

Will the Events of the Past Decade Fundamentally Change the Dental Supply Chain?

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Personal Background Disclosure Statement

O. Napoleon Monroe, B.S. and MBA coursework

Currently, Managing Director of New Directions Technology Consulting, LLC. which is the assignee of a patent portfolio related to telemedicine, primarily focuses on medication management.

In the past, I have been a Vice President managing the Henry Schein private brands, have consulted for the Dental Trade Alliance and a number of public and private companies, and have developed drug delivery and other medical devices. The current nerve agent antidote delivery system, U.S. Patent xxx , was developed by a team I led at a company later bought by Pfizer.

Disclosure Statement

- O. Napoleon Monroe
- I have supported dental education at East Carolina University and a pilot to identify undiagnosed pediatric asthma patients at the University of Pennsylvania
- I am the Managing Director of a New Directions Technology Consulting, LLC. which is the assignee of a patent portfolio related to telemedicine, primarily focused on medication management
- I receive no honorarium for this presentation
- The personal opinions expressed in this presentation are not regulatory, business, strategic or investment advice

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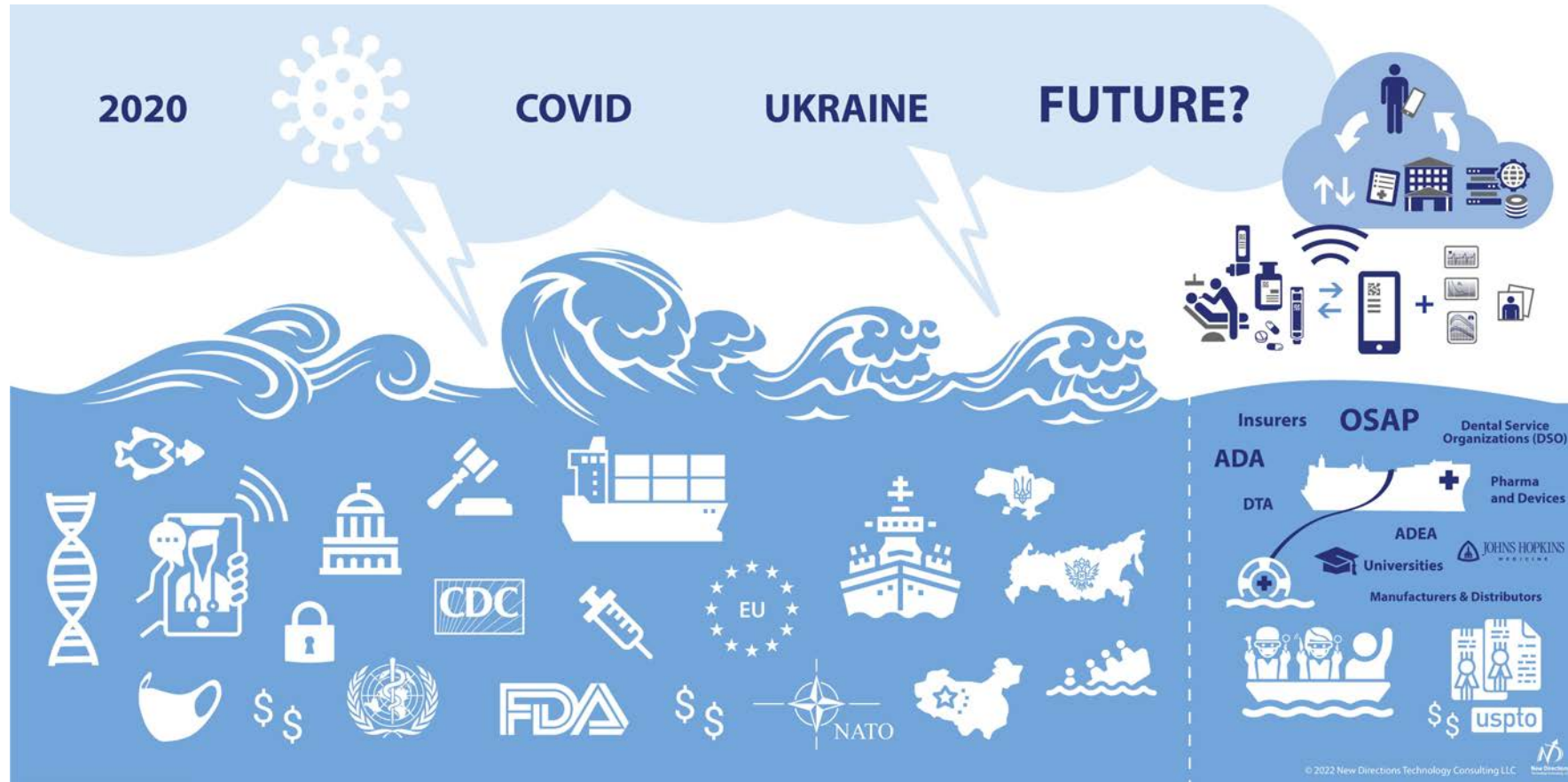
Learning Objectives

- Help develop a broad understanding of the factors impacting healthcare supply chains during the most recent decade
- Discuss some factors which I believe to be important for consideration
- Stimulate and answer audience questions

Supply Chain Background

- The infection control category is the largest category in the dental industry. Medical and dental supply chains are often the same from resource, production, distribution, and regulatory perspectives
- The factors impacting the “dental” supply chain extend from the evolving legacy pre-pandemic environment through recent regulatory, finance, insurance, policy, manufacturers, distributors, practitioner, and PATIENT changes
- The last two years have been chaotic for everyone. Everything is interconnected
- There is no specific dental supply chain for many of the products used in dental offices
- Patients are part of the healthcare supply chain

Navigating Toward Rescue of Dental Patients and Professionals



The “Simple” “Dental” Supply Chain

- Ongoing COVID and other epidemics – Negative effects on patients and dental professionals
- Confusing, changing, mixed messages –Negative effects
- New products – air handling, water management, other infection control, teledentistry, data management + Generally very positive, but expensive
- Increases in demand; volatility; disruptions; sanctions; shipping delays; staff and material shortages; shipping and labor cost increases; counterfeit product; more unscrupulous actors. – Negative effects
- Mergers and acquisitions have changed manufacturing, distribution, and dental practices - DSOs. +Economies of scale, +Ability to invest, - Loss of legacy relationships
- New cost-reduction and sustainability initiatives. +Automation, + Shortening of supply chains, +waste reduction
- Evolving standards and expectations for manufacturers, distributors and practices - Added cost + Improved outcomes
- Patient centricity/empowerment/demands/delays/volatility +/-
- Some unethical entries in the supply chain –Always negative

The Complicated “Dental” Supply Chain

- Many “dental” entities are engaged beyond dental. The demands beyond legacy dental expectations have changed manufacturing, distribution, and professional practice.
- Emergency use and cross-boarder telemedicine approvals, waivers, stimulus payments, tax changes , inflation
- There is money for and emphasis on innovation by non-traditional entities. Innovations are coming in new infection control products, teledentistry, interoperability with other healthcare providers, big data, automated/assisted intelligence
- Insurers and others are restricting products and procedures
- Litigation
- Many patients have lost their corporate insurance
- Regulators (US, Europe and many OUS) are moving toward learning more about post market product performance, incorporating other sources of product performance information, paying for outcomes rather than fee-for-service.

Resources/References

- FDA Unique Device Identifier (UDI) and Drug Supply Security Act (DSCSA) , Digital Health Initiative (Leveraging computing power, sensors, connectivity and software), and Medical Device Safety Action Plan (Protecting Patients, Promoting Public Health), FDA consensus standards
- Supply chain guidance as provided by your counsel and professional and trade association resources. Examples: OSAP, ADA Standards Committees for Dental Products (SCDP) and for Dental Informatics (SCDI), Dental Trade Alliance for manufacturers
- EU MDR 2017/745 Post Market Clinical Follow-up (PCMF)

Questions ???? Comments????

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