



REDICA Systems

Formerly Govzilla

www.redica.com

help@redica.com

(844) 332-3320

The Ecosystem for Smart Combination Products: What About Regulations?

Presented by:

Napoleon Monroe
Managing Director
New Directions Technology Consulting



NAPOLEON MONROE
MANAGING DIRECTOR

**New Directions
Technology Consulting, LLC**



nap.monroe@newdirectionsconsulting.net
(718) 427-3038 US Eastern Time

www.mmedhealth.com

About the Speaker

Napoleon Monroe is the sole inventor of the mMed medication-telemanagement patents owned by New Directions Technology Consulting, a single member LLC.

Napoleon has been involved in the successful commercialization of patents and other intellectual property for decades. He spent 20+ years at Survival Technology (now part of Pfizer), where he built and managed the IP portfolio.

At Survival, he invented and commercialized three patented medical devices. Two were autoinjectors, one of which is still the primary U.S. delivery system for nerve agent antidote. Another was a transtelephonic peak-flow monitor.

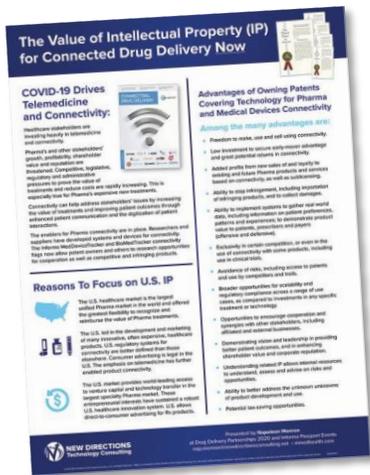
Napoleon led teams that invented, prototyped, commercialized and scaled up pharmaceutical delivery systems. His work included the original EpiPen for treatment of anaphylactic shock.

Napoleon has worked in regulated healthcare industries for many years. However, he is a business leader, not a professional regulatory expert. The opinions herein should not be relied upon as regulatory guidance.

Current Patents in Force and Recent Publications



The mMed patent portfolio:
Five granted U.S. and two international patents related to remote drug delivery and monitoring.



Poster:
The Value of Intellectual Property (IP) for Connected Drug Delivery Now. Presented at Drug Delivery Partnerships, September 2020.



Article:
COVID-19: A CATALYST FOR IMPLEMENTING CONNECTED HEALTHCARE PRODUCTS?

ONdrugDELIVERY, June 2020

Telemedicine is a catalyst for breaking the legacy barriers. Patient and caregiver adoption has moved from 11% to 46% and providers are now seeing 50–175 times the number of patients via telehealth compared with before the pandemic. It is likely that the U.S. will evolve into a German-, Dutch- or French-style system for basic needs and a parallel private free market for anything beyond basic care.

<https://ondrugdelivery.com/covid-19-a-catalyst-for-implementing-connected-healthcare-products/>



Smart Combination Products

What they are:

- Combinations of drugs or biologicals and devices connected to the Internet, usually through a communications device with long- and short-range communications capabilities; e.g., smartphones.
- Part of a diverse, regulated ecosystem.

Why are smart combination products necessary?

- Early combination products met real human-factor needs, but were “dumb,” not Internet connected. And they were all for small- molecule therapeutics.
- Biotech, genetic and personalized-medicine revolutions have changed essential product and patient needs.
- They are often proteins that must be administered other than orally and require home administration, improving compliance, limiting provider costs.
- They assist a broad range of patients, practitioners, other stakeholders; meet patient needs and improve outcomes.
- By connecting stakeholders, they become more patient-centric.
- They also are tools for all stakeholders to improve their products, their businesses and their abilities to improve patient outcomes.

A Short History of Combination Products

The Progression of Several Patented Platforms



Syrette



AtroPen



ComboPen (EpiPen)



Mark 1

- Syrette - WW I - WWII – glass and metal - Atropine and morphine. (Squibb, Wyeth now gsk)
- AtroPen-1970's-metal cartridge - Atropine, morphine, NASA into space, early Parylene coating. Hydraulic braking.
- ComboPen (EpiPen) - chemically tempered glass cartridge- Lidocaine*, epinephrine (1982), pralidoxime, diazepam, midazolam, TMB-4/benactyzine/atropine*. Needle guard added later. Mechanical braking,
- Mark I Nerve Agent Antidote Kit “NAAK”

All (except*) FDA and DoD regulated. All auto-injectors collet and spring front activated. No recalls or reg letters for functionality while involved.

Currently Relevant Progression

US Patent 5,092,843A. Dispersion Multichamber Auto-Injector 1990. Inventors Monroe, Dalling, Mesa. Assigned to Meridian Medical Technologies Inc. (Pfizer). Antidote Treatment – Nerve Agent, Auto-Injector “ATNAA.” First shipped to Operation Desert Storm. Collet and spring, hydraulic braking creating dispersion.

- Leading product in the category for U.S. military, Homeland Security.
- Leading product sold as DuoDote in civilian markets for organophosphorus insecticide poisoning.

Solved problems.

- Reduced size, weight and operational complexities.
- Far fewer parts, lower component cost. Stored incompatible drugs using a by-pass.
- One of the drugs retarded absorption of the more time-critical in tissue. Hydraulic control released the two drugs in different tissue planes.

FDA and DoD regulated. Patents secured financing, which supported operations. Product overcame competitive threat from Philips-Duphar (later sold to Solvay).



The Ecosystem for Smart Combination Products: What About Regulations?

Presented Dec. 10, 2020





What We'll Cover

- **Sharing learnings/highlights:** As reflected in recent industry conferences, smart combination products have taken leading roles in healthcare strategy
- **Key industry themes:**
 - Loads of money invested in telemedicine, including in smart combination products
 - Regulatory issues as part of the ecosystem
 - Challenges and opportunities for smart combination products
 - Themes interplay within Pharma, and between other stakeholders, and regulatory bodies
 - A regulator's digest



Drug Delivery Partnerships

BIOPHARM AMERICA™ DIGITAL»»

BIO-EUROPE® DIGITAL»»



Online Conferences and Offline Conversations

Themes

- Investment and growth – digital health, telemedicine and connected health
 - FOMO
 - Intellectual property
- COVID-19 as a catalyst, effects, virtuality
- Patient centricity, human factors, communications, engagement
- Digital everything, data, analytics, therapeutics, digiceuticals, automated intelligence, value. Far broader than compliance and adherence
- Platforms
- Barriers and silos

Note: Interestingly, there was little specific discussion of ROI

Regulators' Digest

- Regulation and standards
- The future??

* PDA Combination Products Workshop **ADA Standards Committee For Dental Informatics

THIS PRESENTATION CONTAINS MY INTERPRETATION OF CONFERENCE PROCEEDINGS AND OTHER INFORMATION RECEIVED. I ATTEND MANY CONFERENCES, PUBLISH REGULARLY, AND AM A MEMBER OF SEVERAL TRADE AND PROFESSIONAL ORGANIZATIONS. THOSE ORGANIZATIONS DO NOT SUPPORT OR ENDORSE NDTC.

Connected Health: A Healthy Ecosystem

Digital Health: Telemedicine, On-Demand Services

Connectivity to patients and smart healthcare products they use remotely is essential to digital health, which includes telemedicine and providing on-demand services. This can apply to both FDA-regulated and consumer products.

Investments and Growth / Recent Investment Motivations

- More often strategic than financial.
- Trend is larger deals; 24 or more digital health companies raised \$100M or more. Larger deals are generally smarter deals.

Pre-COVID-19: Investments in telemedicine, digital and connected health products were already growing rapidly.

- **Q3 2018:** Some \$3.3B in sector investment - the biggest ever for digital health.
- **Q3 2019:** Slowed with 66 sector deals totaling \$1.5B.

Post-COVID-19:

- **In 2020 so far:** Total sector investment is \$9B+ and growing.
- **Q3 2020:** Medication telemanagement is an essential element of on-demand healthcare services, which is the top-funded and most frequent value proposition through Q3 2020, with \$2B invested across 48 deals.
- **“Deals” are known, internal investments are not well reported.**

Investments and Growth – Digital Health, Telemedicine, Connected Health



Notable:

- **Vertical and horizontal integrations**, such as SMC/Oval/Cambridge, Gerresheimer/Sensile, Sulzer/Transcoject/Hasselmeier, CVS/Aetna, Amazon/PillPack/Health Navigator.
- **Teladoc** acquiring virtual care company **Livongo**, valued at \$18.5B. The deal would combine one of the leaders in the **telehealth** market with a growing digital health firm that targets chronic disease management.
- **As of December 2020, Pharma and others have “dry powder,” (loads of cash) making this a time when the selective investment environment is felt to be the best in 10 years.** Per the WSJ, 12/4/2020, “U.S. companies are sitting on the largest pile of cash ever. Investors are trying to gauge how they are going to use it.”



Investments and Growth – Outlook

Digital Health, Telemedicine and Connected Health



- The Trump Executive Order on most favored nation seems to be tied up in political wrangling.
- JD Health raised \$3.5B in a Hong Kong IPO (12/3/2020). Almost all JD revenue now is from selling drugs, but JD has already expanded to selling services. Chinese policy makers seem to so far accept this retail-healthcare approach.
- My mailbox has been filled with several “Save up to 80% on prescription drugs” discount card offers. Cooperation with many major pharmacy chains is touted in this newer PBM model, aimed primarily toward the uninsured.
- Several other new drug telemarketing approaches have emerged.





Investments and Growth – Outlook

COVID-19 as a Catalyst for Investments

- Worldwide emphasis on healthcare.
- Pace of changes remarkably accelerated.
- Consensus regarding COVID-19 as a lasting driver for telemedicine.
- Pharma and related regulations reduced.
- Patient behaviors changed.
- Data on infections, hospitalizations and deaths peaking again as of December 2020.



Article:
COVID-19: A CATALYST FOR IMPLEMENTING CONNECTED HEALTHCARE PRODUCTS?

ONdrugDelivery, June 2020

<https://ondrugdelivery.com/covid-19-a-catalyst-for-implementing-connected-healthcare-products/>





Human Factors

- Patient behavior is complicated and changes most everything as compared to professional use
 - Purchasing and adherence
 - Storage, dosing and use
 - Efficacy
 - Safety
 - Outcomes
 - Perceived experience, acceptance and complaints
 - Fears, education and training
 - Changes over time. Need feedback
 - Quick-start instructions and more
- Combination products present new and challenging regulatory and operational problems.
- Simplicity and demonstrable value are essential.
- Smart drug delivery products are especially appropriate and valuable for personal support of combination product use.
 - Understanding and overcoming problems.

*Study human factors
and what you
want patients to do
very well before
significant investing
to avoid horror
stories...*





The U.S. Medication Communication System – Patient Centricity?

Direct-To-Consumer (DTC) advertisements.

Information sources after DTC:

Professional: 🕒

Interns, resident fellows, attendings, hospitalists, general practitioners (a.k.a. gatekeepers), certified medication technicians, specialists, specialists, specialists, specialists, dentists, psychiatrists, other specialists, EMTs, nurse practitioners, physician’s assistants, nurses, local doc-in-a-box. Medication reconciliation or “Have your medications changed?”

Non-professional: Insurers by declining reimbursement, the Internet, friends and family, and other sources.



Retail pharmacy: 🕒

“Do you have any questions for the pharmacist?”

“Next customer in line, please.”



Patients:



Package inserts and box warnings: >>>>





The U.S. Medication Communication System – Related Information

- More than 10,000 prescription medications available. Spending \$335B/yr. in 2018.
- Many would benefit from better management...compliance, adherence, improved outcomes, reduced cost, and beyond.
 - Benefits to payers, patients, and other stakeholders.
- A number of groups support legislation demanding EMR interoperability and patient access to their own records.
- *Research estimates non-optimized medication therapy results in 275,689 deaths and costs more than \$528B/yr. Medication errors occur in 3.8M inpatient and 3.3M outpatient visits a year. 7,000 preventable deaths result from medication errors.
- **It is estimated that more than 1M individuals are seen each year in U.S. hospital emergency departments for adverse drug events. More than one-quarter of these patients need to be hospitalized for further treatment. Adverse drug events are an important patient safety problem, and many are preventable.
- Improvements are possible with near real-time actionable patient level data...smart drug delivery and clinical pharmacists' guidance can be part of Comprehensive Medication Management.*

Sources: *Annals of Pharmacology, Institute of Medicine, National Quality Forum. ** US CDC



The U.S. Medication Communication System – Working to Improve

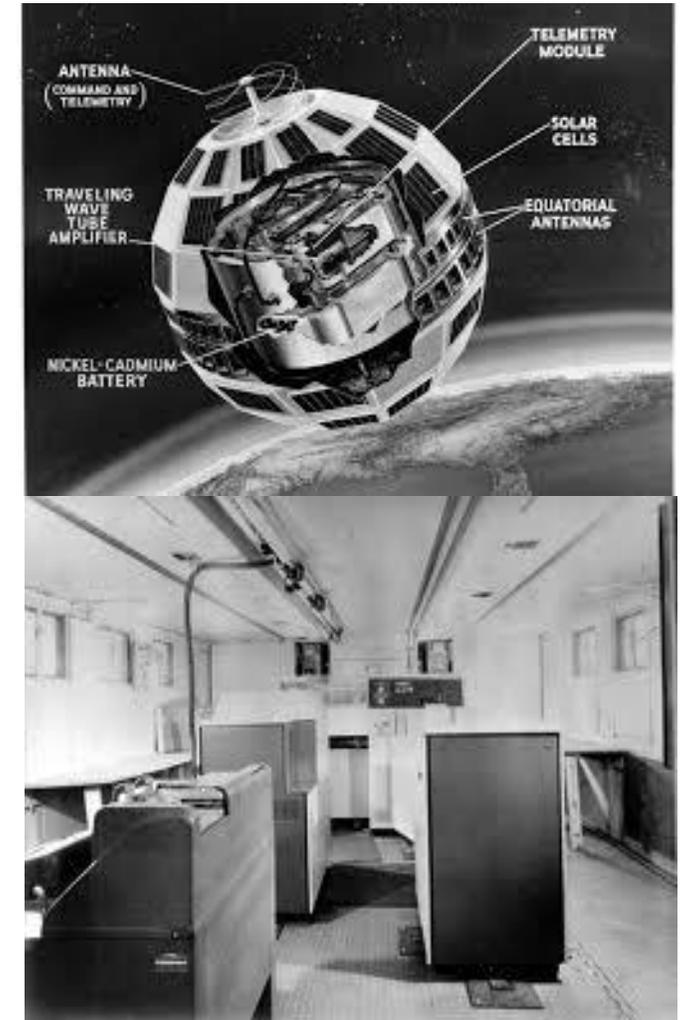
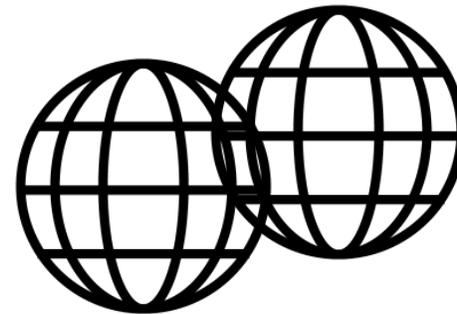
- Investments in telemedicine.
- Understanding human factors.
- Onboarding, training, retraining, support.
- The GTMRx Institute was formed about a year ago. Improvements are possible with near-real-time actionable patient level data. . . smart drug delivery and clinical pharmacists' guidance can be part of *Comprehensive Medication Management (CMM).
- The Health IT Now coalition has been supporting EMR access and interoperability for years. They were influential in promoting legislation passed to require these.
- The American Telemedicine Association has now. . .Pharma.
- As of this year the American Dental Association is adopting HL-7 so dental and medical records can become interoperable. Dentists prescribe.
- Amazon announced that they are adding Rx services, including pharmacist assistance. Already own PillPack.

Sources: *GTMRx Institute. **US CDC

Patient Centricity – Information, Legislation, Regulation, Risks



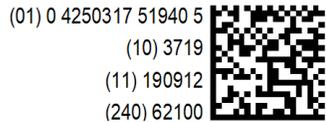
- All digital
- Disruptive
- Healthcare use cannot be restricted forever
- Legal risks, massive amounts of information and misinformation
- Context for opportunities



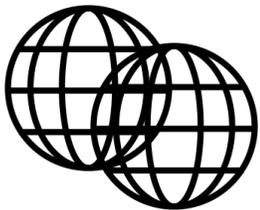
Data, Analytics, Artificial Intelligence, Actionable Information of Great Value

- Information previously unknown, except sometimes in clinical trials
- Who can and will find the information really necessary? How?
- Who will ensure cybersecurity, evaluate to find scientific truths and avoid misinformation? How?
- Real World Data importance
 - Patient level for individual outcome support and product management
 - Anonymized for improving population health
 - Essential to:
 - Value-based payment plans
 - CAPA and Post Market Surveillance
 - FDA signals and national evaluation system for technology (NEST) for regulatory compliance and improvement.
 - A single erroneous complaint or sponsor failure to respond can start a regulatory cascade.
 - Comparative analysis against internal and external data
 - Supply chain and treatment efficiencies





NDC: 59148 011 13
SN: 100000000001
EXP: AUG 22 2015
Lot: AB100613



Automated Identity and Data Capture

CAPTURING DATA TO SECURE USABLE INFORMATION AND EVIDENCE WAS A MAJOR RECURRING CONFERENCE TOPIC

- 2013 final UDI regulation and DSCSA legislation brings convergence.
- The logic is proven by UPC codes in retail.
- UNIVERSAL ACCEPTANCE OF UPC CODES DRIVEN BY WALMART DEMAND, NOT REGULATORY REQUIREMENTS
- Enforcement discretion and implementation delays in healthcare.
- Necessary for business AND TREATMENT efficiencies, especially e-commerce, documentation, analysis, and supply chain.
- Identification for regulatory information – quality, safety, recalls, CAPA and counterfeit control.
- Symbology fairly well harmonized among regulators with some exceptions. Database information requirements vary widely.
- Necessary for Real World Data. FDA and Europe under the MDR are moving toward greater emphasis on post market surveillance.
- Manufacturers and distributors have already invested to include serialized automated identity.
- Combination and specialty drug products are far more expensive and prevalent now than in the recent past.
- Combination products are more complex than the simpler delivery systems, such as vials.
- Systems, including drug delivery combination products, often have associated or embedded software.
- Software is easily and frequently changed and may be the basis for CAPA, recall or other regulatory action.
- “Lot or batch” for pharma does not always recognize supplier-designated “minor” changes in container/closure or drug delivery device component lot numbers. (Supplier changes may or may not be reflected in supplier lot changes but are usually in supplier batch records. Such changes may be the basis for CAPA, recall or other regulatory action.)

Platforms

- Pens, syringes, auto injectors, inhalers, wearables, other, and attachments for all these
- Partnering for the long term
- Exclusivity
- Regulatory filings
- Software-as-a-Medical-Device, Device Master File, 510(k), PMA, Consumer
- Change control
- Cost structures and investments
- Continuing cooperation
- Intellectual property

Important for everyone to know where they really want to go (or be very lucky) before selecting the platform...Otherwise...the minefield.



Barriers - Many Different Silos

- Pharma
 - Corporate and even DEPARTMENTAL stakeholders' interests, attitudes, biases
 - DEVELOPMENT BUDGETS AND DIGITAL VALUE DIFFICULT TO ALLOCATE
 - Conservative and risk averse
 - Partners, including researchers, subcontractors, such as device developers
 - Competitors
- All below have silos, as with Pharma:
 - Practice specialties
 - Distribution - wholesale, retail, PBMs
 - 340B Institutions
 - Import/Export/Co-marketing
 - Payers
 - Disintermediators
 - Governments - regulators, legislators, administrators, lobbyists, litigators
 - Patients and caregivers, interest groups, lobbyists, data collectors and data resellers
 - Geographic, professional and demographic silos
 - Others





Silos Can Be Or Become Dysfunctional



Regulations

CAN BE:

- Confusing
- Overly complex
- Changing and evolving
- Contradictory
- Subject to interpretation
- Sometimes beyond understandable



U.S. Regulators' Digest



- **Audits** - Restrictive policies to control COVID-19 spread has limited the ability of FDA and Pharma personnel to travel to and conduct audits of manufacturers and contract development and manufacturing organizations (CDMOs). This requires new approaches, including virtual audits.
- **REMS** - The FDA has a proposed plan to release information on how drug makers are doing in their implementation of Risk Evaluation and Mitigation Strategy (REMS) programs to implement specific post-market safety measures. Public comments were open as of November 2020.
- **FDA Signals and NEST**- Specifics of how consumer Internet reports will be evaluated are unclear. Erroneous complaints from any source and inadequately investigated complaints may trigger far-reaching, inappropriate responses and product liability claims.
- **Temporary emergency use authorizations (EUA)** have sped some approvals. There has been illegal activity showing unapproved claims. The transition plan to permanent approval is unclear.
- Guidance for **Emergency** use auto-injectors issued April 2020 is extensive and presages the requirements for new emergency and other delivery products. Emergency nasal delivery products fast tracked. Pen, jet, other emergency products.
- **Patent, trademark and intellectual property** regulations can provide commercial advantages.
- **Final Guidance Document** issued last week “Requesting FDA Feedback on Combination Products.”
- **Many, many more...**

Regulators' Digest – Data and Standards

- The 2004 establishment of the Office of the National Coordinator acknowledged the growing importance of software.
- While compliance with standards is voluntary in the U.S. and mandatory in the E.U., compliance with international standards has become ever more important in the U.S.
- The 21st Century Cures Act in 2016 encouraged patient data interoperability and accessibility, and many innovations. Limited compacts for licensure portability allowed some practice across state lines. In addition, complicated, antiquated HIPAA rules, which limited adoption of telemedicine, protected major suppliers and priced out smaller practices from buying telemedicine software, have been under fire.
- Over the years 2016–2020, there has been some interpretation and relaxation of U.S. FDA regulatory requirements for some smart devices. U.S. requirements for others has tightened. E.U. requirements have tightened and remained less clear.
- Post Market Surveillance (PMS) is essentially synonymous with Real World Data/Evidence (RWD/E). PMS gaining more emphasis in both the U.S. and abroad.



Regulators' Digest – Data and Standards



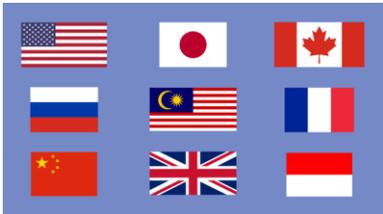
- Digital Health Center of Excellence** - September 2020 - The Digital Health Center of Excellence (DHCoE) is part of the planned evolution of the Digital Health Program in the Center for Devices and Radiological Health (CDRH) and will align and coordinate digital health work across the FDA.
- The U.S. Department of Veteran's Affairs Medical Center in Spokane, Washington, achieved a major milestone on Oct. 24, 2020, in the decades-long \$16B upgrade of the VA health IT systems. The VA's EHR modernization program will continue over the next several years. The VA operates 170 hospitals and 1,074 outpatient sites. VA adopting GTMRx Comprehensive Medication Management
- Surgeon General Jerome Adams will publish the CREP Community Health and Economic Perspective in January 2021. Embracing technology will be a focus.

<https://www.hhs.gov/sites/default/files/community-health-and-economic-prosperity-infographic.pdf>

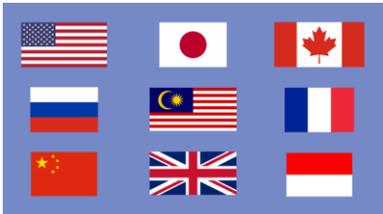


Regulators' Digest – EU Medical Device Regulation (MDR) and Other OUS

- Many unanswered questions as to implementation of the EU Medical Device Regulation (MDR).
- Regulation with the force of law. Scarce Notified Body capacity.
- Only 17 Notified Bodies to review 55,000 more complex files. Some project continued scarcity as of May 26, 2021; many combination products will be included in the EU MDR coverage.
- As of 2020, the European Parliament gave a one-year delay for the implementation of the MDR to May of 2021. The lack of Notified Body capacity.
- Some cited the reason for the delay was COVID-19. Brexit can be a factor. The feasibility of implementing the MDR is still an open question, but don't rely on a further delay.



Regulators' Digest – EU Medical Device Regulation (MDR) and Other OUS



- The evidence burdens in the MDR are shifting to post market surveillance.
- Competent Authorities do not interact to form a unified position on what evidence is necessary for CE marking on combination products that have the effect of a drug. The trend is to grant a CE mark on higher risk products for a one-year, negotiable for the second and follow-on years. This allows companies to try their products in the market.
- Local regulatory bodies globally are enforcing the requirement for product labels to contain translated content and hazard indications (GHS) in order to permit entry and sale in their geographies. This has become a significant source of consternation for labeling organizations in global manufacturing organizations.
- The EU Medical Device Regulation has more requirements for labeling. Warnings on labels, maximum reprocessing cycles, and EU Representative are examples. UDI and more serialization is required.
- EUDAMED post-market program requirements being rolled out now.
- The 2018 EU General Data Protection Regulation is quite stringent.
- Recycling cost recovery in EU is trending into US. Accelerates emphasis on lifecycle management.



Regulators' Digest – ISO 13485 Quality Management System (QMS) Standard which Looks to ISO 14971 Regarding Risk Management

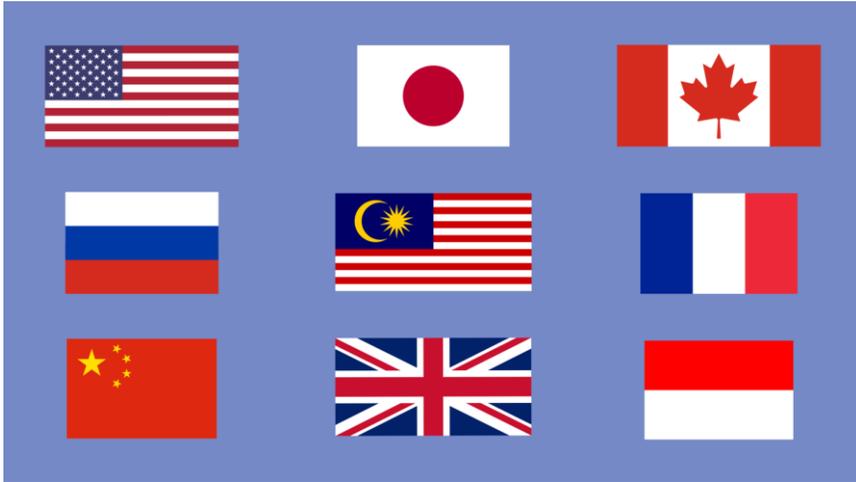
- The International Accreditation Forum (IAF) - IAF manages 1.3M certifications of compliance with standards. A system has been proposed for supporting and managing the 20,000-medical device QMS ISO 13485 certifications. Fake ISO 13485 certifications have been seen for years. The use of such fake certificates became rampant during the COVID-19 pandemic. Fake certificates have now riled regulators. The IAF is pursuing a database of legitimate certificates so it is possible to verify that certs are legitimate.*
- Medical Device Single Audit Program (MDSAP). FDA and others have pursued SAP quality audits. This has been slow to gain traction, especially in countries with lower manufacturing costs.
- With the imminent requirements of the European Medical Device Regulation (MDR) and the up-classification in Europe of many In-Vitro Diagnostics, there is a severe lack of Notified Body resources to audit some 30,000 manufacturer facilities.
- Audit costs have gone up substantially.

*For more on the IAF, please see:

<https://www.bing.com/videos/search?q=youtube+IAFCERTSEARCH&&view=detail&mid=432F950E188759206C82432F950E188759206C82&&FORM=VRDGAR&ru=%2Fvideos%2Fsearch%3Fq%3Dyoutube%2BIAFCERTSEARCH%26FORM%3DHDRSC4>

Regulators' Digest – Regulatory Nationalism

- Local regulatory bodies globally are enforcing the requirement for product labels to contain translated content and hazard indications (GHS) in order to permit entry and sale in geographies under their jurisdiction.
- Demands for local country of origin product and components.
- Tariffs and subsidies.
- Brexit. Probable acceptance of E.U. regulations during transition. Afterward to be determined.
- U.S. may depoliticize regulation, but specifics are unclear.





Election 2020 and Smart Combination Products

- No matter the results of the protests and legal actions, there will be a far greater focus than ever on science and health.
- There is a broad recognition, based on our COVID-19 experience and healthcare costs, that U.S. healthcare system requires an overhaul. There is broad agreement that the current system is unsustainable, but little agreement on direction for change.
- Likely President-elect Joe Biden may face a divided, contentious Congress, a narrow Democratic House advantage, and a Republican Senate majority.
- Congress could block legislative progress on a healthcare agenda. But there are some areas where Republicans and Democrats might cross over.
- Biden and FDA can reverse previous executive orders, progress regulations, end enforcement discretion periods, and issue new executive orders. These actions can move faster than legislation. All US progress is subject to litigation.
- ACA likely remains in place.
- Added relief funds will likely be approved by next year.
- A vaccine rollout will proceed; but improving our lagging treatment of other morbidities will continue to be mandatory.
- Telemedicine should include **smart combination products to help gather actionable data.**
- Hope for bipartisan, future-oriented legislation, and hope that we don't let this crisis go to waste.

Conferences and Conversations: All Virtual



We've covered the primary themes; following are some highlights



“Bumping into” (Connecting with) Colleagues and Friends at Virtual Drug Delivery Conferences

My first **virtual** U.S. conference of the season, Informa’s DDP/BioPharm America, was a learning experience for everyone. Perhaps the best news is that you could still “bump into” friends and make new connections without being there in person.

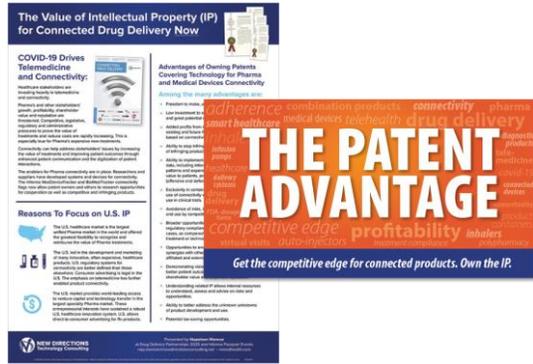
Some event highlights re connectivity were:

-- **Yasemin Bettina Karanis** of IQVIA moderated “Connectivity in Drug Delivery – Strategies from the Leaders of the Pack,” an excellent panel with executives from Eli Lilly, AstraZeneca and Merck KGaA addressing the importance of connectivity. Some key comments from panelists:

- Connectivity is becoming the “new normal” for self-administered products.
- One company intends to introduce connectivity for all its self-administered **combination** products.
- “Just having a better drug or biologic is becoming less important for sales than having an excellent (**smart**) customer experience and user satisfaction.”
- Delivery devices are now “**digital** by design” not digital based on afterthoughts.
- Panelists stressed the **value of data** generated from connectivity for decision making, including for proving outcomes in value-based pricing.

* PDA Combination Products Workshop **ADA Standards Committee For Dental Informatics





Drug Delivery Partnerships

BIOPHARM AMERICA™ DIGITAL»»

BIO-EUROPE® DIGITAL»»



“Bumping into” (Connecting with) Colleagues and Friends at Virtual Drug Delivery Conferences

Some additional event highlights re connectivity were:

-- **Ralph Lipp** led a master class on “Negotiations for Drug Delivery Innovation.” I participated in Ralph’s classes on proven negotiating practices, and played my assigned role in a live, 1:1 session based on a Harvard case study. Since negotiations are now more often conducted **virtually**, this class was a very timely foray into today’s challenging negotiating experiences. And it proved that, just as with virtual childhood education, successful virtual negotiation depends on the participants’ commitment to the process. Our team achieved target savings values.

-- **Cornell Stamoran, Ph.D.**, of Catalent Pharma Solutions, presented 10 keys to drug-delivery success, some of which can be enhanced with connectivity. While much of Cornell’s presentation on “What will it take to succeed in drug delivery - A look into what's coming” centered on what are thought to be the traditional Pharma issues (including **regulation**), his comments on the need for **foundational patents** and nontraditional partnerships (**outside the traditional silos**), can be interpreted to directly apply to achieving success in implementing connectivity.

-- **Kevin Deane** and **Bill Welch** of Phillips-Medisize presented “Past, Present, and Future of Auto-Injectors: Achieving Connectivity, Sustainability, Cost and Usability,” sharing their cost-reducing **platform** design approach, including for smart autoinjectors. Phillips-Medisize had a poster on a new oral dosage form dispenser at DDP. It came up at the conference’s link alongside **our poster on the value of intellectual property to connectivity.**

Hopefully, Informa’s senior management will support improvements in their conference and BioMed Tracker software suggested by participants.

* PDA Combination Products Workshop **ADA Standards Committee For Dental Informatics



Some Highlights

PDA Combination Products Workshop

- Focused specifically on combination products including smart.
- Biannual. Well planned. Very interactive. Extensive time for Q&A.
- Israel is very active in the combination product space especially connected combination products.
- Patents on internal mechanisms and color will not preclude granting an ANDA for a combination product.
 - Learned how TEVA overcame the EpiPen lead to secure generic approval.

American Telemedicine Association

- New leadership.
- Refocused and inclusive now of topics and interests related to smart combination products.

PATSNAP Webinar Series

- Surprisingly broad. Recommended. Topics so far:
 - Investing.
- Transformation to wellness beyond data and telemedicine.



DENTAL TRADE ALLIANCE

ADA

American
Dental
Association®



BIO-EUROPE® **DIGITAL**»»

Some Highlights

Dental Trade Alliance and American Dental Association Standards Committee on Dental Informatics

- Both provided very enlightening regulatory content.
- Slides later in this presentation.
- In 2020, The American Dental Association moved to adopt HL-7.

Two Informa Conferences Were Bundled with Drug Development Partnerships

- Useful for reaching OUS audiences.
- ChinaBio was very China and pharma-science-centric. Connectivity was less emphasized.
- BIO-EUROPE was far more valuable for my purposes.
- Companies attending had a broad geographic reach and interests in connectivity.



What We Didn't Hear (That We've Heard in the Past)

- Diabetes is the only diagnosis that makes sense for smart, connected drug delivery products.
- The elderly will not accept using smartphones.
- Doctors and patients will never accept telemedicine.
- We fully understand combination products and smart combination products.
- Market share is the new intellectual property.

And there was very little “I predict” from Pharma in the conferences.
A great deal of speculation elsewhere. . .including in this presentation.

My Prediction

“It's been a long time, a long
time coming
But I know a change gonna
come, oh yes it will”

-- Sam Cooke 1933-1964



Questions

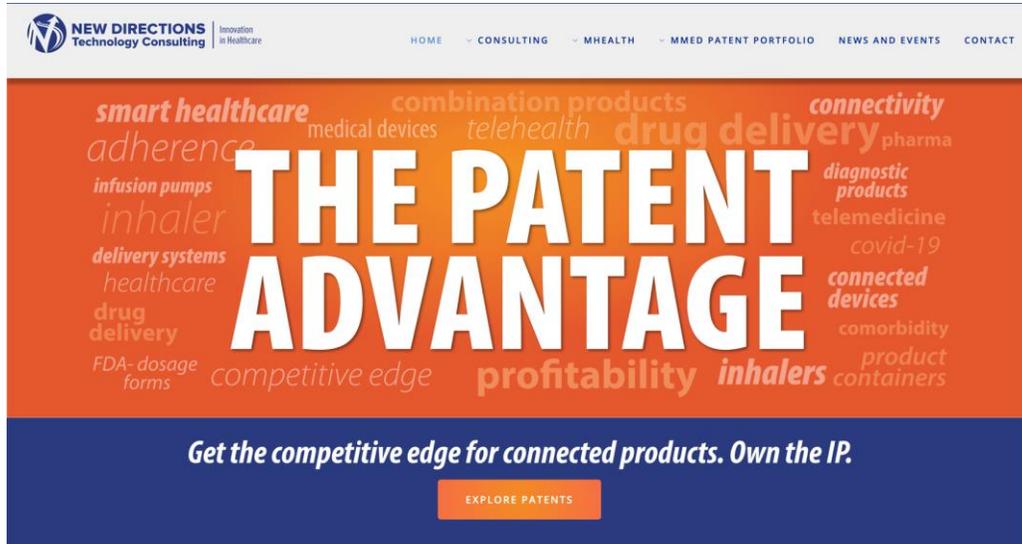


Questions are welcome.
If I do not have an answer, I hope
colleagues attending will chime in.



What questions or
comments do you
have????

Contact New Directions



NEW DIRECTIONS
Technology Consulting

New Directions Technology Consulting, LLC

1442 Drake Lane
Lancaster, PA 17601

Telephone:

(718) 427-3038 MOBILE US EASTERN TIME



Napoleon Monroe

*Managing director, New Directions Technology Consulting, LLC
Member, Parenteral Drug Association,
Prescriptions for a Healthy America, American Telemedicine
Association, Health IT Now, and other organizations*

www.mmedhealth.com

nap.monroe@newdirectionsconsulting.net

<https://www.linkedin.com/in/napoleon-monroe-99ab9b13>



This presentation is provided subject to a Creative Commons License. Recipients may distribute, remix, adapt, and build upon this work, even commercially, as long as you credit Napoleon Monroe and New Directions Consulting for the original creation.