The Bulletin

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Summer, 2023

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Hello Everyone!

I am Dr. Kathryn Hosey, an OBGYN physician at WellSpan York Hospital and soon-to-be associate residency program director. It is with great excitement that I succeed the accomplished Dr. Catherine Bene as board president of the York County Medical Society. During her term, Dr. Bene worked towards fighting physician burnout by hosting a CME event and reconnecting YCMS members with the York County Bar Association for a social engagement to fundraise for a shared goal and connect with other professionals in the community. During my term I want to continue with her efforts to fight burnout by highlighting our members and their medical and non-medical accomplishments in an effort to rejuvenate our love for medicine.

The landscape of healthcare has shifted dramatically over the last several years and skepticism in physicians has grown through the pandemic. Trust is no longer automatically afforded to physicians based on our roles alone. Increased access to uncurated information along with the use of social media as a means to consume health-related content, challenges us to meet and connect with our patients in innovative ways. While this can feel exhausting and isolating, the YCMS offers both educational opportunities to advance professional development and social events to meet our peers and build comradery around our shared experiences.

Another aspect of the Medical Society that resonates strongly with me is that it provides a pathway for me to help shape the future of healthcare. As non medical entities seek to interfere with our patient-physician relationships and limit our shared decision making process, advocating on behalf of our patients and our peers becomes paramount.

Let's reclaim our joy in the practice of medicine together!
Kathryn Hosey, DO

LEVEL UP: Private Equity in Health Care

Last Updated: May 25, 2023

By PAMED President F. Wilson Jackson, III, MD
The opinions expressed within the content are solely the author's views.

There is an adage that beneath a farmer in overalls lies a land developer in a business suit. Over the years, many farmers have sold their farms to developers who then transition the property to housing, retail, or commercial use. Farmers legitimately have equity value in their property and depending on circumstances, have opportunity to monetize their land assets.

Recent trends in health care have independent physician practices selling an equity position in their privately held medical practices. Private equity (PE) firms have moved purposely for health care over the past few years. Those physicians in private practices have been able to capture value in their practices by selling, usually a minority position, but transferring managing control to investment firms. The private equity firms then "roll up" these acquisitions into similar specialty practices and in so doing, increase the value of the larger entity. Often these entities begin regionally, consolidating a series of medical or surgical practices to further increase the book value. Over time, many have grown to a national presence. This may be good for individual physicians and their investor partners but what is the potential impact on our larger health care delivery system, patient care and, ultimately, the cost of care?

Pennsylvania has seen its share of this activity amongst numerous specialties. While I could not find Pennsylvania specific data, nationally there has been a three-fold increase in PE deals in the US between 2010 and 2021. During this time, there were over a thousand PE transactions completed. Private equity is, of course, not new but its presence in purchasing medical practices is. PE has long had a presence in our economy as an investment vehicle, usually by public or privately held investment firms or banks who represent personal and institutional investors. In many ways, they are an engine of growth and innovation, having impacted many sectors of our economy. For example, they have been a significant driver to health care innovation through their investment in the bio-pharma industry. Up until recently, they have not engaged in privately held medical practices. Some years ago, sensing financial opportunity in a very fragmented industry, they moved purposely into many medical and surgical areas of patient care delivery; dermatology, ophthalmology, gastroenterology, pathology, and anesthesia to name a few. The business model is relatively simple. Usually there is a core acquisition of two or three specialty practices within a certain geographic area. The entity comes together under one tax ID number. Insurance contracts are optimized, and some administrative work is consolidated. For example, employee health care expenses may fall as the actuarial risk is spread over more individuals. I've read that a similar business model is followed with individually owned automated car washes rolling up to a larger, PE backed management organization. The umbrella organization increases the collective value of the individual car washes.

What does PE bring to health care delivery? PE investors will typically expand or strengthen existing service lines. This can certainly bring value to a community. For example, a PE fund may purchase a hospital and add a previously unavailable service such as cardiac catheterization. Admittedly, they will bring a business acumen and discipline to these growth decisions. PE purchases of medical practices could do likewise. PE owners are incentivized to find opportunity. Many physicians may welcome investors to bring investment capital that they may otherwise not be able to find or may come with unacceptable individual risk. PE firms can also bring administrative expertise and shore-up support services. Finally, they can help with recruiting new physicians. PE companies see considerable upside to their investment in privately held medical practices. Demographics alone provide a substantial tailwind with the health care needs of an aging population. We all know that Medicare reimbursement has not kept pace with the administrative cost of managing a medical practice. Further, the addition of increasing Medicare reporting requirements such as MIPS has pushed many physicians in private practice to look towards PE firms for help. Private equity can improve efficiency by bringing administrative expertise to these medical practices.

(LEVEL UP: Private Equity in Health Care cont.) What is the long-term consequence of this transition? Health care is and should be different than car washes. Although PE deals can be attractive to the physicians in a position to monetize their practices, what are the downstream effects? The goal of a PE firm is to make a short- or medium-term financial gain, not to be a long-term shareholder in the medical field.

Fundamental to PE investors of medical practices, is that a primary vehicle to purchase privately held medical practices is through a leveraged buyout. This debt financing provides cash for the medical practice enabling them to invest in additional service lines, infrastructure and improve recruiting clout. Through the new entity, the practice takes on more debt but oftentimes the physician owners become stock owners in the new management service organization. Fund managers get paid from some of the profit the practices generate. PE will typically hold an entity for 3 to up to 10 years and then sell. The profit is the difference between the total acquisition costs of the individual medical practices and the final sale price typically pegged to some multiple of EBITDA. I am told that the exit can be profitable, especially for the early investors who took on the initial risks. For example, a large PE backed gastroenterology consortium originally based in Florida, grew substantially through a series of purchases of other gastroenterology practices and backed by further investment, exited with a sale price of around $950 million. The buyer was OMERS (OMERS – Ontario Municipal Employee's Retirement System) which is the defined benefit pension fund for over 500,000 municipal workers in the Province of Ontario, Canada. In essence, part of the profit from the patient care efforts of the physicians within this large consortium of GI practices, now finds its way into the retirement fund for pensioners in Ontario. (As an aside, I find some wry irony that a municipal pension fund in a country with a public health system would invest in a US based GI medical practice). What is the impact to health care costs? There is some data. The below study by Singh et. al. published in *JAMA Health Forum*[1] looked at the before and after PE acquisition on unit cost of care. The study looked specifically at dermatology, gastroenterology, and ophthalmology. Care costs went up through higher reimbursement. The increased reimbursement may have been driven by improved documentation to enable higher billing, better discipline around accounts receivables or, as a larger entity, better leveraged insurance contracting. I suspect a combination of the three and perhaps other factors. Not included in this study was measurements of care quality.

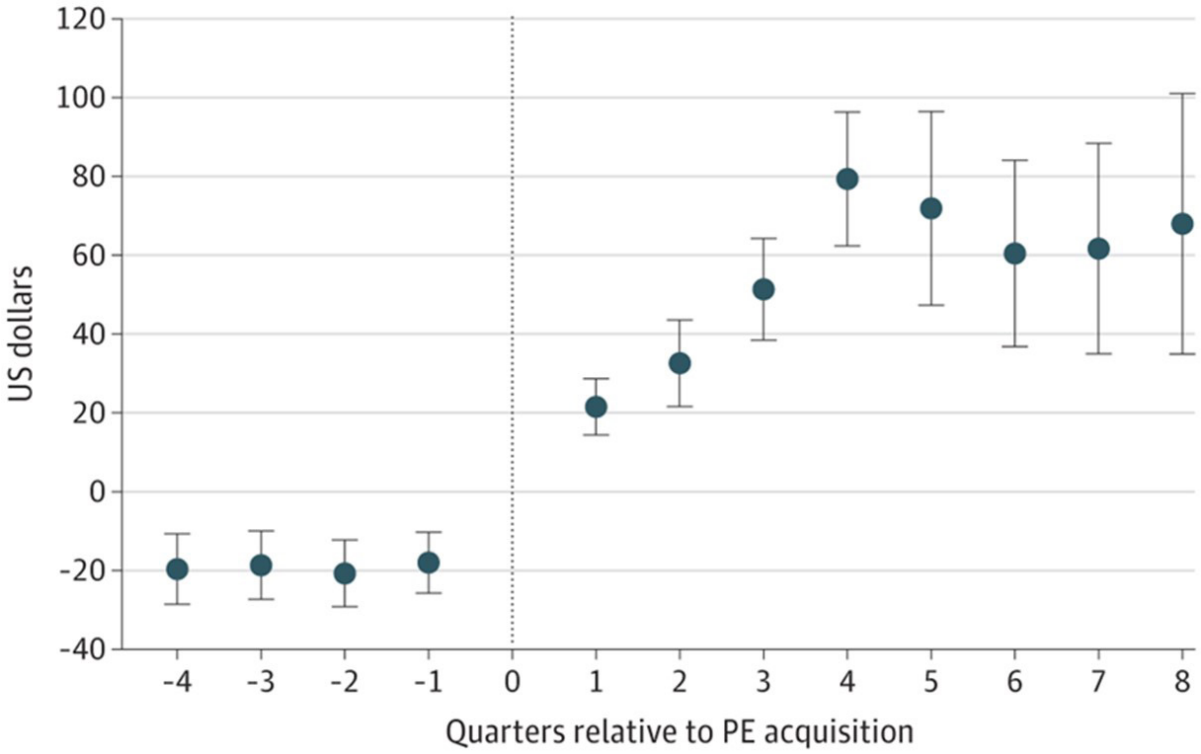


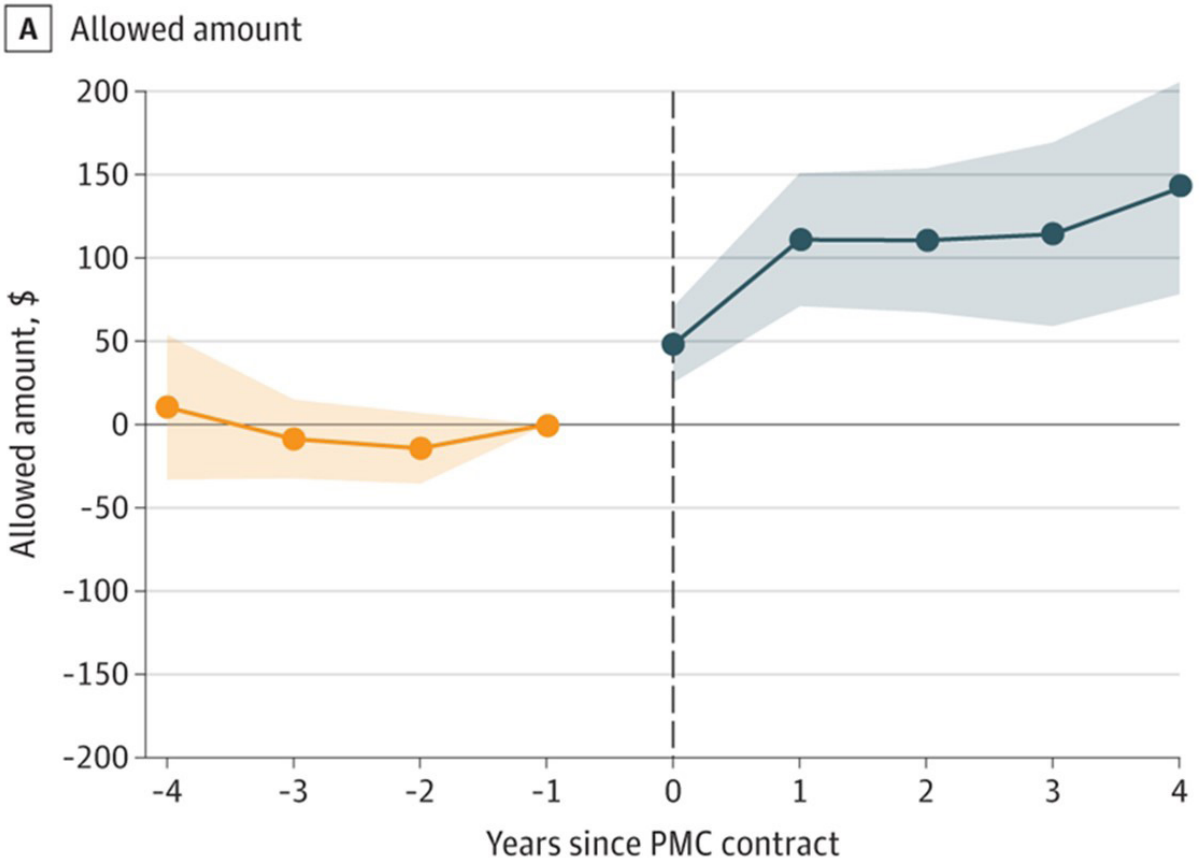
Table 2. Differential Change in Practice Patterns for PE- and Non–PE-Acquired Physician Practices[a]

	PE-acquired practices		Controls		Unadjusted	Adjusted		
Variables	Before	After	Before	After	DiD	DiD	% (95% CI)	*P* val
Allowed amount/claim, $	206.0	285.0	201.0	260.0	20.0	22.8	11.0 (5.6 to 16.5)	<.00
Utilization								
Unique patient	105.0	147.0	93.0	108.0	27.0	27.1	25.8 (15.8 to 35.6)	<.00
New patient	57.0	89.0	47.0	57.0	22.0	21.6	37.9 (25.6 to 50.2)	<.00
Practice patterns								
Charge/claim, $	353.0	514.0	372.0	474.0	59.0	71.4	20.2 (13.1 to 27.3)	<.00
Patient HCC score	1.2	1.3	1.4	1.5	-0.1	0.01	1.0 (-2.4 to 4.8)	.64
E&M visit >30 min								
Established patient, %	0.2	0.2	0.2	0.2	0.0	0.01	9.4 (1.7 to 17.0)	.03
New patient, %	0.3	0.3	0.3	0.3	0.0	0.02	5.8 (-3.2 to 14.8)	.21
E&M visit	86.3	115.7	77.0	90.2	16.0	32.0	37.1 (-48.5 to 122.5)	.40
Encounters	138.1	191.1	123.8	143.5	33.0	91.0	16.3 (1.0 to 32.0)	.04

Abbreviations: DiD, difference in differences; E&M, evaluation and management; HCC, Hierarchical Condition Category; PE, private equity.

[a] Unadjusted and adjusted differential changes in outcome variables averaged at the practice level for PE practices and matched controls. Adjusted regression coefficients were estimated using a linear DiD model that included specialty fixed-effects and was weighted by average patient volume per practice over the study period. Standard errors were clustered at the level of the matched cohort. Regressions with m of patient volume as dependent variables (ie, total No. of unique patients ar patients) are unweighted. Adjusted percentage differential change was calcu dividing the adjusted differential change obtained from the DiD regression, preacquisition mean for PE-acquired practices. DiD are between PE-acquire and controls or the differential change.

There is another study published in *JAMA Internal Medicine*[2] that looked specifically at anesthesia practices before and after PE ownership. Similar to the JAMA study, cost per care encounter increased.



What about our commonwealth, Pennsylvania? An August 2021 PA Department of Health report examined "Health Care Resiliency" in our state.[3] It was done to assess our health care system's adaptation through Covid-19. Part of the report, however, examined the impact of PE in our state. They concluded; "These findings align with academic research suggesting PE firms target already profitable facilities while focusing on rapidly

 improving bottom line profitability. "

This is not to say PE does not bring resources and in fact many PE owned hospitals as well as nursing homes fared well through the Covid-19 crisis.

To be clear, however, the primary objective of private equity is profit. Hospital CEOs and Boards often say, "no profit, no mission." Private equity ownership increases revenue per patient encounter as demonstrated in the two above studies. I would submit, however, that the primary objective of medical practices and the physicians who work in that practice is patient care. The danger is that the focus on patient care can become secondary to the financial business of medicine.

Different from other sectors of our economy is that the consumer in health care is the patient. Patient care has appropriately been central to the remarkable growth of our health care industry. A differentiator of health care from other economic sectors, however, is the lack of transparency to the cost of care. You know the cost to run your car through an automated carwash. You can also choose to pay a surcharge for additional cleaning. The consumer cost for health care is too often opaque. It is also difficult for the average patient, without specialized medical knowledge, to make a judgement about the quality of their medical care. Another and important differentiator of health care cost is the substantial government subsidy unlike other business sectors where PE has also made substantial investment. Has quality followed the post PE acquisition increased reimbursement as one would expect – do we pay more for higher quality?

PE owned medical practices earn more per patient encounter after PE acquisition but what about quality? There is some available data on care quality delivery after PE acquisition in the health care delivery space. One study published in *JAMA Health Forum* **[4]** in 2021 examined nursing homes acquired by PE firms. The study found about a 10% increase in emergency room visits, hospitalizations, and Medicare costs following PE acquisition. Other studies of nursing home quality measures after PE acquisition have demonstrated increased rates of bedsores and other patient care quality measures of PE owned nursing homes compared to a reference cohort.

I have previously commented on consolidation in health care delivery systems and the impact on cost of care without a commiserate increase in care quality.**[5]** One can draw higher cost of care parallels between increasingly consolidated integrated delivery networks and rolled up PE backed medical practices. Unfortunately, there is currently a dearth of data on quality care metrics amongst medical and surgical practice before and after PE purchase.

Who is in charge? The FTC has little to no jurisdiction in the PE acquisitions of individual medical practices. Oftentimes, the PE purchases of medical practices are small scale and fall well below the reporting requirements of the Hart-Scott-Rodino Act criteria. **[6]**

A final question is what plays out down the road, and specifically once the original PE investors exit and a new, oftentimes, institutional investor takes ownership? There is little published research data. One paper published examined the leveraged buyout of a very large hospital system, HCA.**[7]** One conclusion from the study; "The behavior change implies the corporate chain decided to improve inpatient revenue streams by ratcheting up the quantity of hospital stays—despite the marginal hospitalizations having questionable medical necessity. Insurers would presumably have a salient financial interest in curtailing such a strategy but failed to do so—even years later." There was not, however, a material decrease in care quality. I could find not published literature on the care impact by PE on previously independent medical practices. It is still a nascent industry. Payers, however, are likely taking notice.

We ultimately will want to align the PE investors with physicians, taxpayers and, most importantly, the patients. Is there a sweet spot? We cannot roll back the current trends of consolidation in the marketplace and return to the days of individual physicians making house calls. It now becomes imperative for physicians to stay involved in high levels of the decision-making process in whatever health system they find themselves. There needs to be

Installation Ceremony Photos

Dr. Catherine Bene presents 50 Year Service Award to Dr. Marsha Borndt

Dr. Catherine Bene presents 25 Years of Service Award to Dr. Alyssa Moyer

Society President Dr. Kathryn Hosey presents Outgoing President plaque to Dr. Catherine Bene

Dr. Catherine Bene presents 25 Year Service Award to Dr. Matthew Howie

FDA Approves First Oral Antiviral for Treatment of COVID-19 in Adults

May 25, 2023

Today, the U.S. Food and Drug Administration approved the oral antiviral Paxlovid (nirmatrelvir tablets and ritonavir tablets, co-packaged for oral use) for the treatment of mild-to-moderate COVID-19 in adults who are at high risk for progression to severe COVID-19, including hospitalization or death. Paxlovid is the fourth drug—and first oral antiviral pill—approved by the FDA to treat COVID-19 in adults.

Paxlovid manufactured and packaged under the emergency use authorization (EUA) and distributed by the U.S. Department of Health and Human Services will continue to be available to ensure continued access for adults, as well as treatment of eligible children ages 12-18 who are not covered by today's approval. Paxlovid is not approved or authorized for use as a pre-exposure or post-exposure prophylaxis for prevention of COVID-19.

"While the pandemic has been challenging for all of us, we have made great progress mitigating the impact of COVID-19 on our lives," said Patrizia Cavazzoni, M.D., director for the FDA's Center for Drug Evaluation and Research. "Today's approval demonstrates that Paxlovid has met the agency's rigorous standards for safety and effectiveness, and that it remains an important treatment option for people at high risk for progression to severe COVID-19, including those with prior immunity. The FDA remains committed to working with sponsors to facilitate the development of new prevention and treatment options for COVID-19." Under the Federal Food, Drug, and Cosmetic Act, approval of a new drug requires, among other things, substantial evidence of effectiveness and a demonstration of safety for the drug's intended use(s). In considering approval of a drug, the FDA conducts a benefit-risk assessment based on rigorous scientific standards to ensure that the product's benefits outweigh its risks for the intended population.

The efficacy of Paxlovid was primarily supported by the final results of the EPIC-HR clinical trial. EPIC-HR was a randomized, double-blind, placebo-controlled clinical trial studying Paxlovid for the treatment of non-hospitalized symptomatic adults with a laboratory confirmed diagnosis of SARS-CoV-2 infection. Patients were adults 18 years of age and older with a prespecified risk factor for progression to severe disease or were 60 years and older regardless of prespecified chronic medical conditions. All patients had not received a COVID-19 vaccine and had not been previously infected with COVID-19. Paxlovid significantly reduced the proportion of people with COVID-19 related hospitalization or death from any cause through 28 days of follow-up by 86% compared to placebo among patients treated within five days of symptom onset and who did not receive COVID-19 therapeutic monoclonal antibody treatment. In this analysis, 977 patients received Paxlovid, and 989 patients received placebo, and among these patients, 0.9% who received Paxlovid were hospitalized due to COVID-19 or died from any cause during 28

Cont. on page 8

days of follow-up compared to 6.5% of the patients who received the placebo.
Benefit of Paxlovid was observed in patients with prior immunity to the virus that causes COVID-19. Among patients in EPIC-HR who were antibody positive at trial enrollment, the risk of COVID-19-related hospitalization or death from any cause during 28 days of follow-up was 0.2% among the 490 patients treated with Paxlovid compared with 1.7% of the 479 patients receiving placebo. EPIC-SR was another clinical trial that enrolled vaccinated patients with at least one risk factor for progression to severe COVID-19. Although not statistically significant, among these vaccinated patients, there was a reduction in the risk of COVID-19 related hospitalization or death from any cause.

FDA Approves New Buprenorphine Treatment Option for Opioid Use Disorder

May 23, 2023

Today, the U.S. Food and Drug Administration approved Brixadi (buprenorphine) extended-release injection for subcutaneous use (under the skin) to treat moderate to severe opioid use disorder (OUD).

Brixadi is available in two formulations, a weekly injection that can be used in patients who have started treatment with a single dose of a transmucosal buprenorphine product or who are already being treated with buprenorphine, and a monthly version for patients already being treated with buprenorphine.

"Buprenorphine is an important treatment option for opioid use disorder. Today's approval expands dosing options and provides people with opioid use disorder a greater opportunity to sustain long-term recovery," said FDA Commissioner Robert M. Califf, M.D. "The FDA will continue to take the critical steps necessary to pursue efforts that advance evidence-based treatments for substance use disorders, which is a strategic priority under the FDA's Overdose Prevention Framework."

Buprenorphine is a safe and effective medication for the treatment of OUD. According to the Substance Abuse and Mental Health Services Administration (SAMHSA), patients receiving medication for their OUD cut their risk of death from all causes in half.

The FDA continues to implement a comprehensive approach to increase options to treat OUD. Earlier this month, the agency issued a joint letter with SAMHSA to clarify the importance of counseling and other services as part of a comprehensive treatment plan for OUD, and to also reiterate that supplying buprenorphine should not be made contingent upon participation in such services. The agency also held a virtual public workshop that highlighted the need for additional strengths and dosing regimens for extended-release formulations.

Brixadi is approved in both weekly and monthly subcutaneous injectable formulations at varying doses, including lower doses that may be appropriate for those who do not tolerate higher doses of extended-release buprenorphine that are currently available. The weekly doses are 8 milligrams (mg), 16 mg, 24 mg, 32 mg; and the monthly doses are 64 mg, 96 mg, 128 mg. The approved weekly formulation in various lower strengths offers a new option for people in recovery who may benefit from a weekly injection to maintain treatment adherence. Brixadi will be available through a Risk Evaluation and Mitigation Strategy (REMS) program and administered only by health care providers in a health care setting.

The most common adverse reactions (occurring in ≥5% of patients) with Brixadi include injection-site pain, headache, constipation, nausea, injection-site erythema, itchy skin at the injection site (injection-site pruritus), insomnia and urinary tract infections.

The safety and efficacy of Brixadi were evaluated in a behavioral pharmacology study assessing the ability of two weekly doses of Brixadi to block the subjective effects of opioids, and one randomized, double-blind, active-controlled clinical trial in 428 adults with a diagnosis of moderate-to-severe OUD. After an initial test dose of transmucosal buprenorphine, patients were randomized to treatment with Brixadi plus a sublingual placebo, or active sublingual buprenorphine plus placebo injections. After titration over the first week, patients were

(Continued on page 10)

treated with weekly injections over 12 weeks and then transitioned to monthly injections for an additional 12 weeks. A response to treatment was measured by urine drug screening and self-reporting of illicit opioid use during the treatment period. Patients were considered responders if they had negative opioid assessments at the end of each of the two treatment phases. The proportion of patients meeting the responder definition was 16.9% in the Brixadi group and 14.0% in the sublingual buprenorphine group.

The agency remains focused on responding to all facets of substance use, misuse, substance use disorders, overdose and death in the U.S. through its FDA Overdose Prevention Framework. The framework's priorities include: supporting primary prevention by eliminating unnecessary initial prescription drug exposure and inappropriate prolonged prescribing; encouraging harm reduction through innovation and education; advancing development of evidence-based treatments for substance use disorders; and protecting the public from unapproved, diverted or counterfeit drugs presenting overdose risks.

The Debt Ceiling and the United States Economy Post Covid-19

By: Wayne A. Wolfe, Adjunct Professor of Economics, Wilkes University, Wilkes-Barre PA
wayne.wolfe@wilkes.edu June 3, 2023

The recent debate over raising the United States debt ceiling highlights an important reality as we move forward together after Covid-19, and that is the need to address the Federal levels of debt, driven higher by the necessities of battling Covid-19 and its aftermath. In this short article I hope to bring added perspective to that question post Covid-19.

As we know, last month the head of the UN World Health Organization declared an end to Covid-19 as a public health emergency. We do not need to look extremely far to recognize the effects of Covid-19, whether in the loss of human life, opportunity cost, or the way we live our lives today compared to the way we lived prior to the pandemic.

Much of the recent debate I read and heard over the debt ceiling reminded me of the analogy of focusing on a hole in a barn door but ignoring the door itself. Debt ceilings have been raised on more than 40 occasions since the early 1980's. The U.S. National Debt has grown during that time to more than thirty-one ($31 T) trillion dollars and there is no end to that growing number in our immediate future.

The real question is at what point will the increased national debt generate negative externalities which promote public interest in the effects of the debt on our quality of life. Let me suggest one overarching reality: the national debt creates what we call in Economics, the function of "Crowding Out."

"Crowding Out" is a term describing the effects of increasing government debt and the payments required to service that debt, resulting in promoting higher interest rates and effectively crowding out the more important long-term aspects of the economy such as increased productivity, through borrowing to make capital improvements or investments in improving technologies.

In short, the old analogy of economics "there is no free lunch" proves once again to be true. Resources targeted to service debt cannot be used simultaneously for the other good things they might have been used for, in short, the increasing debt is a major lost opportunity for our growth and development. It promotes inflation and misery. It is a weight which holds down the productive capacity of our economy to provide the opportunities we all agree are important.

The answer to the problem of the increasing Federal National Debt is reducing the size and scope of the Federal government and to reduce Federal government spending. This will serve to reduce the crowding out effect and unleash the creative capacities of United States citizens and business entities as well as those outside the United States who are interested in investing here. Such approaches, having proved themselves in the past, should promote a healthy and vibrant economy as we look to the future.

UPCOMING EVENTS

AUGUST 26TH – PICKLEBALL TOURNAMENT – 1:00 P.M. – 4:00 P.M. Veterans Memorial Park $35.00 PP. Sponsored by York County Medical Society and York County Bar Association. Check YCMS website at www.yorkcomedsoc.org or e-mail lizycms@comcast.net , or register Cheryl.kauffman@yorkbar.com A liability waiver will need to be completed. Checks and liability waivers can be mailed to YCBA, 137 E. Market St., York, Pa. 17401 or register at https://shorturl.at/PGHK7

Society proceeds to benefit York Opioid Coalition.

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(LEVEL UP: Private Equity in Health Care cont.) a physician presence in high level management and at the health system board level and now within the PE board of directors and not only a presence on subsidiary committees. Otherwise, the core principle of compassionate and quality patient care runs the danger of becoming secondary within the very institutions that patents turn to for their health care needs.

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[2] La Forgia A, Bond AM, Braun RT, et al. **Association of Physician Management Companies and Private Equity Investment With Commercial Health Care Prices Paid to Anesthesia Practitioners**. *JAMA Intern Med.*2022;182(4):396–404. doi:10.1001/jamainternmed.2022.0004

[3] https://www.health.pa.gov/topics/Documents/Facilities%20and%20Licensing/PA%20DOH%20Health%20Care%20Resiliency.pdf

[4] Braun RT, Jung HY, Casalino LP, Myslinski Z, Unruh MA. **Association of Private Equity Investment in US Nursing Homes With the Quality and Cost of Care for Long-Stay Residents**. JAMA Health Forum. 2021 Nov 19;2(11):e213817. doi: 10.1001/jamahealthforum.2021.3817. PMID: 35977267; PMCID: PMC8796926.

[5] https://www.pamedsoc.org/list/articles/level-up

[6] https://www.ftc.gov/enforcement/premerger-notification-program.

[7] https://www.rand.org/content/dam/rand/pubs/working_papers/WRA600/WRA621-7/RAND_WRA621-7.pdf