



## mMed™ Patent Portfolio for mobile medication management

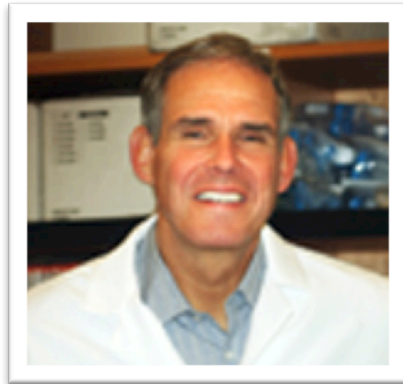
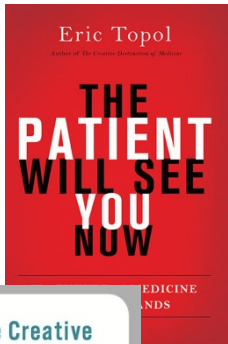
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# The Roles of Connected Combination Products in the Creative Reconstruction of Pharma

*Presented Feb. 7, 2017,  
by Napoleon Monroe at*





Director, Scripps  
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*[Improvements in adherence are] especially noteworthy because only half of patients demonstrate adherence to prescriptions, and **this problem represents an important, if not the most important, reason for failure of management of chronic diseases.***

– Dr. Eric Topol,\* The Patient Will See You Now, p.128

\*Thanks to Dr. Eric Topol for inspiring our title today.



# Intro to Presenter



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- Pharma-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.
- Former employer, Henry Schein, filed and was subsequently granted 7 patents essential to drug delivery telemanagement. These are known as the mMed Patent Portfolio, with all patents based on my inventions. Priority dates are 2006.
- Later, founded New Directions Technology Consulting LLC (New Directions), which was contracted by Henry Schein, the patent assignee, to monetize the mMed Patent Portfolio.

# New Research Reports

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## Increasing cost/loss estimates

- The Express Scripts 2015 Drug Trend Report updates the estimated U.S. cost of medication non-adherence to \$337B/yr., up from the customarily cited \$290B/yr. This increased amount still does not capture all societal costs.
- The November 2016 CapGemini/HealthPrize Technologies report raises estimated global pharma revenue losses due to non-adherence to \$637B, up from \$564B in 2012.

# New Research Reports (cont'd)



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## Advertising and investing

- A Wharton expert's research shows Pharma's direct-to-consumer (DTC) ads:
    - Work better for "initiates," who, however, on average, are less compliant with treatment
    - Expand utilization for entire classes of drugs
    - What about the implications in a value-based, real world evidence (RWE) environment? Service and the value of DTC ads.
  - A Wharton expert's research shows Pharma's direct-to-consumer (DTC) ads:
    - Work better for "initiates," who, however, on average, are less compliant with treatment
    - Expand utilization for entire classes of drugs
- Markets and Markets, and nearly \$200M was invested in related startups last year.



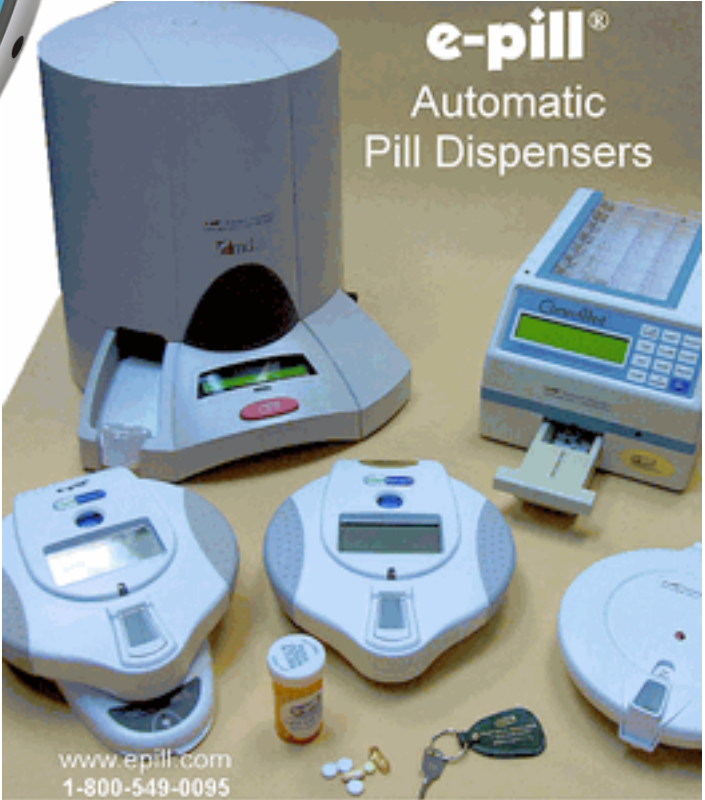
- **Biotech Feels the Wrath of Trump** Health-care investors got an ugly preview...
- **Trump Assails Drug Industry, Prices** Donald Trump attacked the pharmaceutical industry in his first news conference as president-elect...
- **Big Pharma Sales Need Booster Shot** It will take more than the election passing by to bring the good old days back...
- **Big Pharma: 'Take Your Medicine'** It may be time for big pharma to revisit an old, familiar problem: helping patients adhere to prescription drug regimens.



# Internet-connected Biopharma Delivery Products

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# Internet-connected Biopharma Delivery Products (cont'd)

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# Internet-connected Biopharma Delivery Products (*cont'd*)

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- Connected dispenser products have been developed for many dosage forms.
- **Specialty focus. Fragile, expensive, parenterals.**
- **Service becoming part of biopharma product value.**
- Waves of partnering, including investments in IP, services and devices.
- Many different design approaches.
- Expect many more wearables, **including pumps and patches. Telemanagement to guide placement, refill and use** through a smartphone. **Also “carryables.”**

# Internet-connected Biopharma Delivery Products (*cont'd*)

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## Many regulatory approaches in the universe of delivery systems

- Non-medical-device consumer products
- Class 510(k) exempt Medical Device Data Systems
- 510(k) FDA-cleared apps
- 510(k) connected dispensers
- Approved pharma products dispensed in connected systems
- Connected combination products
- Other possibilities? Accessories? New device *guidance*

# Growing Awareness

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- **DDP attendance growth 12% YoY.**
- **Parenteral Drug Association:** “Universe” connected product focus. Combination Products interest group.
- **Industry research.**
- **Coalitions:** e.g., Prescriptions for a Healthy America, Health IT Now.
- Pharma evening-news sponsorships.
- **FDA** human factors concerns guidances and postmarket Sentinals program.
- **EpiPen** and other pricing controversies.
- **Payment for outcomes.**

# Known Unknowns



## Major changes in policy



Many speculate that the Trump Administration and the 115th Congress could be very aggressive in support of cost-saving healthcare innovations. If this proves true, adding value through medication telemanagement could well be even more strategically important than ever to all stakeholders.

# Various Roles For Connectivity

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## Connectivity can provide

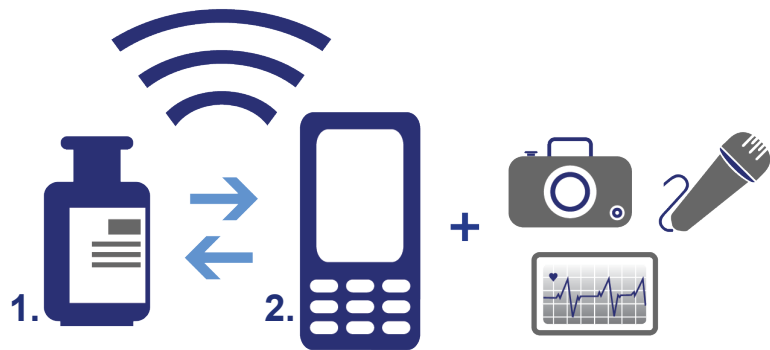
- **Improved outcomes** through enhanced compliance.
- **Information** to meet requirements for real world evidence (RWE), demonstration of product value.
- **A “sentinal”** to learn direct information from patients to enable improved service, CAPA, clinical trial completion.
- **Understanding of human factors.**
- **Product loyalty.**
- **Added value** to biopharma products.
- **Reduced overall costs** for many stakeholders.



# Telemanagement IP Possibilities

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## Potential System Elements

Capabilities for communications of medication telemanagement 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. A medication container with embedded sensors and AIDC capability
2. Communication device with integrated applications

# What Some Are Saying About Connected Health

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## Practitioners/Pharma

- **We don't/can't get paid** for this.
- My **time is limited**, better spent diagnosing/marketing.
- I'm **already overwhelmed** and can't deal with innovations.
- I **can't be pinged** when a patient/customer fails to act or wants to chat.
- It's EMRs all over again. The systems **aren't built for our workflow.**
- How does all this fit into **HIPPA**? What about privacy?
- Hacking is all over the news. This has to be a **security threat.**
- I've seen **some of these toys**; they **are worthless.**
- Patients abandon **apps** because they **are a pain.**
- The **ACA is being repealed and...**

# Others Are Saying: 'This Is an Opportunity!'

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- CMS, hospitals (including ACOs), PBMs, payers (including 3rd-party admins), plan sponsors, wellness/PERS providers, community health centers, pharma companies, individuals, patient advocacy groups.
- Pharmacy chains: There are many of us, we're local, and are in regular contact with patients. Pharmacists can sell devices and our service to other stakeholders.
- We have an interest in -- and can be paid for -- medication therapy management.
- Healthcare as reimbursed is dysfunctional and such innovations as biopharma telemanagement are essential to improving the system.
- **We** should lead efforts.



# Questions?

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

# Roles of Telemanagement IP

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- **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 Telemanagement IP (*cont'd*)

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- **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 Telemanagement IP (*cont'd*)

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- 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.

# For More Information

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## Sources/links

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- **Rock Health:**  
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- **Modern Healthcare:**  
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- **MarketsandMarkets:**  
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- **Prescriptions for a Healthy America:**  
<http://adhereforhealth.org/>
- **Health IT Now:**  
<http://healthitnow.org/>

# Thank You



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**New Directions is the exclusive market developer for the MMed patent portfolio found at**

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

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