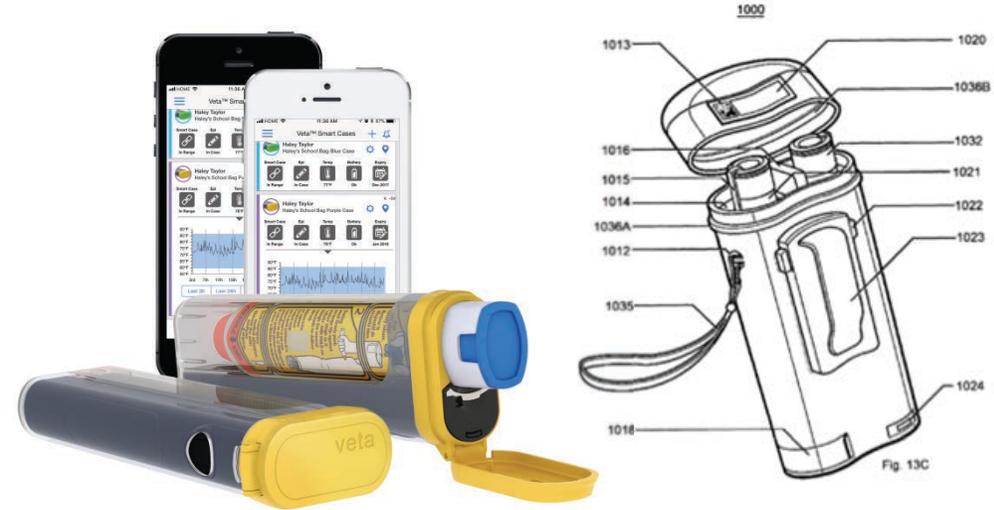
Offering design/build/sell partnerships  
leveraging our biomedical, mechanical, sw/  
fw/cloud & connected device expertise



# Going Forward



*“empowering individuals and families to actively manage their health on their own terms”*



- Creating solutions that people want to use every day
- Reaching individuals and families through DTC & B2B partnerships

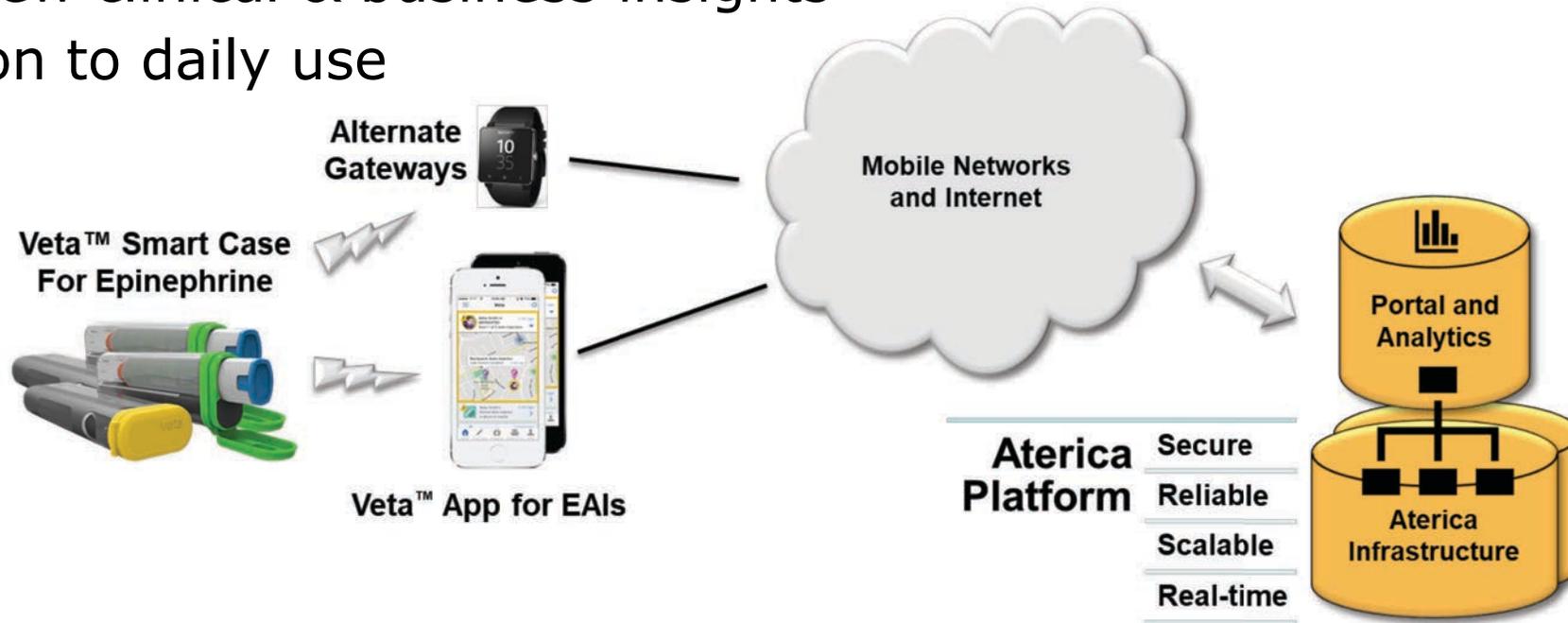
## Aterica Partnerships:

- Aterica's platforms brings life-changing solutions to market.
- Crafting unique partner solutions leveraging our design, engineering, and commercialization experience.
- Creative partnerships, including custom solutions and private label.
- Most flexible and fastest go-to-market strategy for our Pharma partners.

# Going Forward

## Platform Benefits:

- Creating inspiring, problem-solving products through connected devices
- Improving medication management, adherence, & brand affinity
- Delivering new clinical & business insights
- From ideation to daily use



# Questions?

**Information on Roles of Intellectual Property in biopharma management, links to studies, contacts and presentation attribution in following slides.**

# Thank You

## Contact for Consulting: Napoleon Monroe

Managing director, New Directions Technology Consulting, LLC

718-427-3038

[nap.monroe@newdirectionsconsulting.net](mailto:nap.monroe@newdirectionsconsulting.net)

mMed patent portfolio found at

[www.mmedhealth.com](http://www.mmedhealth.com)

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PRODUCTS

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**Thank You**



## **Contact for Partnerships & Licensing: Mike Fisher**

**VP Marketing & Business Development, Aterica Digital Health**

**855-476-1390 x205**

**[mfisher@aterica.com](mailto:mfisher@aterica.com)**

**Aterica's Website:**

**[www.aterica.com](http://www.aterica.com)**



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# Roles of Connectivity IP

- **Freedom to operate.**
- **Bolster ongoing value** in rapidly changing environments.
- **Extend product life and reach.**
- **Revenue growth potential** from new products/services, and from sale/licensing of rights.
- **Enhanced ability to license/cross license/exclude**, as in other industries.

## Roles of Connectivity IP (cont'd.)

- **Channel control** possibilities.
- **Avoidance of costs** of litigation/settlement with other IP owners.
- Possible **tax advantages**. Foreign and potential future domestic.
- Added **incentives to partner**.
- **Improved stakeholder relations**.

## Roles of Connectivity IP (cont'd.)

- Licenses/acquisitions may be capitalized. Previous costs were likely expensed.
- Economies of scale when extending use to other products, acquisitions.
- IP assets can be used as collateral.
- A platform to encourage **internal creativity** inventions and synergies within existing businesses.
- **Builds a reputation** for **management strength, longer-term vision, culture** that fosters intrapreneurship and innovation.
- **Synergies** among benefits.