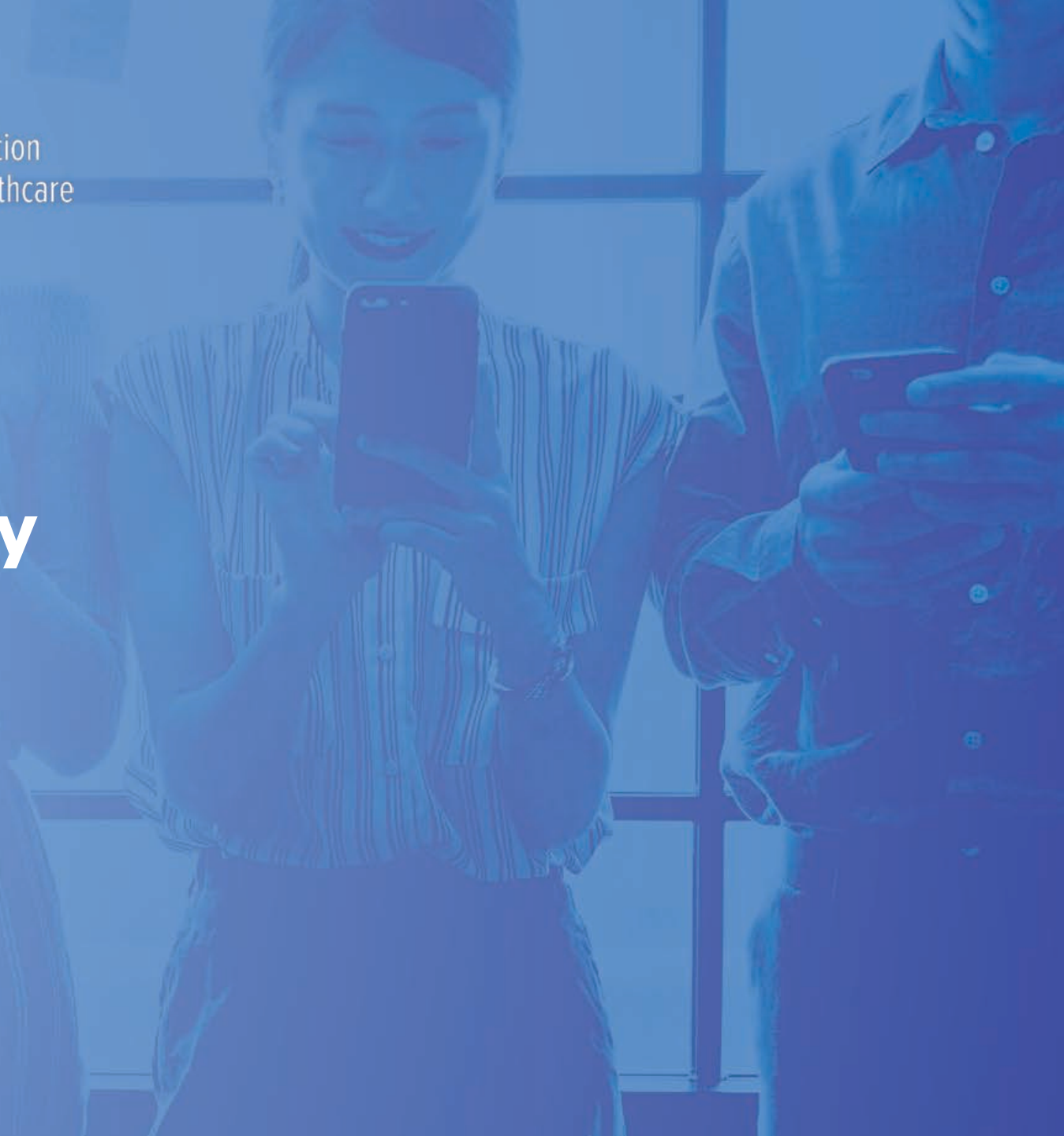
NEW DIRECTIONS
Technology Consulting
Innovation
in Healthcare

Connectivity Using Consumer Technology

To Create Real Value For Patients

BREAKING NEWS EDITION

Drug Development Partnerships
January 28, 2019



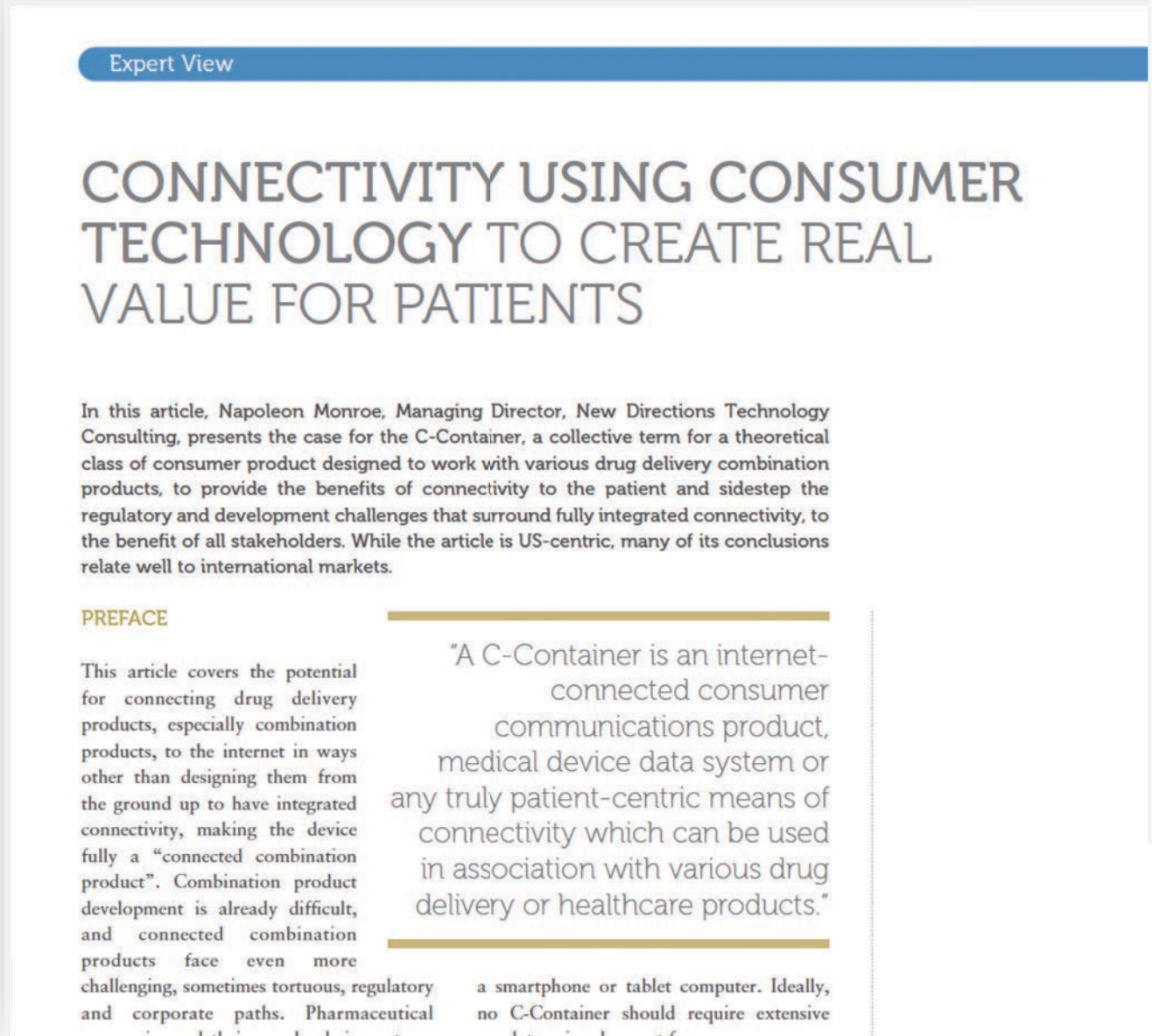
Introduction and Objective

Introduction: Napoleon Monroe

- Bio is in the OndrugDelivery article
- Connections to combination products and telemedicine
- Disclosure of IP interests
- More information and contacts at www.mmedhealth.com
- U.S. centric, but with international implications

Objective: To stimulate discussions of possibilities for connected medication delivery systems

ONdrugDELIVERY



Expert View

CONNECTIVITY USING CONSUMER TECHNOLOGY TO CREATE REAL VALUE FOR PATIENTS

In this article, Napoleon Monroe, Managing Director, New Directions Technology Consulting, presents the case for the C-Container, a collective term for a theoretical class of consumer product designed to work with various drug delivery combination products, to provide the benefits of connectivity to the patient and sidestep the regulatory and development challenges that surround fully integrated connectivity, to the benefit of all stakeholders. While the article is US-centric, many of its conclusions relate well to international markets.

PREFACE

This article covers the potential for connecting drug delivery products, especially combination products, to the internet in ways other than designing them from the ground up to have integrated connectivity, making the device fully a "connected combination product". Combination product development is already difficult, and connected combination products face even more challenging, sometimes tortuous, regulatory and corporate paths. Pharmaceutical

"A C-Container is an internet-connected consumer communications product, medical device data system or any truly patient-centric means of connectivity which can be used in association with various drug delivery or healthcare products."

a smartphone or tablet computer. Ideally, no C-Container should require extensive

- This presentation is largely based upon a pre-print of an article that appears in the February edition of ONdrugDELIVERY, the publication that best covers the field of drug delivery.
- An article in the publication's June *Connectivity* issue will cover some highlights of this conference.

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Drug Delivery-Institutional Centricity

- My previous view of drug delivery connectivity
- Institution-centric
- The person in the white coat could just as well be in a suit
- Still the predominant view of most stakeholders

Drug Delivery-Patient Centricity

- A new view of drug delivery connectivity
- Patient-centric
- Patient or parents/caregivers select how to distribute and manage information
- More specifics in the article
- Not without problems, but an alternative view

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Recent Events: Some Examples PDA (Article)

- **October 2018 Parenteral Drug Association (PDA) Universe of Pre-filled Syringes and Injection Devices conference**
  - Genentech's Paul Upham said, "Consumer behaviour is hard to change, so why not just give them what they need?"
    COMMENT: A blinding flash…of logical insight
  - He made the points that:
    - Almost nobody's apps have good retention
    - Failures of connectivity are due to not having a strong business reason
  - Paul Jansen, now on Hasselmeier BoD and always knowledgable, told of his personal experiences with connected combination products, discussed the criticality of the supply chain and briefed on a new standard under development

Another Recent Event (Article)

- **Oct. 31, 2018, Cambridge Design Partnership Webinar, Uri Baruch, head of Drug Delivery, made these points:**
  - Uri discussed the "unknown unknowns" of combination product development and manufacture. COMMENT: The managerial revolution has led to the proliferation of experts, all of whom are well trained but few of whom have personal experiences these areas. COMMENT: Pharma experts are generally not versed in the "unknown unknowns" of devices or consumer software
  - Smaller companies often fail because they do not have adequate resources. COMMENT: Many app developers and other small entrants have not demonstrated the market value of their work.

Speakers at PDA, other events and observing trends that impact drug delivery helped bring some thoughts together

Patients (Article)

- Patients do not particularly care about:
  - regulations;
  - Pharma, HCP or payer revenue or cost; or
  - HCPs' time

- Patients care far more about:
  - treatment availability;
  - quality;
  - expense; and, most important,
  - outcomes

Industry (Article)

- Pharma, HCPs, payers and others want to generate revenue and limit cost. All three talk about models for creating shared value
- Ultimately industry has to remain cost conscious and revenue driven. This slows innovation in patient-centric connected combination products
- Big companies are generally siloed
- The cultures of pharma and healthcare administrative practice are very cautious and slow-moving. Consumer culture is quick and agile
- Product lifecycles for pharma and device are typically looooong
- The lifecycle for a consumer software may be years for the brand, but with constant evolution and updates.

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Industry (Article)

- Industry is typically risk averse and short termist
- Product introductions are often highly time sensitive
- To speed drug approval, pharma may wish to exclude connectivity in filings to avoid becoming a connected combination product caught in a never-ending regulatory loops
- Consumer medication telemanagement software can be flexible
- Mergers, acquisitions, new entrants and new ideas in the pharma space are bringing new conflicts and disruptions

Regulators (Article)

- Regulators are mandated and expected to ensure safety and efficacy
- One way to stay out of trouble is to approve products in an extraordinarily cautious way, or not at all
- Regulatory issues go a long way towards explaining why Pharma cannot easily execute on the various business cases that advocate for a connected combination product
- Regulators may not move quickly
- Pharma regulators have difficulty dealing with combination products and even more difficulty dealing with the greater number of “what-ifs” associated with connected combination products
- There is good Breaking News

Data Security (Article)

Aggregated information from multiple sources on one patient is far less a target for theft or abuse than information on thousands of patients in a corporate database.

Still, always a concern.

The January 28, 2019, TIME magazine cover story, "I HELPED CREATE THIS MESS. HERE'S HOW TO FIX IT," by Roger McNamee, may be instructive.

Benefitting From Public Initiatives (Article)

- The US Department of Defense, the largest employer in the world and the inventor of military technologies that changed civilian life, is adopting consumer technologies
- Consumer tech boosts the performance and reduces the price of military equipment
- Public organizations have long led in healthcare due to their aims and structural needs.
- The potential (as yet not fully realized) benefits of EMRs and sensor-based medical products are examples of industry taking advantage of public initiatives
- The adoption of healthcare standards can be a positive for all stakeholders

Patients (Article) (Again)

- Patients do not particularly care about:
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Pharma Benefits from Patient Access to C-Containers (Article)

Beyond the benefits of C-Containers and their associated B-C-B model to patients, there are also benefits to Pharma, including:

- Separating the C-Container from the drug regulation can:
  - improve time to market;
  - reduce regulatory and product liability risks; and
  - eliminate the need for pre-launch regulatory approval (as long as regulators exercise regulatory discretion towards consumer products or affirmatively declare policies enabling their use)
- Multi-product platforms and personalized versions of products are more easily achieved with consumer products
- C-Containers can still enhance Pharma revenue stream and patient loyalty
- C-Containers can help ensure regimen compliance and even combination product reliability by having experts in patient needs and device manufacturers design them per requirements of patients and their devices

Pharma Benefits from Patient Access to C-Containers (Article)

- Approved digital therapeutics allow patients to self-diagnose, enabling home treatment. More are emerging, which will expand the potential appropriate use of C-Containers
- A C-Container can be designed, tested, documented as if it were a medical device to allow ongoing future development of more highly regulated medical devices with added claims
- Contracts can allow proper oversight of a C-Container by a Pharma company without it becoming a connected combination product
- Differentiated C-Containers can be platforms for multiple combinations

Summary

- Connecting combination products for drug delivery to the internet in ways other than fully integrated connected combination products can:
  - improve patient outcomes
  - provide benefits to other stakeholders
- C-Containers could be the tool to provide those benefits:
  - more quickly
  - more efficiently
- C-Containers can even help ensure that pharma products are:
  - safer
  - more effective

Questions?

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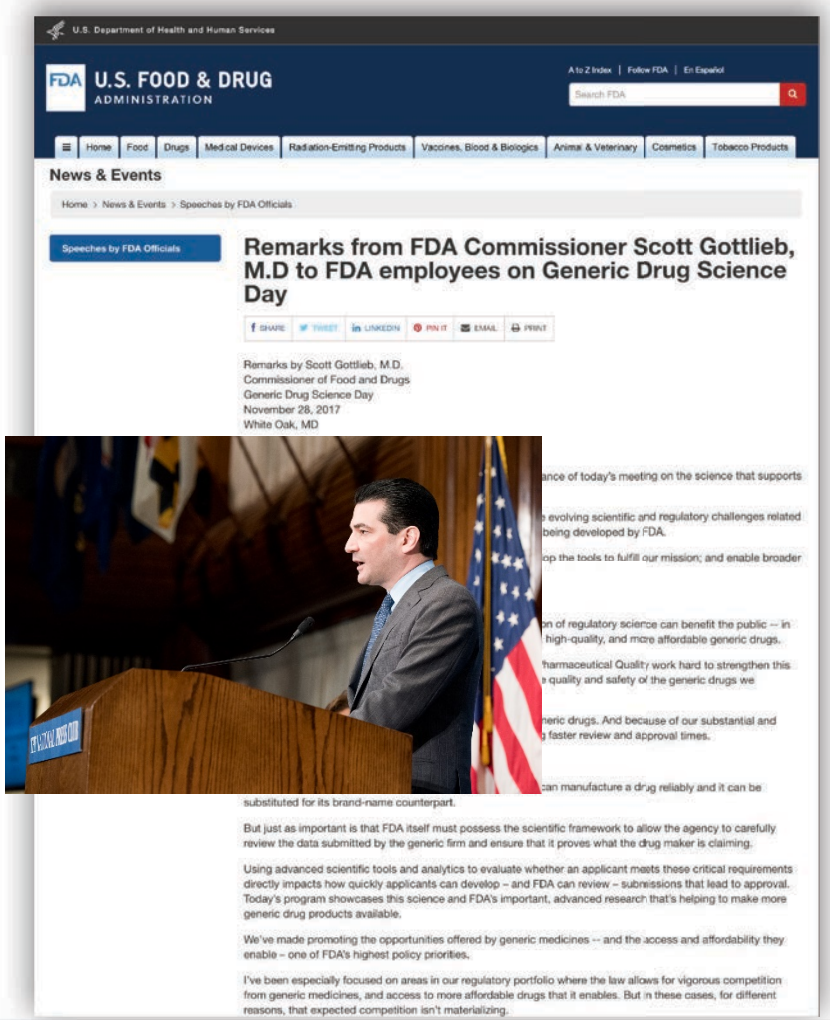
BREAKING NEWS

Drug Development Partnerships 2019

Regulatory Initiatives To Support Innovation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Speeches by FDA Officials

Remarks from FDA Commissioner Scott Gottlieb, M.D to FDA employees on Generic Drug Science Day

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Remarks by Scott Gottlieb, M.D.
Commissioner of Food and Drugs
Generic Drug Science Day
November 28, 2017
White Oak, MD

ance of today's meeting on the science that supports

evolving scientific and regulatory challenges related being developed by FDA.

op the tools to fulfill our mission; and enable broader

on of regulatory science can benefit the public -- in high-quality, and more affordable generic drugs.

harmaceutical Quality work hard to strengthen this quality and safety of the generic drugs we

neric drugs. And because of our substantial and faster review and approval times.

can manufacture a drug reliably and it can be substituted for its brand-name counterpart.

But just as important is that FDA itself must possess the scientific framework to allow the agency to carefully review the data submitted by the generic firm and ensure that it proves what the drug maker is claiming.

Using advanced scientific tools and analytics to evaluate whether an applicant meets these critical requirements directly impacts how quickly applicants can develop – and FDA can review – submissions that lead to approval. Today's program showcases this science and FDA's important, advanced research that's helping to make more generic drug products available.

We've made promoting the opportunities offered by generic medicines -- and the access and affordability they enable – one of FDA's highest policy priorities.

I've been especially focused on areas in our regulatory portfolio where the law allows for vigorous competition from generic medicines, and access to more affordable drugs that it enables. But in these cases, for different reasons, that expected competition isn't materializing.

The effects of last year's report are still BREAKING NEWS

- FDA Commissioner Gottlieb announced on Nov. 28, 2017 (Generic Drug Science Day) guidance on regulatory simplification. 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.
- COMMENT: Patients using and manufacturers of both branded and generic products can benefit from a C-Container companion product.

Regulatory Initiatives To Support Innovation

Recent FDA guidances and statements emphasize attempts to promote greater innovation in access to care and competition. As with any broad regulatory initiative, this will be fully defined over time. There appears to be significant Congressional support for these initiatives.

- November 2018 Pharmaceutical Technology Regulatory Watch: Washington Editor Jill Wechsler wrote in *FDA Promotes Complex Generics and Combination Products:* "FDA is …spurring development…" "…outlined by FDA Commissioner Scott Gottlieb in a statement…"
- The work of Health IT Now and Prescriptions for a Healthy America aligns well with support of innovation.

Political

In *The Wall Street Journal,* Jan. 10, 2019, "Collins Presses for Drug Rebate Fix," by Jared S. Hopkins, Sen. Susan Collins (R. Maine) said, "… the marketplace is failing here." "…the opacity of these financial interactions…distort the pharmaceutical market."

The HILL, Dec. 25, 2018, "2020 Dems go on offense over drug prices", by Peter Sullivan, "Potential 2020 Democratic presidential contenders are rolling out a slew of plans to lower prescription drug prices, highlighting the importance the issue will hold in the coming campaigns."

COMMENT: Stakeholders, including politicians on both sides of the aisle, are pressing for lower drug costs. **Why not use connectivity to improve the value of drugs to patients?**

Industry - Value Based Pricing

History shapes current news.

The rationale for outcomes-based pricing is dependent on the assumption of compliance.

Patients lie about the taking of medications.

Hippocrates

Medications don't work if patients don't take them.

C Everet Koop, former Surgeon General

Industry

- November/December 2018 PharmaVoice, YEAR IN PREVIEW 2019, *Trend Tracking*: Creating shared value was one of the 10 identified trends that "will have a meaningful impact, not just in the near term, but also potentially for disrupting the business of healthcare for years to come."
- Nov. 6, 2018, European Pharmaceutical Manufacturer: Connecting the dots: Why connected health could be the answer to chronic diseases. Chris Evans (West Pharmaceutical Services) "…adherence is directly linked to favourable treatment outcomes…." "…patient compliance with…medication therapies is remarkably low…"

Consumer Electronics Show - Innovation

- Jan. 12, 2019, Associated Press: "Privacy, please: New gadgets want greater peak into lives," by Prof. Franziska Rosener (Univ. Washington): "…industry is trying to find the right balance between useful services and protecting people's privacy…"
- Jan. 7, 2019, *The Wall Street Journal,* Katherine Bindley: "Health Gadgets Get More Personal": 511 companies registered in the digital health category, up from 472 last year.
- Anshel Sag (Moor Insights and Strategy) "You'll see more of these devices giving users more things to do based actionable data."
- Julie Ask (Forrester) "Nobody's really benefitting yet." "…there isn't an open ecosystem of data exchange."

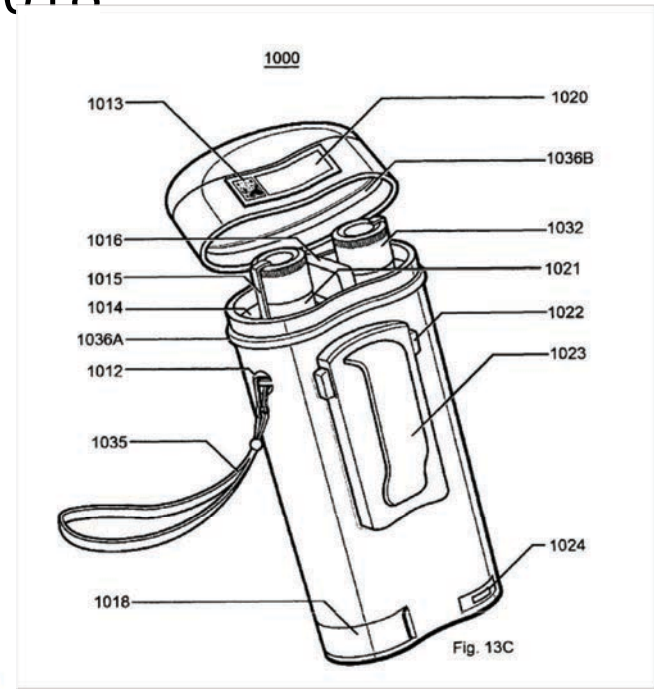
Industry- Innovation

- March 1, 2018, Flex (NASDAQ: FLEX) press release announces launch of BrightInsight, connected health solution on Google Cloud
- A novel approach
- BrightInsight Master File was accepted by the FDA
- Quality Management System is ISO 13485:2016 certified
- BrightInsight manages the regulatory filings and updates related to BrightInsight to alleviate the regulatory burden for its biopharma and medtech customers

Industry- Innovation

An example of a C-Container

Aterica's VETA Smart Case was formally launched in 2018



Monroe 2011 '778 Injection device and case with reporting ability

IP News - Innovation

- The mMed portfolio shown at www.mmedhealth.com is owned by New Directions Technology Consulting, LLC
- NDTC has non-exclusive, narrow field of use licensees for the portfolio.
- The earliest expiring of the seven granted U.S. and international patents is 2026
- The portfolio is available for sale or license
- The portfolio can provide freedom to operate for patient-centric consumer drug delivery products. C-Containers
- I'm available for the entire DDP and will be glad to discuss your further thoughts

Questions?

Thank You

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

www.mmedhealth.com

Footnotes in the ONdrugDELIVERY article relate to some of the information in this presentation.

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