Journal of Orthopaedic Experience & Innovation
Clinical, Economic, and Innovative Orthopaedic Experience

Warner, Jon J.P., Jonathan B. Ticker, Ronald A. Navarro, Derek A. Haas, Eric Dremel, and J. Avi Roop. 2020. "The Business of Orthopedics: Post-Pandemic Challenges and Opportunities - A Codman Shoulder Society Discussion." *Journal of Orthopaedic Experience & Innovation* 1 (2). https://doi.org/10.60118/001c.17393.

Editorial

The Business of Orthopedics: Post-Pandemic Challenges and Opportunities - A Codman Shoulder Society Discussion

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Keywords: orthopedic clinical practice, orthopedic business, post-pandemic, orthopedic industry, data-analytics, mergers and acquisitions

https://doi.org/10.60118/001c.17393

Journal of Orthopaedic Experience & Innovation

Vol. 1, Issue 2, 2020

This paper considers several perspectives for the business of orthopedics resulting from the COVID-19 pandemic. It includes the viewpoint of orthopedic surgeons in private practice as well as in large medical centers, both academic and non-teaching facilities. The perspective of a large not-for-profit is also presented. We consider the potential for this crisis to lead to alignment between orthopedic industry and the hospitals and physicians they serve. Finally, we also consider the potential for data-analytics to create value, as well as the overall impact on mergers and acquisition of orthopedic businesses on a macro-level.

Codman Shoulder Society Logo

INTRODUCTION:

We are now more than nine months since the "Pandemic" of COVID-19 started in the USA [1]. The morale and economic health of the world has been affected adversely. The healthcare industry is one of the largest components of the US GDP [2,3]; and musculoskeletal care is one of the largest economic engines of healthcare in the United States [4]. In fact, elective orthopedic surgery accounts for the lion's share of hospital revenue [5]. Many patients have been forced to live with pain and disability with reduced access to elective orthopedic care inclusive of joint replacement; and the opioid crisis has been exacerbated by this reality as well. Thus, the business of orthopedics affects both the economic health of the country and physical and mental health of our population.

This article is actually Part 2 of a series of presentations which started immediately after the Pandemic began in the US. Part 1 is featured in a short video on VuMedi, a network for healthcare providers, and considers the impact of the Pandemic on Orthopedic Business as of April, 2020 - ***Part 1: VuMedi Video Link: https://www.vumedi.com/video/post-pandemic-orthopedic-care-challenges-opportunities/***

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This paper representing Part 2 consists of a series of presentations from June 29, 2020, considering the business of orthopedics from several perspectives. We present the viewpoint of orthopedic surgeons in private practice as well as in large medical centers, both academic and non-teaching facilities. The perspective of a large not-for-profit healthcare organization is also presented. We also consider the real potential for this crisis to lead to alignment between orthopedic industry and the hospitals and physicians they serve. Finally, the potential for data-analytics to create value and the overall impact on mergers and acquisition of orthopedic businesses on a macro-level is also considered. The entire program has been broken into manageable sections which allow an individual to view in each segment, as overall it is an extensive presentation and discussion. Part 2a introduction is at the following link:

Part 2a: VuMedi Video Link: ***https://www.vumedi.com/channel/codman-shoulder-society/tab/part-2a/video/post-pandemic-orthopedic-care-challenges-and-opportunities-part-2a-the-road-ahead/***

Each section presents the viewpoint of an expert in the topics outlined above. Included in each written section below is the link to their presentation. At the completion of all the sections is a roundtable discussion from July 13, 2020, and this is presented as a link on VuMedi.

Part 2b: VuMedi Video Link: https://www.vumedi.com/video/post-pandemic-orthopedic-care-practice-issues-what-different-models-are-going-to-play-a-role-here-wh/

The Pandemic is underway, but it will end. What will last is the impact on how we provide musculoskeletal care and the changes ahead will likely redefine our industry in orthopedics. We believe that out of this value will be created. A view of such a future is provided by the following perspectives.

I. ORTHOPAEDIC GROUP PRACTICE - JONATHAN B. TICKER, MD

(VuMedi Video Link: https://www.vumedi.com/channel/codman-shoulder-society/tab/part-2a/video/post-pandemic-challenges-and-opportunities-for-orthopaedic-surgery-orthopaedic-group-practice-opport/)

The COVID-19 pandemic has had substantial effects on the practice of medicine, including orthopaedic group practices. Much of this has been chronicled in publications, media postings, and other manner of communications. [6-11] These effects have varied across the United States, and the world, by a number of factors. In the US, these include region and timing when the pandemic presented and surged, population features, resources, and differences in the responses by the authorities and individuals, among other aspects. Like most locales, Nassau County, Long Island, New York was not spared. An important part of the immediate practice response focused on safety, for patients, staff, and families, to minimize exposure, and to direct efforts in support of the public health response. This vigilance by our citizens will need to continue until sufficient immunity is achieved. Such actions include wearing a mask, washing hands, social distancing, and avoiding crowded indoor spaces.

There are many peri- and post-pandemic challenges, realities, and opportunities. Is every challenge an opportunity? [12] Opportunities can be viewed akin to "necessity is the mother of invention", while realities may be considered as "desperate times call for desperate measures". A positive outcome can result from either viewpoint. The following are some aspects which orthopaedic group practices, as well as other practice types, may consider or have considered, in no particular order, as a result of the COVID-19 pandemic.

Communication - In a rapidly evolving dynamic, such as the initial stages of the pandemic in the New York region, intramural communication, within the practice, can lead to a more cohesive understanding and response, as well as a shared sense of purpose. With the initial forced downtime, opportunities presented for specialists within a practice to share experiences and to educate their colleagues and staff, as well. Extramural communication, outreach to patients and the local community across various media, allowed for dissemination of immediately useful information, urgent and other care options, practice notifications, and other information of value. This sincere outreach may also serve to benefit the practice.

Business operations - The pandemic and responses to it forced many practice decisions without full information. The key early on was to make enough of the right decisions, identify early and correct those decisions that were less than optimal, and to learn from all actions to improve on providing safe patient care. In this vein, with the elimination or modification of the waiting room, check-in, and check-out to promote social distancing, many staff roles can be repurposed to insure as safe and efficient an environment to rendering care in the office setting. This included screeners of staff and patients for exposure or sickness and escorts or runners, among other roles. The use of smart phones to transition patients into and out of the office has been helpful, and may present further technology-based innovation or adaptation.

Physical plant - Practice preparation for patients returning for office visits varied based on the office setting. For patients who drive to an office visit, a suburban single-story office building with an easily accessible parking lot can consider options not available to an urban practice in a multi-story office building with limited or inaccessible parking. Curb-side check-in with staging and screening patients who arrive by car, more common in the suburbs, has its advantages. If a practice is planning office construction or is in the early stages of construction, designing for the new reality and adjusting those plans, such as to create a staging area, may offer useful options as part of providing safe patient care.

Virtual alternatives - Telehealth presents an obvious opportunity in this area [13-15]. If a practice was able to quickly pivot and employ or adopt a virtual platform, this

allowed for some continuation of safe patient care, especially in the early and heightened stages of the pandemic [16]. Special approaches to the aspects of the orthopaedic exam are necessary, though not insurmountable [17, 18]. This virtual care option also benefitted from the temporary reduction of regulatory and reimbursement barriers. Telehealth options continue to demonstrate their strengths and weaknesses, with more of the former, and will remain part of medical care as the pandemic recedes. Patient education options have also benefitted from virtual formats, for example in pre-operative total joint classes, and this opportunity should be expanded upon. Remote surgeon education, with a "student" receiving a virtual invitation into the operating room of a "teacher", will also grow and create vast opportunities to share knowledge. Technical support in many settings, especially in the operating room, should be more prevalent as virtual platforms expand, to allow for immediate representative support with the "click of a button".

Physician hiring - Current graduates from orthopaedic residencies and fellowships are facing unique challenges in the new climate of this job market. Practices may even be considering contracting in response to reduced volume for office visits and surgeries, and the uncertainty from the ebb and flow of the coronavirus cases affecting demand. This reality with hiring will vary by locale, and by specific specialty needs of a practice. Further, how does the pandemic affect the mindset of new hires, be they recent graduates or experienced practitioners, to compensation models? Do higher guaranteed salaries offer more financial security compared with lower base salaries with more incentives? In any model, it is imperative for the practice to provide the tools necessary for these new hires to develop their individual practice.

Transition to ambulatory surgery centers (ASC) - Ambulatory surgery has seen adoption and growth, initially due to efficiency, especially cost reductions, and then demonstrated quality and safety [19-24]. It is the last aspect, safety, which has come to the fore during the pandemic. Traditionally in-hospital cases, such as total joint replacement and spine surgery, are prime for further growth into the ASC setting. For those ASCs with a program already in place, this option is an opportunity ripe for expansion. However, with the capital costs and logistics involved, initiating a new program during a pandemic or in the early post-pandemic period has challenges. Patients' perception in seeking the safest option, especially with COVID-19 in-patients, the ASC offers a natural alternative to the hospital setting [10]. In response, hospitals have an opportunity to improve service, expand hours to court surgeons' cases, adapt and provide these outpatient services, and enhance the patient experience.

Ancillaries - For those practices which offer the gamut of ancillary services, such as physical therapy, imaging, durable medical equipment, diagnostic testing, pain management, etc., and which demonstrate safety and practice safely, patients may choose to obtain these services under one roof and not go to many different businesses for these services. An all-inclusive care provider may have a competitive advantage to deliver more components of the episode of care.

Practice acquisitions - Solo orthopaedic practitioners or small orthopaedic group practices were more likely to be exposed to greater financial risk during, and after, the early pandemic response and lockdowns, which initially limited office visits and eliminated elective surgery [25,26]. This vulnerability varied by regions and local business market dynamics. The challenge these smaller practices face presents an opportunity for growth for those orthopaedic group practices with greater financial stability and more resources. It's clearly an advantage if those groups have sophisticated and integrated business operations already in place, and experience with acquisitions. This will likely hasten the changes with consolidation already underway.

Factors beyond our control - Individual patient circumstances directly related to the pandemic will affect demand for services. It starts with an individual's sense of safety and need for seeking orthopaedic care. There are also financial aspects, such as employment or health insurance coverage [26]. In addition, the microclimates around an office may have an effect, in part related to the surrounding socioeconomic environment. Further, peaks and waves of coronavirus cases cannot be controlled, but these changes can be anticipated and preparations made for a better response in the future. Orthopaedic surgeons can serve public health initiatives by continually educating our patients about the importance of consistently wearing masks, washing hands, practicing social/physical distancing, and avoiding crowded indoor spaces.

It remains an imperative for the orthopaedic group practice to provide excellent care safely and to demonstrate a sincere focus on patient safety. This will be necessary to sustaining the practice's primary function of patient care. The opportunities, realities, and challenges highlighted above are evolving and worthy of continued consideration. For each and every aspect and the decisions which are made, the patient experience must remain in the forefront. At this moment, safety appears to be the patient's principal concern. Reality has forced changes, and therein lies the opportunity.

II. HEALTHCARE SYSTEMS NARROW WINDOW OF COVID-19 INNOVATION OPPORTUNITY - RONALD A. NAVARRO, MD

(VuMedi Video link: https://www.vumedi.com/channel/codman-shoulder-society/tab/part-2a/video/health-care-systems-innovation-sprint-covid-19-altered-narrow-window-of-opportunity/)

COVID-19 has upended the healthcare landscape [27]. Many are rightly managing the challenges directly in front of them as it relates to the expression of the SARSCoV-2 virus as the COVID-19 disease in healthcare systems. Some have also utilized this time to understand the deeper aspects of this pandemic and realize that we will not live a post COVID-19 world, but maybe a COVID-19 -altered world as there is greater realization that healthcare life will not go "Back to Normal." Ongoing and continuous educa-

tion will be necessary in order to deal with the pandemic's effects on our national health, healthcare, the economy and even national security. That realization may offer an impetus to consider new frameworks for the optimal offering of health and healthcare. The potential is for a new condition-based paradigm for healthcare systems which facilitates better administration of health and care.

Michael Porter has described value in healthcare as outcomes relative to costs [28]. Further the Institute for Strategy & Competitiveness at Harvard Business School (founded by M. Porter) asserts that in order to deliver more value, providers must focus on deepening their expertise, and expanding their ability to serve the complex and interrelated needs of each patient over the full cycle of care.[29] The greatest improvements in health care outcomes and efficiency will come from sustained, team-based focus on a carefully defined set of medically integrated services and practices. Care must be organized around medical conditions over the full cycle of care [29]. This is clearly not the norm in the current American Healthcare System.

At the University of Texas Dell Medical School, there is an ongoing initiative to develop integrated practice units that seek to provide multidisciplinary care around discrete medical conditions [30]. The aspiration of this initiative is to shift the focus from a siloed system of care toward delivering high-value, patient-centered care over the full cycle of care for a specific condition. This will be achieved through better coordination and continuity of all elements of care [30]. In the current system, the high level of acknowledged waste results in inefficient care. The model being proposed is a path to actually reinvesting those resources in ways that benefit patients directly [30]. A key component of such change must be based on the financial implications of how the payors will pay for condition-based care.

During the disruption of care by the COVID-19 pandemic, many have taken the opportunity afforded by extra time away from care responsibilities in order to consider important changes to our system of care. Initially care based on a surgical episode was the consideration. Iterative discussions in some healthcare systems have led us to reconsider care in the context of overarching conditions. Let us use shoulder pain as an example. This broad condition has many places where patients can enter the formal healthcare delivery system, from calls to appointment call centers to primary care and from urgent and emergent entry points, to name a few. Patients can have an end point to shoulder pain at a variety of treatment options, from self-care to conservative measures, injections and on to different surgical options (arthroscopy to cuff repair to arthroplasty etcetera) depending upon the age, symptoms, examination and diagnostic test findings.

An end goal to provide more value might be to virtualize care of the many paths contained within the overarching shoulder pain condition example used here. Consider a system that makes upstream targeted surveys available to the patient virtually. These focus on typical history queries based on initial complaint and age among other things, just as the physician would alter an in-person history question set based on those very same queuing factors, in the moment face to face. This is a conscious attempt to wean off wasted visits and virtualize more of the direct care from the musculoskeletal team (as increased use of virtual care is one of the dominant "silver lining" outgrowths of this pandemic [31]), an optimized care paradigm that the patients prefer may be an end result. Aligned with this is smart information technology embedded within the electronic medical record which can utilize focused healthcare history already obtained and further drive smart ordering of diagnostics (radiography {XR} and magnetic resonance imaging {MRI} in this shoulder, for example). By standardizing XR and MRI reads via the use of externally validated grading accepted by local content experts, these diagnostic exams can help to categorize patients into different treatment regimens and levels of physician, surgeon or other allied provider interaction. This type of standardization may prove to be the best innovation in creating value for patients and for the system. IT systems can help bridge test results and virtual data from patient question and answer that can provide upstream and downstream patient steerage. Contained within this paradigm is an exit for patients who wish to be seen face to face. The end result would be more efficient management of shoulder pain from beginning to the end of the care cycle.

Of course, we must measure the effectiveness of such diagnostic and treatment approaches by use of patient reported outcomes & other quality measures. This includes transparently monitoring end results and the reduction in extraneous care as Codman and Hawthorne would expect [32]. Aided by tech enabled surveys, systems that employ texting as patient reminders, targeted content specific videos, soft copy handouts and virtual "classes", this care path can become and is becoming a reality.

Technology enabled patient steerage due to a symptomatic orthopaedic condition based on patient derived focused information and early critical diagnostics will eliminate visits of little value. This will create patient happiness and satisfaction with this patient centered approach, as well as added efficiency and reduction of wasted resources. This coupled with overarching condition-based care (as validated by the peer reviewed evidence and content experts) will supersede bundles for less encompassing episodic bundle-based care. The outcomes will be the same or better and, with leaned out care paths and more virtual care imbedded, will be less costly and create capacity in the system to care for other patients. This will serve the ultimate goal of value creation in musculoskeletal care.

III. HOW SURGEONS, HOSPITALS, AND SURGERY CENTERS CAN ADDRESS THE ECONOMIC CHALLENGES CREATED BY COVID-19 - DEREK HAAS, MBA

(VuMedi video link: https://www.vumedi.com/channel/codman-shoulder-society/tab/part-2a/video/how-surgeons-hospitals-and-surgery-centers-can-address-the-economic-challenges-created-by-covid-19/)

COVID-19 is creating unprecedented challenges for orthopedic care. The virus continues to be a major public health concern. State and local restrictions and guidelines vary significantly, and many places have paused or reversed their re-opening guidelines as case counts grow, including re-imposing restrictions on performing elective surgery [33]. These changes, which can be made with short notice, make it difficult to reliably plan and schedule care.

COVID-19 is also impacting the demand for orthopedic care in three ways. First, there has been a substantial reduction in not only sports, but human activity in general due to COVID-19—one study found that during this spring the amount of seismic noise caused by human activity dropped by 50% globally [34]. Second, the unemployment rate is still high, and so many people have lost their employer sponsored health insurance. Third, many patients are continuing to defer care out of fear of going to the hospital and being exposed to COVID-19.

While each of these challenges is significant, surgeons, hospitals, and surgery centers can successfully navigate through these difficult times. It is important to be prepared and have contingency plans depending on how both the pandemic itself and the governmental response evolve. In an environment with reduced and variable levels of demand, and changing ability to operate, providers need to focus on the economic lever they can most control—their costs.

There is a common perception that most of a provider's costs beyond supplies are fixed, i.e. do not fluctuate much based on the volume of services performed. As my colleague and mentor, Professor Bob Kaplan at Harvard Business School, has put it though, "there ain't no such thing as a fixed cost." As Professor Kaplan explains, if you have more than one of something, whether it is an x-ray machine, or a physical therapist, then each incremental unit is a variable cost that could be flexed up or down based on need.

In a *Harvard Business Review* article with Professor Michael Porter, Bob Kaplan introduced the concept of Time-Driven Activity-Based Costing (TDABC) to health care as a more robust way for providers to understand and manage their costs [35]. The idea is to understand what care is being provided for each patient, what type of clinician or staff is involved in providing each type of care, how much time they are spending and the cost of their time. For instance, if a nurse who costs sixty dollars per hour spends twenty minutes with a patient then that patient interaction costs twenty dollars.

TDABC enables providers to understand both their variable costs and their unused capacity (unutilized time that they have people available to do work), and to identify ways to reduce their costs through changes in care, who is involved in delivering the care, and the amount of time spent. This is critically important to do given the financial pressures caused by COVID-19. It does not necessarily mean letting people go if demand temporarily drops, which may hurt organizational performance in the long-term [36], but rather learning how to use your people as productively and efficiently as possible.

IV. HOW DEVICE MANUFACTURERS CAN ENHANCE THE POST PANDEMIC ORTHOPAEDIC RECOVERY - ERIC DREMEL

(VuMedi Video Link: https://www.vumedi.com/channel/codman-shoulder-society/tab/part-2a/video/how-device-manufacturers-can-enhance-the-post-pandemic-orthopedic-recovery/)

The COVID-19 pandemic will be a disruption accelerator. Technologies that were slowly gaining traction have quickly become mainstream. Examples include remote office work, virtual/mixed reality surgical systems, single use instrumentation, and web based educational conferences. Post-COVID healthcare systems will have less tolerance for products that create a burden for hospitals and ASCs; examples are extensive inventories, complex instruments with numerous sterilization trays, large robotic platforms, and implant systems that require extensive sales representative service. To follow are five recommendations on how industry can enhance the post pandemic recovery.

Support increasing hospital case volumes & shift to ASCs - Industry should focus its considerable patient education budgets to assuage COVID related fears causing patients to delay elective surgery. An AAOS survey reported that 34% of patients have postponed surgery by more than 3 months [37]. Manufacturers should streamline scheduling, sterilizing, inventory & service requirements and provide surgery support with less physical contact. Short term pricing concessions, flexible consignment inventory policies, and extended payment terms should be considered.

Reset sales representative expectations - As product support demands increase, sales representatives must adhere to new and extensive policies and procedures. Restricted access to clinic and hospital facilities, expanded vendor certification requirements and exacting loaner instrument policies will require a collaborative mindset. Salespeople are typically reluctant to embrace marketing and sales operations technology fearing it will dilute their customer relationships. A recent survey by ExplORer Surgical reported that 77% of MedTech executives strongly agreed that remote access tools will play a role in case support [38]. Salespeople who adopt digital marketing tools, virtual surgery support and operations technology will thrive in the post COVID market. Companies will likely tie compensation to the adoption of these new systems if tied to internal cost reductions.

Create clinician friendly digital marketing platforms - Digital marketing channels will soon overshadow traditional marketing efforts. Companies must resist the temptation to simply amplify the volume of digital content. The most successful marketeers will provide in-depth, high impact and truly useful content via mobile platforms. New product demonstration will also evolve to include cyber booths at medical conferences, virtual reality product detailing and surgical simulation, and product sample kits mailed directly to the physician for review.

Reimagine medical education activities - Stambaugh and colleagues considered lessons learned from the COVID-19 pandemic [39]. They described the evolution of orthopaedic

education and significant paradigm shifts necessary for continuing medical education and training of future thought leaders emphasizing that mentor relationships are critical even if limited. Surgeons desire and benefit from interpersonal connections and mentoring. Industry activities should help reimagine educational activity, not reinvent it. New training technologies and methods must be complimented by these important face-to-face interactions. Financial support for academic training should be prioritized along with virtual reality platform development. Mobile cadaveric training and remote proctoring that limits overnight travel will be in high demand. Broadcast surgical demonstrations with thought leader Q&A should be readily available via industry meeting websites, clinically based social media vehicles and/or proprietary media channels.

Innovation focused on healthcare sustainability and patient value - Michael Porter's observation that today's medical technology is delivered with outdated organizational structures, management practices, and pricing models has never been more relevant [40]. Delivering value for patients is more than just lowering costs and outcome measures, and this is paramount to determining value. Industry must accelerate new product development that considers the site of service and optimization of surgical efficiency in addition to improved clinical outcomes. Low or no capital investment is critical. Implant pricing will ultimately be tied to reported outcomes and reductions in cost of care. Manufacturers are exploring expanded product warranties and shared risk arrangements which add considerable value but only for those companies with exceptional medical education and clinical outcomes [41].

V. THE IMPACT OF THE PANDEMIC ON ORTHOPEDIC MEDICAL DEVICE MERGERS AND ACQUISITIONS - J. AVI ROOP, MBA

(VuMedi Video Link: https://www.vumedi.com/channel/codman-shoulder-society/tab/part-2a/video/pattern-recognition-post-pandemic-risk-management-impacts-on-orthopedics-ma/)

The Business Cycle Dating Committee of the National Bureau of Economic Research maintains a chronology of the peaks and troughs of U.S. business cycles. The committee has determined that a peak in monthly economic activity occurred in the U.S. economy in February 2020. The peak marks the end of the expansion that began in June 2009 and the beginning of a recession. The expansion lasted 128 months, the longest in the history of U.S. business cycles dating back to 1854. The previous record was held by the business expansion that lasted for 120 months from March 1991 to March 2001 [42].

Since March of 1991, an estimated $70 billion in mergers and acquisitions occurred within the orthopedic medical device industry. Prior to 1991, several large orthopedic device firms were held within larger pharmaceutical companies and many other major orthopedic device companies were small companies when compared to current standards. Howmedica was owned by Pfizer, DePuy was owned by Boehringer Manneheim then Roche, and Zimmer was owned by Bristol Meyers Squib.

In the first expansionary phase between 1991 and 2001, approximately $10 billion in consolidation deals occurred in addition to the spin out of Zimmer from BMS in an IPO carrying a $5 billion market capitalization. In 1991, Danek went public, merged with Sofamor in 1993, and subsequently was purchased by Medtronic in 1998 for $3.7 billion. In 1998 DePuy was purchased by Johnson and Johnson for $3.5 billion. Also, in 1998, Stryker purchased Howmedica for $1.7 billion. In the two recessionary years following the March 2001 peak, orthopedic device M&A activity collapsed to approximately $400 million in aggregate value.

In the second expansionary phase between 2003 and 2008, approximately $4.2 billion in consolidation deals occurred. Of note, $3.1 billion of those deals occurred in 2003 including the $2 billion purchase of Centerpulse by Zimmer. In the two recessionary years following the housing crisis, orthopedic device M&A activity collapsed to approximately $250 million in aggregate value.

In the third expansionary phase between 2011 and 2020, approximately $55 billion in consolidation deals occurred. Of note, the $22 billion acquisition of Synthes by Johnson & Johnson occurred in 2011 and approximately $44 billion of the $55 billion in deals occurred by 2014 including the initiation of the $13.4 billion merger of Zimmer and Biomet.

Over the years between 1991 and 2020, M&A activity in the orthopedic medical device industry was not dissimilar to M&A activity in the broader United States economy. Simplistically, broad economic growth typically supports scale, and the public markets typically *reward scale* when it portends enhanced *economies of scale*. Economies of scale are magnified in the healthcare sector because of high, and growing, barriers to entry. Smaller orthopedic medical device companies face a faster growth rate of barriers to entry due to expanding costs associated with satisfying the combination of increasing regulation and decreasing market access. Because the cost of surmounting healthcare specific regulation and access requires a significant up-front investment and because it does not directly scale with revenue, a larger firm holds a significant advantage in the market and has thus been rewarded for growth through merger and or acquisition.

Increasing regulation and decreasing market access for the orthopedic medical device industry have been largely driven by similar economies of scale rewards in the hospital/healthcare-delivery and insurance/payment industries. Payors, hospitals, and healthcare providers experience enhanced market power, enhanced limitation of liability, and more predictable profitability through consolidation. In their own best interest, the delivery side must reduce the number of vendors they work with and more closely control their operations to preserve these scale-based rewards. As we look at the years ahead, orthopedic medical device companies will continue will consolidate. However, how this activity will unfold over the next three to five years is uncertain and valuable to model.

To plan, it is critical to form an opinion on three key questions: First, what will be the duration of the contractile and trough phases of the current recession? Second, what will be the scope and scale of M&A activity during this period? Three, what types of acquisitions could transact at the beginning of the next expansionary phase? Based on historical patterns, it is reasonable to assume that the contractile and trough phases of this this recessionary period will last for at least two years. The COVID-19 pandemic is the nidus of this contraction; however, the duration of the lock-down phase combined with the economic stimulus response could significantly extend the time before we see economic expansion. Based on the current scope and scale of Federal Government economic stimulus, there has been a disconnect between the value of the US equity markets and US economic activity. If one assumes that equity markets will devalue 35% [43] after Federal stimulus runs out, on par with the 1Q20 5% annualized drop and the 2Q20 33% annualized drop in gross domestic product [44], then it is reasonable to assume that the current recessionary and trough phases could last until the first quarter of 2023. To model the scope and scale of M&A activity during the current recession we again look to prior patterns. In the prior two recessions, orthopedic medical device industry M&A activity dropped to 4% to 6% of the previous expansionary phase. Thus, it is possible that $2 billion to $3 billion in deals could occur over the next three years; however, the projected aggregate value could fall below $1 billion based on the dollar value of acquisitions in prior cycles. Finally, we have seen a pattern of pent up consolidation demand in a recession satisfied by a very large merger or acquisition shortly after the initiation of economic expansion.

CONCLUSION:

In considering the business of orthopedics in the context of the COVID-19 pandemic, we have provided the perspectives of many stakeholders in our healthcare market. From the perspective of industry, Eric Dremel has offered five broad recommendations. These require a collaborative approach and may contribute to a rapid, patient centric recovery. Industry should do everything possible to assist customers at this difficult time. Disruptive organizations that translate new market needs into efficient, value based, products and services will thrive. Ron Navarro has noted that the COVID-19 pandemic has created an opportunity for improvement of care to reimagine care from the traditional pathway via innovative lean management based on an expanded role for virtual care and better physician-patient engagement. The result should be patients obtaining earlier satisfaction and equivalent or better outcomes for orthopaedic conditions while delivering on the value proposition. Derek Haas has made the point that it is increasingly important for surgeons, hospitals, and surgery centers to rigorously understand their costs and cost drivers in order to successfully manage through the reduced and variable levels of demand for orthopedic care caused by COVID-19. He clarifies that Time-Driven Activity-Based Costing (TDABC) is a methodology providers can use to gain insight into the cost of care, and that this will help them manage their costs. TDABC methodology considers the individual providing care for each patient, how much time they are spending, and the cost of their time.

Jon Ticker has highlighted a number of opportunities for orthopedic group practices to consider given the reality of the pandemic. For practices to survive or maintain and thrive in this challenging environment, creative transformation touching all aspects of the practice will be required. This will include changes in the front and back office and with in-patient surgery as well as out-patient surgery. One opportunity to highlight is the potential for a group to deliver the entire episode of care. If management of the entire episode of care, from non-operative care to surgery to post-acute care, is in the control of an orthopedic group, this will give the group a competitive advantage over traditional fragmented care models that most orthopedic groups employ. Avi Roop has emphasized that major orthopedic product companies drastically reduce their merger and acquisition activity during market downturns in order to manage business risk. There is evidence that large deals can happen shortly after the business cycle shifts back to expansion. He notes that, historically, these risk adverse periods last for approximately two years. However, the pandemic combined with a potential correction in the public markets could expand the period of low M&A activity to three or more years. As JP Warner noted in Part I, adversity always creates challenges. From the COVID-19 pandemic, an opportunity has been offered for transformation of healthcare through innovation, with the goal to create value.

REFERENCES

1. https://https😕/en.wikipedia.org/wiki/COVID-19_pandemic_in_the_United_States
2. https://usafacts.org/issues/health-care/?utm_source=google&utm_medium=cpc&utm_campaign=ND-Healthcare&gclid=EAIaIQobChMImN-nAmNKx6wIVCo_ICh3-eQtUEAAYASAAEgK9-_D_BwE
3. https://en.wikipedia.org/wiki/Expenditures_in_the_United_States_federal_budget
4. https://www.boneandjointburden.org/fourth-edition/if1/direct-costs#:~:text=For the years between 2012,equivalent of 5.76%25 of the
5. Best MJ, Aziz KT, McFarland EG, Anderson GF, Srikumaran U: Economic implications of decreased elective orthopaedic and musculoskeletal surgery volume during the coronavirus disease 2019 pandemic. Int Orthop 2020; Published online 17 July 2020 doi.org/10.1007/s00264-020-04713-8
6. Halim A; Grauer JN: Orthopedics in the Era of COVID-19. Orthopedics 2020;43(3):138-139.
7. McIntyre LF, Cole BJ, Getelman MH, Stone JW, Stiefel EC, Sgaglione NA: The New Coronavirus and Practice Management Strategies to Keep Your Practice Alive and Well Q2-Q4 2020. March 31, 2020. https://www.aana.org/aanaimis/Members/News/at-

tend-aana-webinar-coronavirus.aspx?WebsiteKey=10f6eed0-bcab-4019-8f57-18dad8aaf2d7
8. McIntyre LF, Cole BJ, Getelman MH, Stone JW, Stiefel EC, Sgaglione NA: The Novel Coronavirus and Practice Management: Where We Are Now and How to Plan to Reopen Your Practice. April 17, 2020. https://www.aana.org/aanaimis/Members/News/attend-2nd-aana-webinar-coronavirus.aspx?WebsiteKey=10f6eed0-bcab-4019-8f57-18dad8aaf2d7
9. Ranuccio F, Tarducci L, Familiari F, Mastroianni V, Giuzio E: Disruptive Effect of COVID-19 on Orthopaedic Daily Practice A Cross-Sectional Survey. J Bone Joint Surg Am. 2020;102:e77(1-5)
10. Truumees E, Samora JB: Financial Fears and the COVID-19 Response. AAOS NOW, July 2020. https://www.aaos.org/aaosnow/2020/jul/commentary/commentary01/
11. Vaccaro AR, Getz CL, Cohen BE, Cole BJ, Donnally III CJ: Practice Management During the COVID-19 Pandemic. J Am Acad Orthop Surg 2020; 28(11):464-470.
12. Bosco JA: Every Challenge an Opportunity. AAOS Presidential Address, March 2020. https://www.aaos.org/annual/meetings-events/your-academy/your-academy-videos/
13. Hollander JE, Carr BG: Virtually Perfect? Telemedicine for Covid-19. N Engl J Med 2020; 382:1679-1681.
14. Lanham NS, Bockelman KJ, McCriskin BJ: Telemedicine and Orthopaedic Surgery: The COVID-19 Pandemic and Our New Normal. J Bone Joint Surg REVIEWS 2020;8(7):e20.00083
15. Makhni MC, Riew GJ, Sumathipala MG: Telemedicine in Orthopaedic Surgery Challenges and Opportunities. J Bone Joint Surg Am. 2020;102:1109-15.
16. Loeb AE, Rao SS, Ficke JR, Morris CD, Riley LH, Levin AS: Departmental Experience and Lessons Learned With Accelerated Introduction of Telemedicine During the COVID-19 Crisis. J Am Acad Orthop Surg 2020;28(11):e469-e476.
17. Mather RC, Myers K, Galan E, Wittstein J: Adapting Your Practice During the COVID-19 Crisis: Telemedicine and Patient Self-Examination in Orthopedics. March 30, 2020 https://www.vumedi.com/video/telemedicine-and-patient-self-examination-for-orthopedic-surgeons/?list=02b25a11-823d-4533-9bbf-a26d3ca0058e
18. Tanaka MJ, Oh LS, Martin SD, Berkson EM: Telemedicine in the Era of COVID-19: The Virtual Orthopaedic Examination. J Bone Joint Surg Am. 2020;102:e57(1-7).
19. Brolin TJ, Mulligan RP, Azar FM, Throckmorton TQ: Outpatient total shoulder arthroplasty in the ambulatory surgery center environment is a safe alternative to the inpatient hospital setting: a matched cohort study. J Shoulder Elbow Surg 2016:25;e318.
20. Buterbaugh KL, Liu SY, Krajewski A, Buterbaugh GA, Imbriglia JE: Safety of outpatient shoulder surgery at a freestanding ambulatory surgery center in patients aged 65 years and older: A review of 640 cases. J Am Acad Orthop Surg Glob Res Rev. 2018;2:e075
21. Erickson BJ, Shishani Y, Jones S, Sinclair T, Griffin J, Romeo AA, Gobezie R: Outpatient vs. inpatient reverse total shoulder arthroplasty: outcomes and complications. J Shoulder Elbow Surg 2020:29;1115-1120.
22. Goldfarb CA, Bansal A, Brophy RH. Ambulatory surgical centers: A review of complications and adverse events. J Am Acad Orthop Surg 2017;25:12-22.
23. Lewis HF, Sexton TR, Dolan MA: An Efficiency-Based Multicriteria Strategic Planning Model for Ambulatory Surgery Centers. Journal of Medical Systems 2011;35:1029-1037.
24. Qin C, Curtis DM, Reider B, Shi LL, Lee MJ, Athiviraham A: Orthopaedic Shoulder Surgery in the Ambulatory Surgical Center: Safety and Outcomes. Arthroscopy 2019;35(9):2545-2550.
25. Anoushiravani AA, O'Connor CM, DiCaprio MR, Iorio R: Economic Impacts of the COVID-19 Crisis An Orthopaedic Perspective. J Bone Joint Surg Am. 2020;102:937-41.
26. Blumenthal D, Fowler EJ, Abrams M, Collins SR: Covid-19 - Implications for the Health Care System. N Engl J Med 2020 Jul 22. doi: 10.1056/NEJMsb2021088. Online ahead of print.
27. Wu YC, Chen CS, Chan YJ. The outbreak of COVID-19: An overview. J Chin Med Assoc. 2020;83(3):217-220. doi:10.1097/JCMA.0000000000000270
28. Porter ME: What Is Value in Health Care? N Engl J Med 2010;363:2477-2481 .
29. Organize Care Around Medical Conditions. https://www.isc.hbs.edu/health-care/value-based-health-care/key-concepts/Pages/organize-care-around-condition.aspx. Accessed August 2, 2020.
30. Jayakumar P, Grogan Moore ML, Hill AD, Koenig KM: Integrated Practice Units: What Are They and How Can They Be Applied to Orthopaedic Trauma? J Orthop Trauma 2019;33(Suppl 7):S43-S48. doi:10.1097/BOT.0000000000001618
31. Navarro RA, Reddy NC, Weiss JN, Yates AJ, Fu FH, McKee M, Lederman ES: The Orthopaedic Forum. Orthopaedic Systems Response to and Return from the COVID-19 Pandemic: Lessons for Future Crisis Management. J Bone Joint Surg Am 2020;102A(14):e75(1-8). (published online: May 11, 2020). DOI: 10.2106/JBJS.20.00709.
32. Johanning JM, Arya S: Codman, Hawthorne, and end results of a watched system. JAMA Surg 2016;151(12):1165. doi:10.1001/jamasurg.2016.2901
33. American Academy of Ophthalmology. https://www.aao.org/practice-management/article/states-begin-easing-elective-procedure-restriction Accessed on August 9, 2020
34. Lecocq T, Hicks SP, Van Noten K, van Wijk K: Global Quieting of High-Frequency Seismic Noise Due to COVID-19 Pandemic Lockdown Measures." *Science*. First Release July 23, 2020. https://science.sciencemag.org/content/early/2020/07/22/science.abd2438
35. Kaplan RS, Porter ME: How to Solve the Cost Crisis in Health Care. Harv Bus Rev 2011;89(9):46-52.

36. Senior J: More People Will Be Fired in The Pandemic. Let's Talk About It. *The New York Times*. June 14, 2020 https://www.nytimes.com/2020/06/14/opinion/layoffs-coronavirus-economy.html?fbclid=IwAR0sJ9R5KKc0jWUvF9lIBUZQsWqBpKLx2Cm8Q8aE6lBFyMdZMoMTbi-jSDE
37. AAOS COVID-19 Member Resource Center, Surgical Volume Impact Survey, online June 2020 https://www.aaos.org/globalassets/about/covid-19/research/covid-19-surgical-volume-impact-survey-final.pdf
38. ExplORer Surgical Blog: MedTech Executive Survey, online June 2020 https://explorersurgical.com/blog/part-1-introduction-covid-19-causes-a-paradigm-shift-in-medtech-physician-interactions/
39. Stambaugh JB, Curtin BM, Gililland JM, Guild GM, Kain MS, Karas V, Keeney JA, Plancher KD, Moskal JT: The Past, Present, and Future of Orthopedic Education: Lessons Learned From the COVID-19 Pandemic. J Arthroplasty 2020;35(7):S60–S64. Published online 2020 Apr 18. doi: 10.1016/j.arth.2020.04.032
40. Redefining Health Care: Creating Value-Based Competition on Results – Harvard Business Review, May 25, 2006 ISBN 9781591397786
41. Filmore, D: Skin In The Game: Risk Sharing Models for MedTech. MedTech Strategist Market Pathways 2020;2.5:20-24.
42. Hall R, Gordon R, Poterba J, Ramey V, Romer C, Romer D, Stock J, Watson M: "NBER Determination of the February 2020 Peak in Economic Activity." The Business Cycle Dating Committee of the National Bureau of Economic Research (June 8, 2020). https://www.nber.org/cycles/general_statement.html" and replace it with "https://www.nber.org/cycles/june2020.html
43. Greene M, Hunter C: NABE Survey Shows Last Quarter One of the Worst Since Global Financial Crisis, But Sharp Rebound in the Three-Month Outlook. Business Conditions Survey, National Association for Business Economics July 2020. https://nabe.com/NABE/Surveys/Business_Conditions_Surveys/July_2020_Business_Conditions_Survey_Summary.aspx
44. Mataloni L, Pinard K: Gross Domestic Product, Second Quarter 2020 (Second Estimate) Corporate Profits, Second Quarter 2020 (Preliminary Estimate). Bureau of Economic Analysis, U.S. Department of Commerce August 2020. https://www.bea.gov/news/2020/gross-domestic-product-2nd-quarter-2020-second-estimate-corporate-profits-2nd-quarter

Submitted: September 17, 2020 EDT, Accepted: September 26, 2020 EDT