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## All Health Care Is Local: Exploring the Roles of Cities and States in Health Care Delivery and Reform Industry Panel

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ALL HEALTH CARE IS LOCAL: EXPLORING  
THE ROLES OF CITIES AND STATES IN  
HEALTH CARE DELIVERY AND REFORM

INDUSTRY PANEL

PANELISTS:

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ANDREW McDONALD, *LPMC FAMILY OF COMPANIES*  
JULIE WATSON LAMPLEY, *BUTLER SNOW, LLP*  
KIM LOONEY, *WALLER LANSDEN DORTCH & DAVIS, LLP*

*Moderated by Craig Stewart, Bass, Berry & Sims, PLC*

FEBRUARY 9, 2018

**Mr. Stewart:** Thanks, Julianne, for the introduction. Thanks to the students who are working on the Belmont Health Law Journal for organizing this event and for allowing me to participate. Thanks to all the audience members for returning to the second session of the day, welcome back. We are lucky to have four, wonderful, accomplished, insightful, intelligent and experienced panelists, who I am happy to introduce.

To my immediate right, is Kim Looney. Kim is a partner at *Waller* here in town. She advises healthcare providers on day-to-day operational issues such as recruitment and employment and regulatory issues such as ongoing compliance with STARK and federal and state anti-kickback regulations. She earned her law degree from Vanderbilt University and her B.S. in Business Administration from the University of Tennessee. Kim currently serves on the board of directors of the American Health Lawyers Association (AHLA) and she previously served as the vice-chair of the AHLA's physician organization's practice group. She frequently speaks at state and national teleconferences and seminars on a wide range of healthcare topics and she's recognized by Chambers USA

for her healthcare regulatory experience, and by Best Lawyers in the category of healthcare law.

To Kim's immediate right, is Jay Hardcastle, who is a partner at *Bradley*. He advises hospitals, surgery centers, physicians with a particular emphasis in radiology, long-term care providers, imaging centers, cancer centers, and other participants in the healthcare industry in connections with joint venture formation, general regulatory issues, corporate matters, and the purchase and sale of healthcare facilities. Jay also focuses on drafting contracts for providers and physicians, advising clients on Medicare and Medicaid issues, providing assistance in the defense of whistleblower claims, and advising tax-exempt entities in healthcare areas. He's a member of the AHLA; the National Bar Association—he's the former chair of the health law committee; the Tennessee Bar Association—former chair of the health law section; and the American Bar Association—a member of the health law section. Jay has served on many boards of directors of local non-profits, interestingly, including the boards of the Nashville Symphony, Friends of Radnor Lake, the conservancy for Centennial Park and the Parthenon, as well as Nashville Table, now part of the Second Harvest Food bank.

To Jay's immediate right, is Julie Watson-Lampley from *Butler Snow*. She's the practice group leader of the healthcare regulatory and transactions group. She focuses on healthcare law, commercial contracting, mergers and acquisitions and anti-trust law. Her experience includes the broad representation of pharmaceutical and medical device companies, including both publicly held and privately owned pharmaceutical manufacturers, medical device companies, and research organizations. Julie has provided advice and services regarding Stark, anti-kickback, anti-trust issues, privacy policies and programs, compliance programs, manage care contracting, physician recruitment and employment, hospital-based physician contracting, entity formation and operation, and issues related to tax-exempt healthcare providers.

To my far right is our final panelist, Andrew McDonald. As shareholder in charge of healthcare consulting at LBMC, PC, and owner and operator of LBMC Physician Business Solutions, LLC, Andrew works with a team of experienced healthcare professionals that possess diverse backgrounds in accounting, coding, compliance, financial analysis, hospital and physician integration, IT consulting, revenue cycle, transaction advisory services, and other healthcare management services. Andrew is a graduate of the University of Alabama with a bachelor's degree in commerce and

business administration and a master of science degree in hospital and health administration from the University of Alabama at Birmingham. The American College of Healthcare Executives recognized Andrew as a fellow of the college in 1994, highlighting his commitment to the highest standards of executive performance, community leadership, and continuing education for the betterment of patient care through outstanding leadership in healthcare entities.

So between the four of them, we've covered just about every conceivable healthcare industry item. It's my great joy to introduce them; we've got a great group of panelists. Let's briefly thank them for their time.

[applause]

Let's jump right in. I'm going to try to reserve 10 minutes for questions at the end, but we'll see how the discussion goes.

As is the theme of today--all healthcare is local—the federal government appears to be putting more emphasis on states regulating healthcare. For example, as the previous panel mentioned, the Trump administration recently announced a policy to have work requirements for able-bodied Medicaid beneficiaries.<sup>1</sup> From an industry perspective, how do you see this shift impacting our healthcare industry here in Tennessee as well as clients in other states? For this one, Kim, can you get us kicked off?

**Ms. Looney:** I think this is definitely a trend that a lot of states have already jumped on board with.<sup>2</sup> I think I saw that Tennessee is looking to do this as well.<sup>3</sup> I don't think it's necessarily a bad thing to give more control to the states. I'm just not sure how well having this work requirement, in addition to the many other requirements we have on Medicaid, would work.

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<sup>1</sup> See Exec. Order No. 13,828, 83 Fed. Reg. 15941 (Apr. 10, 2018), available at <http://www.federalregister.gov/documents/2018/04/13/2018-07874/reducing-poverty-in-america-by-promoting-opportunity-and-economic-mobility/>.

<sup>2</sup> Currently, Arkansas, Indiana, and New Hampshire have an approved Section 1115 waiver from CMS that implement some form of work requirements in their Medicaid programs. Another seven states, Arizona, Kansas, Maine, Mississippi, Ohio, Utah, and Wisconsin have pending Section 1115 waivers from CMS that would implement similar work requirements. See generally *Medicaid Waiver Tracker: Which States Have Approved and Pending Section 1115 Medicaid Waivers?* KAISER FAM. FOUND., <https://www.kff.org/medicaid/issue-brief/which-states-have-approved-and-pending-section-1115-medicaid-waivers/> (last modified Jul. 26, 2018).

<sup>3</sup> See 2018 Tenn. Pub. Acts 869 (H.B. 1551).

I think that partly, it will be difficult to administer. I think it would be difficult for the state and I think that, from the standpoint of the client—any of the providers—it could actually adversely impact the people that they currently provide services to who may be on Medicaid.

Something else one of the other states is doing is changing from offering Medicaid to people up to 138% of the poverty level and bumping it back down to the poverty level.<sup>4</sup> That is going to make a difference as well. The thinking is that in some ways this shifts the burden of providing care to the federal government. At the end of the day, this is still something that is going to be difficult to administer and it's going to be hard for the clients because if it's going to impact the people that are covered, it's going to be hard for them to get reimbursement.

One of the things I also thought was interesting is that there are a number of advocacy groups that have challenged that requirement. It's been approved by the federal government that you can have a work requirement and that's been challenged in Kentucky. There's a class action suit and the Southern Law Poverty Center, the National Health Law Program and the Kentucky Equal Justice Center are all challenging that,<sup>5</sup> so I think it will be interesting to see how that works out.

**Mr. Stewart:** Did anyone else want to chime in? I think this is an interesting topic. Kim had suggested there might be an adverse impact and difficulty in administration. I thought that was an interesting point.

**Mr. Hardcastle:** What this means to me, as someone who's really been with providers for most of my career, is less money. That's what I hear when I hear this. And I don't mean that as a bad thing—it may be that less money is okay, but that is what I hear when I hear

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<sup>4</sup> Arkansas and Massachusetts have sought to reduce the income eligibility level for Medicaid beneficiaries to be set at 100% of the Federal Poverty Level. However, both of these requests have been denied by CMS “at this time.” *See generally* Centers for Medicare & Medicaid Services (for Massachusetts, available at <https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/ma/ma-masshealth-ca.pdf>), (Jun. 27, 2018); for Arkansas, available at <http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/ar/ar-works-ca.pdf>), (Mar. 5, 2018)).

<sup>5</sup> *See* Stewart v. Azar, No. CV 18-152 (JEB), 2018 WL 3203384 (D.D.C. Jun. 29, 2018).

“block grants”<sup>6</sup>, when I hear “per capita caps.”<sup>7</sup> I don’t hear anyone saying “we’re going to give you more money than we used to give you for doing the same thing. In fact, it’s just like a lot of industries under pressure, including professional industries, where clients are asking for the same thing for less money. And they may be asking for different things for less money.

I think if we’re going to go that route, and I think we are—since healthcare as a portion of the GDP is so high now,<sup>8</sup> we’re all going to be working just to pay our health insurance premiums and it’s this giant thing where we may all be working for health insurance companies and providers to pay our health insurance premiums—we’re going to have to stop thinking along the lines we’ve always thought and maybe take some sacred cows off the table and not focus on legal absolutes.

So, for example, it’s been a long-time thesis in the private bar and compliance departments and enforcement mechanisms at the state and federal level that the purity of the referral decision cannot be corrupted by money.<sup>9</sup> It’s been a big thing among the

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<sup>6</sup> A “block grant” is a grant from the government to be used for a specific service offered by the State. In the context of Medicaid, states would get a fixed amount of federal grants that would be based on the state and federal Medicaid spending in that state. *See* Shefali Luthra, *Everything You Need To Know About Block Grants – The Heart Of GOP’s Medicaid Plans*, KAISER HEALTH NEWS (Jan. 24, 2017), <http://khn.org/news/block-grants-medicaid-faq/>.

<sup>7</sup> A “per capita cap” is a grant from the federal government based on the number of people in a particular program. Thus, in the Medicaid context, federal funding per enrollee would be capped at a fixed amount, and then multiplied by the number of enrollees. *See* Robin Rudowitz, *5 Key Questions: Medicaid Block Grants & Per Capita Caps*, KAISER FAM. FOUND. (Jan. 31, 2017), <http://www.kff.org/medicaid/issue-brief/5-key-questions-medicaid-block-grants-per-capita-caps/>.

<sup>8</sup> As of 2016, healthcare spending grew to \$3.3 trillion, or \$10,348 per person, equaling 17.9% of the GDP. Healthcare spending is projected to grow at an average rate of 5.5 percent per year for the 2017-2026 period, reaching an estimated total of \$5.7 trillion in healthcare spending by 2026. *See* Centers for Medicare & Medicaid Services: NHE Fact Sheet (last modified Apr. 17, 2018, 8:29 AM), *available at* <https://cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/nationalhealthexpenddata/nhe-fact-sheet.html/>.

<sup>9</sup> Many professions, such as the practice of medicine and law, are often forbidden from referring patients or clients that will result in a financial gain to the referring person (*see* 42 U.S.C. § 1395nn, also known as the “Stark” law, which generally prohibits physicians from making a referral to another entity in which that physician has a financial relationship; *see also* Model Rules of Professional Conduct r. 5.4 (Am. Bar Ass’n, 8th Ed. 2015), which, in relevant part, prohibits lawyers from permitting a person who refers, employs, or pays the lawyer to

commercial consultants and the anti-trust bar and the FTC and the DOJ that scale is bad and that corroboration can deepen vertical sorts of scales, and can create heavy market power in one area that can be very disruptive for society as a whole. In the tax exemption area, there are plenty of folks that have grown up in an environment where venturing outside of your core charitable mission is bad,<sup>10</sup> and creates some exemption risks and in, of course, Stark areas—very, very technical, it's sort of like the kickback areas—feeling amongst the private bar, enforcement mechanisms, and compliance departments if you step outside the guidelines, you could get in really big trouble and that is the current state of affairs. I think if we're going to go this route and start thinking that you need to toss everything into a giant public policy blender and think what the best outcome is and not skew so closely to those former sacred cows.

And there's some thinking in Congress and CMS that it might be okay, and even in the DOJ and FTC and states' Attorney Generals as they look at anti-trust enforcement. The anti-trust folks have healthcare principles that have been out for a long time that relax enforcement amongst certain cooperative activities that create anti-trust concerns.<sup>11</sup>

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render legal services for another, from regulating or influencing “the lawyer’s professional judgment in rendering such legal services.”)

<sup>10</sup> The joint venture structure between non-profit and for-profit hospitals has, in many cases, jeopardized the tax-exempt status of nonprofit hospitals. By working with a for-profit hospital, a nonprofit hospital risks venturing outside of its charitable purpose (providing care to the poor and the community at large), as a for-profit hospital largely operates to benefit private, not public, interests. This, in turn, can result in the revocation of a nonprofit hospital’s tax-exempt status. See generally Andrea I. Castro, *Overview of the Tax Treatment of Nonprofit Hospitals and Their For-Profit Subsidiaries: A Short-Sighted View Could Be Very Bad Medicine*, 15 PACE L. REV. 501 (1995); see also *Utah County v. Intermountain Health Care, Inc.*, 709 P.2d 265, 271-72 (Utah 1985) (there is “increasing irrelevance of the distinction between nonprofit and for-profit hospitals for purposes of discovering the element of charity in their operations...Nonprofit corporations can own for-profit corporations without losing their federal nonprofit tax status as long as the profits of the for-profit corporations are used to further the nonprofit purposes of the parent organization...The emergence of hospital organizations with both for-profit and nonprofit components [, however,] has increasingly destroyed the charitable pretensions of nonprofit organizations[.]”).

<sup>11</sup> In 2011, the Federal Trade Commission (“FTC”) and the Department of Justice (“DOJ”) (collectively, “the agencies”), in consultation with the Centers for Medicare & Medicaid Services (“CMS”), released their final Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program, 76 Fed. Reg. 67,026 (Oct. 28, 2011) (hereinafter “Statement”). The Statement is intended to foster the formation of Accountable Care Organizations (“ACOs”) by loosening the enforcement of antitrust laws, when applicable. First, the Statement applies to

ACOs require various incentives to work, and those incentives may run afoul of tax-exemption laws, sometimes even anti-trust laws, but mostly anti-kickback and Stark laws.<sup>12</sup> There are waivers associated with some of that material built into the ACO and just recently there is a lot of pressure from this administration and the prior administration to get healthcare to be more efficient. One way to do that is through pending MACRA payment system, which involves sending payments to doctors.<sup>13</sup> It's hard for the private healthcare bar and the private compliance community to understand exactly how all those payments are going to be effective with Stark.

One of my colleagues has been briefing me on HR-4206 and its companion bill in the Senate that would actually relax Stark to allow for more creative payment mechanisms that would essentially allow for payments to physicians that would otherwise curdle your

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“collaborations [(ACOs)] among otherwise independent providers and provider groups that are eligible and intend, or have been approved, to participate in the Shared Savings Program.” *Id.* at 67,027. The agencies will then apply a “rule of reason” analysis to ACOs that meet certain conditions, evaluating “whether the collaboration is likely to have anticompetitive effects and, if so, whether the collaboration’s potential procompetitive efficiencies are likely to outweigh those effects.” *Id.* The Statement further establishes a “safety zone,” *see id.* at 67,028, in which the agencies will not enforce, absent extraordinary circumstances, the antitrust laws for ACOs that meet the CMS eligibility criteria for and intend to participate in the Shared Savings Program, and are highly unlikely to raise significant competitive concerns.

<sup>12</sup> 42 C.F.R. § 425.20 (Oct. 25, 2014) (An [accountable care organization] participant means an entity identified by a Medicare-enrolled billing [Taxpayer Identification Number] through which one or more ACO providers/suppliers bill Medicare, that alone or together with one or more ACO participants compose an ACO, and that is included on the list of ACO participants that is required under § 425.118.”); Notice 2014-67, 2014-46 I.R.B. 822 (addressing initial guidance for an entity to avoid breaching the private business prohibition for tax-exempt bond financing under § 501(c)(3) of the Internal Revenue Code); *see also A Roadmap for New Physicians: Fraud & Abuse Laws*, Office of Inspector General United States Dep’t of Health & Human Services (2018), <https://oig.hhs.gov/compliance/physician-education/01laws.asp> (analyzing the basics of the “five most important Federal fraud and abuse laws that apply to physicians).

<sup>13</sup> Medicare Access and CHIP Reauthorization Act of 2015, 42 U.S.C.A. §§ 1395w-6, 1395kk-2; *MACRA In a Minute*, American Academy of Family Physicians, (2018), <https://www.aafp.org/practice-management/payment/medicare-payment/macra60.html>; *Quality Payment Program*, Ctrs. for Medicare and Medicaid Servs. (Dec. 19, 2016) available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/MACRA-Quality-Payment-Program-webinar-slides-10-26-16.pdf>.



blood as to the potential associated regulatory implications.<sup>14</sup> Now, that's just on the drawing board. MACRA is a reality, so the regulatory stuff is behind it.

So that's my theme here is that we need to toss this absolutism over some of these things and think about broader public policy because some of the thinking behind tax exemption, anti-trust laws, some of those public policies and some of the bad things they're designed to prevent may in fact occur, but you may pick up efficiencies in quality improvements that might make it okay.

**Ms. Looney:** I think, actually, I have heard at one time that Pete Stark said that if he had known how it would turn out he would not have started down that road.<sup>15</sup> So, it is kind of interesting. I've heard Jim Cooper say during a discussion, "would [we] like to see some of these laws relaxed?" and it's like, yeah, clients would love to see them relaxed a little bit. I think that I agree with Jay—I know there's a lot going on with this requirement to work—and that may be one answer, but maybe we need to take a broader picture and see what else is out there and really revamp it.

Tennessee is one of those states that's been operating under a Medicaid waiver for a long time now.<sup>16</sup> I mean, some of the people in this room, if they're still in law school at Belmont probably weren't born when TennCare came into being. It was in January of 1994.

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<sup>14</sup> H. Res. 4206, 115th Cong. § 2 (2017), S. Res. 2051 § 2, 115<sup>th</sup> Cong. (2017) (proposed legislation in both chambers of Congress to relax payment prohibitions within the Stark Law to enable alternative payment methods and promote consumer protections); But see Roy Edroso, *Foot-dragging on Stark reform leaves APMs at risk*, Decision Health: Part B News (March 29, 2018), [https://www.greensfelder.com/media/news/312\\_Butler\\_Part%20B%20News\\_Foot-dragging%20on%20Stark%20reform%20leaves%20APMs%20at%20risk\\_Apr2018.pdf](https://www.greensfelder.com/media/news/312_Butler_Part%20B%20News_Foot-dragging%20on%20Stark%20reform%20leaves%20APMs%20at%20risk_Apr2018.pdf).

<sup>15</sup> Janet Adamy, *Pete Stark: Law Regulating Doctors Mostly Helped Lawyers*, WALL ST. J. (Oct. 22, 2014), <https://blogs.wsj.com/washwire/2014/10/22/pete-stark-law-regulating-doctors-mostly-helped-lawyers/> (addressing how Senator Stark would likely not vote for his namesake bill today and "the law got to be as thick as a phonebook for all the exemptions").

<sup>16</sup> Tenn. Div. of TennCare, *Extension of TennCare Demonstration* (2018) <https://www.tn.gov/tenncare/policy-guidelines/extension-of-tenncare-demonstration.html> (explaining that "TennCare is a Medicaid demonstration program that has operated under waivers of certain provisions of federal law since 1994).

**Mr. Hardcastle:** And 1994 was about where the first anti-trust guidelines came out and we still see massive anti-trust enforcement in healthcare.<sup>17</sup> One of the interesting things about this bill is that it changes the statutory language that authorizes the publication of exceptions to Stark. It says in lieu of allowing exceptions that are okay as long as they do not present a risk of program or patient abuse, they've added the word "significant risk."<sup>18</sup> That may seem subtle, but it's shifting away from an absolute way of thinking to a relative, kind of holistic, public policy way of thinking. To me, that is the most important thing in an otherwise inscrutably technical bill talking about EPMS and MIPs.

**Ms. Looney:** Well, there's room for argument.

**Mr. Hardcastle:** Mhmm, right.

**Mr. McDonald:** I think, thinking about Tennessee, we basically did not elect to expand Medicaid throughout the state, so what happened? We had 8 hospitals that closed.<sup>19</sup> Right, wrong, or indifferent. Maybe some of them needed to close, but we've got a really unique situation in northeast Tennessee where Mountain States and Wellmont have basically stiff-armed the FTC and created, in essence, a monopoly in both their market and in

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<sup>17</sup> U.S. Dept't of Justice & FTC, *Statements of Antitrust Enforcement Policy in Health Care* (Aug. 1996) available at [https://www.ftc.gov/sites/default/files/attachments/competition-policy-guidance/statements\\_of\\_antitrust\\_enforcement\\_policy\\_in\\_health\\_care\\_august\\_1996.pdf](https://www.ftc.gov/sites/default/files/attachments/competition-policy-guidance/statements_of_antitrust_enforcement_policy_in_health_care_august_1996.pdf);

Bill Baer, *The Role of Antitrust Enforcement in Health Care Markets* (Nov. 13, 2015), available at <https://www.justice.gov/opa/file/794051/download>; Lisl Dunlop, *Top Five Healthcare Antitrust Trends to Watch in 2017* (January 23, 2017), <https://www.manatt.com/Insights/Newsletters/Health-Update/Top-Five-Healthcare-Antitrust-Trends-to-Watch-in-2>; Emily Rappleye, *Healthcare antitrust enforcement remains a top priority for DOJ* (May 30, 2018), <https://www.beckershospitalreview.com/hospital-transactions-and-valuation/healthcare-antitrust-enforcement-remains-a-top-priority-for-doj.html>.

<sup>18</sup> S. 2051, 115th Cong. § 2 (Nov. 1, 2017) available at 4, 7 <https://www.congress.gov/115/bills/s2051/BILLS-115s2051is.pdf>.

<sup>19</sup> Carole R. Myers & Madison Kahl, *Stop cascade of rural hospital closures in Tennessee*, THE TENNESSEAN (June 23, 2017), <https://www.tennessean.com/story/opinion/2017/06/23/stop-cascade-rural-hospital-closures-tennessee/425504001/>; Jordan Buie, *Medicaid expansion may be unlikely in Tennessee*, THE TENNESSEAN (Jan 21, 2018) <https://www.tennessean.com/story/news/politics/2018/01/21/medicaid-expansion-may-unlikely-tennessee-even-backers-seek-compromise/1046118001/>; *Where the states stand on Medicaid expansion*, Advisory Board (June 8, 2018), <https://www.advisory.com/daily-briefing/resources/primers/medicaidmap>.

Virginia.<sup>20</sup> So you have two states that basically, and I think on January 31<sup>st</sup>, the merger finally went through, so it's going to create a really unique situation to watch there.

My glass is usually half-full. I, with the expertise in everything that we have being healthcare in my company . . . The level of expertise and what we will do with a block grant may end up being, actually, more money for the state of Tennessee as opposed to less than what we're getting now and compared to other states, too. I think it's going to be really neat to watch and interesting to see how it all plays out.

**Mr. Stewart:** Drilling down a little further on this point: Of course, if we knew all the answers, we wouldn't have a panel anyway and we wouldn't have clients asking us questions, but what issues do your clients worry most about in this area arising if Congress continues to put more responsibilities on states with block grant funding, and increased flexibility of waiver programs? Are there certain things your clients are more concerned than others?

**Ms. Lampley:** You know, the money is going to be a big thing.

**Ms. Looney:** But I also see something . . . if it goes back to the states, that might be good in some ways, but in other ways it's a bigger challenge for your large national healthcare companies because instead of worrying about a lot of the reimbursement and payment on a federal level, now they're going to have to worry about it more on a state level than they already do. So that also adds potentially some infrastructure to those companies. So, I think that that might not be a good thing.

**Ms. Lampley:** I agree. What we hear a lot about is the financial liability as funds get tighter and tighter. More facilities are closed and we see a lot of others who are struggling so we really have to watch that balance between cutting funding and putting providers at risk—especially in rural areas—of going out of business in the process.

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<sup>20</sup> Phil Galewitz, *In Appalachia, Two Hospital Giants Seek State-Sanctioned Monopoly* KAISER HEALTH NEWS (July 24, 2017), <https://khn.org/news/in-appalachia-two-hospital-giants-seek-state-sanctioned-monopoly/> (addressing that antitrust concerns are being subverted by appealing to the public interest and establishing a legal agreement, known as a Certificate of Public Agreement (COPA), to come under state oversight); See also Alex Kacik, *Mountain States, Wellmont skirt federal regulations and score state merger approval*, MODERN HEALTHCARE (Nov. 3, 2017), <http://www.modernhealthcare.com/article/20171103/NEWS/171109954>.

**Mr. Stewart:** Closing the loop on this topic, do you see certain long-term consequences of work requirements for entitlement programs, generally, that you may not have already touched on?

**Mr. Hardcastle:** I've got a view on that. It's an uninformed view as a citizen as opposed to a policy-maker . . . I know we had the policy folks up here before us and they're welcome to change things. My own feeling is that a long-term consequence of that would be some administrative cost and burdens on folks enforcing that as opposed to a big societal shift.

Because I spend a big hunk of my life in another role working with a nonprofit that's currently out its executive director and so I have to step in and do a lot of stuff that an executive director would normally do and it works with the working poor and supplying emergency rental assistance and I should send you the link and you should all go there [laughter] and from that I have a somewhat biased view of the working poor which is that they're working already, so I'm just not sure there's this large population of employable—I know there are certain people who are disabled and have addiction issues and things like that—people who are now in the expansion program who are not working. That's just, I don't have any data to support that. Mark's over there shaking his head thinking “now I know who you voted for” [laughter] Anyway, I don't see that as having a long-term effect on anything because I don't think it's a huge problem to begin with other than now people are going to have to administer these enforcement programs.

**Mr. Stewart:** Great. I'll shift gears a little bit. Under the current health plan there has been an increase in mergers and acquisitions in our healthcare sphere. How has that impacted the industry as a whole from your perspective? I'll kick this one to Andrew to get us started.

**Mr. McDonald:** It's exciting stuff.

**Ms. Looney:** I will say, it's really cool and really exciting.

**Mr. McDonald:** The deal flow in 2017 was off from a transaction standpoint by a couple of points compared to a record setting year in 2016 but the actual deal value average was up to 145% total deal value for 2017.<sup>21</sup> Nine hundred and sixty-seven (967) deals resulted

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<sup>21</sup> Jacqueline LaPointe, *Healthcare Merger, Acquisition Deal Value Increases 145% in 2017* REVCYCLE INTELLIGENCE (Jan. 29, 2018),

in a total deal value of 175 million dollars.<sup>22</sup> We rocked along during the year with some pretty interesting stuff.

I'm like all these folks up here, I tend to follow the physician piece. In my mind, I've been doing this for a week or two and physicians—nothing really happens in our 2.7 trillion-dollar healthcare system without a physician picking up a pen or an iPad and ordering something—these are the folks I tend to take note of and try to take care of. But for a long time, they've been divided and conquered and it's really nice to see a 22% rise in most deals.

And we're seeing at LBMC a lot of single specialty roll ups on a national platform, primarily in dermatology and anesthesia [and] urgent care, certainly, even had success with orthopedic and ophthalmology. So, it's been neat to see that but when the mergers hit, we hit 5 mega deals that absolutely changed the landscape.

The star in all this activity was a real head-scratcher initially for me when I heard it coming out in October and November. CVS, the country's largest drugstore is buying Aetna.<sup>23</sup> I said, "what in the wide world of sports are we doing here?" And in essence when you really drill down, you've got 10,000 stores that are basically going to be converted into more clinic-type retail space with 23 million enrollees through Aetna. I'm sure they're going to be strongly encouraged to go through those 10,000 doors instead of going to Walgreens. So, it creates a really interesting scenario and puts the insurance company closer to the patient than I've seen in a long, long time.

Other deals of note, on a vertical and a horizontal basis, the Catholics were very, very active on the topic of systems. The 5 big systems, you had CHI out of Denver and Dignity Health out of San Francisco announce they're putting a merger together--27 states--it's going to be a pretty big deal.<sup>24</sup> Ascension out of St. Louis and

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<https://revcycleintelligence.com/news/healthcare-merger-acquisition-deal-value-increased-145-in-2017>.

<sup>22</sup> *US Health Services Deals 3 Insights Year-end 2017*, PricewaterhouseCoopers, 1 (2018).

<sup>23</sup> Michael J. de la Merced & Reed Abelson, *CVS to Buy Aetna for \$69 Billion in a Deal That May Reshape the Health Industry*, N.Y. TIMES, Dec. 3, 2017, <https://www.nytimes.com/2017/12/03/business/dealbook/cvs-is-said-to-agree-to-buy-aetna-reshaping-health-care-industry.html>.

<sup>24</sup> Press Release, Dignity Health, Dignity Health and Catholic Health Initiatives to Combine to Form New Catholic Health System Focused on Creating Healthier Communities (Dec. 7, 2017) <https://www.dignityhealth.org/about-us/press-center/press-releases/dignity-health-and-catholic-health-initiatives-announcement>.

you have Providence St. Joe out of Washington who are putting together a 28-state deal that will be about \$45 billion in overall revenue and will fly right on past our own HCA, which is the largest hospital operator.<sup>25</sup> Those two deals were not even included in the \$175 million so it's been interesting.

The other, on the physician front, you have DaVita selling their physician service line to United Healthcare and United healthcare now owns 30,000 physicians and clinicians.<sup>26</sup> So, you're seeing a lot of different types of activity and it's exciting to see the payers.... you look up, you have Anthem and Cigna. They basically were trying to merge and the FTC shut that down.<sup>27</sup> You have Aetna and Humana, and they ended up, Aetna ended up with a billion-dollar breakup fee along with about \$800 million in transaction fees,<sup>28</sup> so the payer market was interesting and then they turned around and were purchased by CVS. So it was a very interesting year. Thoughts?

**Mr. Hardcastle:** I've got a lot of regrets, regrets of my career and among them is I did not get one cent of \$800,000,000. Yeah, I think this is a response to some of the things Julie and Kim were saying that there's a perception, whether it's a state and local driven thing or federal driven thing, there'll be less money. And so what are we going to do about it? Well we're going to do something. I mean, you know, a lot of, uh, you know, type A executives out there for all their fresh out of business school type A hard running folks, and they're going to do something. Um, and then I took a look at somebody who probably had the same source materials as we were preparing, but there was United SCA. Okay. That's kind of a vertical thing. United

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<sup>25</sup> Keshia Hannam, *Ascension and Providence St. Joseph in Talks to Form U.S.'s Largest Hospital Operator*, FORTUNE (Dec. 11, 2017), <http://fortune.com/2017/12/11/ascension-providence-merger/>.

<sup>26</sup> Reuters Staff, *UnitedHealth to buy DaVita primary care unit for \$4.9 billion*, Reuters (Dec. 6, 2017), <https://www.reuters.com/article/us-davita-m-a-unitedhealth/unitedhealth-to-buy-davita-primary-care-unit-for-4-9-billion-idUSKBN1E01HJ>.

<sup>27</sup> *United States v. Anthem, Inc.*, 236 F.Supp.3d 171, 259 (D.D.C. 2017) (enjoining the merger because Anthem's acquisition of Cigna may substantially lessen the competition in the market for the sale of medical health insurance to national accounts in the fourteen Anthem states and the sale of medical insurance to large group employers in the Richmond, Virginia market).

<sup>28</sup> Bertha Coombs, *The Mega Merger Is Off: Aetna and Humana End \$34 Billion Deal, Aetna to Pay \$1B Fee*, NBC NEWS (Feb. 14, 2017), <https://www.nbcnews.com/business/business-news/mega-merger-aetna-humana-end-34-billion-deal-aetna-pay-n720591>.

insurance company buying SCA.<sup>29</sup> The country's largest outpatient surgery center provider.

So now we have a provider and you had the insurance company, United, buying big hunks of DaVita's medical practices. So now United owns all these medical practices--they did beforehand--now they own more. CVS and Aetna, I mean that is a very interesting combination. Ascension, Providence, CHI, Dignity, DaVita, Humana, Aetna, Cigna, (both those blew up) Carolinas and UNC, two big nonprofits, high market, Penn State, Advocate and Aurora Steward and Iasis and Ascension and Providence. Not all those closed and some, I bet you, wouldn't. Carolina's, it's getting so big. That's what I call the other CHS, Carolinas Health System based in Charlotte. It's changing its name, or just changed it last week to Atrium because it's buying a system in Georgia and doesn't want to be known as Carolinas anymore.<sup>30</sup> Of those I count, let's see, nine that are what I would call mergers of scale. So, they're just reacting to the phenomena that Kim was describing by getting bigger.

And some of those, if you're looking, are not in overlapping markets or they are in overlapping markets, but that can't be the primary thesis behind the move. When you kind of get concentration on market, you can, frankly, raise prices and dominate. That's not really what's happening here. What's happening is people just want to get bigger because they think of safety and it'll be too big to fail and they can reduce overhead costs and fire. You know, you've taken Aetna Humana and you have probably \$300 or \$400 million for the management costs savings you can throw out of the system on day one. The United SCA, [...], CVS, Aetna...clearly, you know, interesting plays trying to break out of the mold. Another reason not to think in absolute terms. It might be okay for an insurance company to own a medical practice. It may be okay for a, you know, a drugstore, to own an insurance company. And now I saw in the cover of *Modern Healthcare*, until we want to figure out what they were talking about, the Inner Mountain, Ascension, SSM and Trinity--four gigantic nonprofit systems--now want to make their own generic drugs because they feel like they've been held up by

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<sup>29</sup> Press Release, UnitedHealth Group, Surgical Care Affiliates (SCA), OptumCare to Combine (Jan. 9, 2017), <https://www.unitedhealthgroup.com/newsroom/2017/0109scaoptumcare.html>.

<sup>30</sup> Press Release, Carolinas HealthCare System, Atrium Health Announced as Newest Chapter in Storied History of Carolinas HealthCare System (Feb. 7, 2018), <https://www.carolinashealthcare.org/about-us/newsroom/News/2018/02/Atrium-Health-Announced-as-Newest-Chapter-in-Storied-History-of-Carolinas-HealthCare-System>.

some generic drug manufacturers on some pricing issues.<sup>31</sup> So they want to get into the actual manufacturing business. I think that's all a response to stuff.

**Ms. Looney:** Well you've got big companies that want to get into their own healthcare business, they're going to start with their employees and then probably make a market and the point is to keep the overhead down so you know if you're not going to get--you can either cut expenses or you can get more money-- and if you're not going to get more money then you got to cut expenses in response. I mean, you know, it's just sort of the way the world works and the way the market, but I will say when you do look at some of these, and Jay said maybe it's okay, I think that's kind of a point also is you're going to have to be careful. I mean for CVS to own Aetna, you've got to make sure there's not some inappropriate control there. For United owning all the physician practices, you've got to make sure they're not dictating and doing something that's contrary to the physicians' independent medical judgment and there's a lot they can do and it may or may not be good, but it is interesting.

**Mr. Hardcastle:** You have to watch some of these incentives go the other direction. The general feeling now and, in truth, fee for service where the physician is not with the insurance company, I mean I've seen someone do this--do you know what I'm going to say?--this is the most expensive piece of medical equipment in the world, right here. But now it's going to be the other way and there may be some abuses on the other side. [cross talk] And it depends. Your vocabulary is different depending on the situation you're in. If you were a British doctor you would not say that it is medically necessary for an 82 year old person to have a hip replacement and it would not be in your vocabulary in a system largely driven by budget as opposed to a system that where it's more or less fee for service and there is no real budget.

**Mr. McDonald:** When I started my healthcare career in 1983, I think our GDP percentage was around eight percent, so today it is 18 percent and I think everybody, everybody is up in arms about that and that type of spending can't be supported.<sup>32</sup> We can't support that anymore so we're going to see some real interesting things. I think this year, I think the CVS, while it was an interesting move, the more

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<sup>31</sup> Press Release, Intermountain Healthcare, Leading U.S. Health Systems Announce Plans to Develop a Not-for-profit Generic Drug Company (Jan. 18, 2018), <https://intermountainhealthcare.org/news/2018/01/leading-us-health-systems-announce-plans-to-develop-a-not-for-profit-generic-drug-company/>.

<sup>32</sup> See U.S. Ctrs. for Medicare & Medicaid Servs., NHE Fact Sheet (2018).



you drill down on it, you have disruptors like an Amazon with what they're talking about,<sup>33</sup> JP Morgan and Berkshire Hathaway, top of their list is the drug management program,<sup>34</sup> and I think it really scares CVS. I think it scares Walgreens, so you have a disruptor that's coming in. We've had other people take a run at healthcare, like Google health and they kind of came in and they googled right on out.<sup>35</sup> It's an interesting career and you'll find it's harder than it looks.

**Ms. Lampley:** The discussion on the generic drugs brings my world into the discussion too, as far as mergers and acquisitions and things going on in the life sciences industry. Pharma, medical device research organizations...we're seeing a lot of unusual activity in those areas as well where they are normally competitors. Big pharma companies are actually coming together and collaborating on projects. One that we were lucky enough to work on a few years ago was between Eli Lilly and Boehringer Ingelheim when they did really an unprecedented--at that point--collaboration to co-market their suite of diabetes drugs.<sup>36</sup> So that was a very unusual-- but it's all about pharma companies being under price reduction pressure, increased costs to research and bringing products to market, increased difficulty in insurance formulary approvals and things like that. They're looking for creative ways to do that. Another thing we're seeing a lot of is that the big pharmas are looking more, not at in-house development of their products, but going out and licensing or buying small and mid-cap companies.

I spend a lot of time in the bay area and San Francisco with smaller pharma companies and it's just astounding, the movement in that industry. It really is just a constant movement of buying and

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<sup>33</sup> Amazon enters the online pharmacy market. See Robert Langreth & Zachary Tracer, *Amazon Makes \$1 Billion Splash in Health Care, Buying PillPack*, Bloomberg (June 28, 2018), <https://www.bloomberg.com/news/articles/2018-06-28/amazon-makes-big-foray-into-health-care-with-pillpack-purchase>.

<sup>34</sup> Zachary Tracer, *Amazon-Berkshire-JPMorgan Health Venture Takes Aim at Middlemen*, BLOOMBERG (June 24, 2018), <https://www.bloomberg.com/news/articles/2018-06-24/amazon-berkshire-jpmorgan-health-venture-takes-aim-at-middlemen>.

<sup>35</sup> Brian Dolan, *Official: Google Health shuts down because it couldn't scale adoption*, MOBIHEALTHNEWS (June 24, 2011), <https://www.mobihealthnews.com/11453/official-google-health-shuts-down-because-it-couldnt-scale>.

<sup>36</sup> Eli Lilly and Co., *Lilly and Boehringer Ingelheim Announce Strategic Alliance to Bring New Diabetes Treatments to Patients Worldwide*, PR NEWSWIRE (Jan. 11, 2011), <https://www.prnewswire.com/news-releases/lilly-and-boehringer-ingelheim-announce-strategic-alliance-to-bring-new-diabetes-treatments-to-patients-worldwide-113263519.html>.

selling and collaborating and coming together in a lot of unusual ways at a speed much faster than we've seen before. Not to mention academic medical centers and other research organizations who are combining their own networks so that the research clinical sites are coming together and forming a larger and larger network to conduct the research. It's all about the economies of scale and trying to do it efficiently.

**Mr. Stewart:** I'm going to interrupt and cut us off talking about M & A. You can tell the five of us are curious and fiery about mergers and acquisitions, but write down your questions and ask us at the end or ask us at lunch because I'm going to move on a little bit. Julie, you actually provided us with a bit of a segue. I wanted to ask about certain sectors of the healthcare industry, for example, hospitals, physician practices, and home health. You mentioned the pharmaceutical industry will react differently to this system that relies more heavily on control by the states, are there any certain industries that you work with particularly that will react curiously? Not necessarily just Julie. Anybody?

**Ms. Lampley:** In my world, life sciences, it's not so much state specific because it is federally driven. Now in my work with dialysis providers, hospitals, and other institutions there are a lot of state specific issues that come up.

**Mr. Hardcastle:** On the budget side, there will be benefit management initiatives that focus on pharmaceuticals. I believe one of our prior panelists mentioned that a drug was substituted, but I think that was as a result of opioid abuse issues. But there are private companies that specialize, pharmacy benefit managers or PBMs, that work with insurance companies and Medicaid programs and other people who were influential in buying lots and lots of drugs, and they would come to the state and they would help you develop this so-called formulary of drugs. So, we'll drive volume to a particular manufacturer and maybe distributors are somehow in there also, in return for price concessions. But also, it's mostly, you know, we're just frankly looking for the cheapest, most effective drug and we're going to cut out all the marketing noise and the influence that the marketing apparatus has on the medical professions and say you can prescribe whatever you want.

This is why if you're a patient, we're going to have various mechanisms to call the pharmacy to fill this drug for this condition. And that is a very local state response I think. But it usually relies on national companies to help them figure that out. You can go to school for, I think Belmont is a great example here, for a PharmD

program, which is essentially the equivalent of a PhD and that sort of thing.<sup>37</sup> And you need these pharmacies to help you figure out how to handle that if you're in Medicaid.

**Ms. Lampley:** I was just going to say that one of the things when TennCare came into being and they started their formulary was they had a limit on the drugs.<sup>38</sup> There are a lot of major companies whose drugs were not included on the formulary because they were more expensive.

**Mr. Hardcastle:** There are other ways to manage that, by the way, besides the state looking to a formulary and the formulary people looking to an expensive for-profit company. I mean the state could get into the business of buying drugs, which would of course curdle the blood of many of us in here and has all kinds of political implications. But, with the state probably in that business already in subtle ways by buying drugs for various state operated clinics or metro, you know, the city operated clinics.

The national healthcare council has this trip every other year. They go to another country, you study a healthcare system in the other country. And I've always thought it was a giant waste of money and who are these money-wasting, time-wasting people who go on these trips? And then they said it was going to be in Paris and I said I was going to go. And I did. And they set up these lunches and one of the lunches was a "meet a French pharmaceutical executive" lunch. And so every table got a french pharmaceutical executive and so I sat with the Pfizer person who was head of Pfizer, France, and he was telling me interesting things like, for example, it is completely out of the question, it never will happen, culturally unthinkable to have an ad for a drug in France will--we will never tolerate that. So I don't know what you do with all the paired bathtubs in France, but they're not in sales.

But the other thing they do is they buy their health system. They have sort of like four Medicares over there, depending on who joined your Medicare system, depending on whether you're in a certain kind of industry, they're industry specific sorts of things.<sup>39</sup>

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<sup>37</sup> See Belmont University, PharmD Curriculum, <http://www.belmont.edu/pharmacy/academics/curriculum.html>

<sup>38</sup> Cyril F. Chang & Stephanie C. Steinberg, *TennCare Timeline: Major Events and Milestones from 1992 to 2016*, Methodist Le Bonheur Center for Healthcare Economics, the University of Memphis, 2 (September 2016), <http://www.memphis.edu/mlche/index.php>.

<sup>39</sup> Isabelle Durand-Zaleski, *The French Health Care System*, International Health Care System Profiles,

And they buy the drugs and they would have one negotiation per year with Pfizer and they go to the mat and then they're done for another year. And that's the price of that drug. And it's all budgeted in the budget. And guess what, it's a lot cheaper over here. Now I'm not advocating we do that. The states could have a different response and that's what we're going to buy it. And guess what, we're not going pay very much.

**Mr. Stewart:** Does anybody else have a comment on what you think we should do, federal or state, changing our regulations in this area? Okay.

Speaking of, when pharmaceutical companies get a patent on a new molecule, they have 20 years to recoup the cost of developing a drug out of it. So these companies look for loopholes in the law to have the ability to extend their patent and they'll often develop a new chemical entity to prevent the drug from going generic.<sup>40</sup> There's a big debate about whether we should allow this. Are there any changes that you guys would recommend to balance the interest of protecting the patients who are in need but also encouraging drug companies to continue to conduct extensive research on the new drugs?

**Ms. Lampley:** I'll take the first stab at that one. Then I'll sort of combine it with some of the conversation that we've been having. And that is about FDA regulatory changes that have been discussed a lot, not really at state level, but more at federal level. The Trump administration has made some pretty bold statements about its desire to reduce the time required for the whole development and approval process.<sup>41</sup>

Quite frankly, I think we probably have it about right because the FDA's primary purpose really is to protect the patient, right? That's what they need to be looking at. So what may save

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<https://international.commonwealthfund.org/countries/france/> (last visited Aug. 2, 2018).

<sup>40</sup> Cynthia Koons & Robert Langreth, *The Loopholes Drug Companies Use to Keep Prices High*, BLOOMBERG (Dec. 20, 2017), <https://www.bloomberg.com/news/features/2017-12-20/the-loopholes-drug-companies-use-to-keep-prices-high>.

<sup>41</sup> Jen Christensen, *Trump Vows to 'Slash Restraints' on Drug Development for FDA*, CNN, <https://www.cnn.com/2017/03/01/health/trump-fda-slash-restraints/index.html> (last visited July 20, 2018) (Speaking to a group of pharmaceutical company executives, Trump vowed to "streamlin[e] the process so that from [the pharmaceutical companies'] standpoint . . . [they] can actually get [the drugs] approved – if it works – instead of waiting for many, many years.").

some time and some money on the private side might also put patients more at risk on the healthcare side. So I think probably we have that balance about right. And I thought it was also interesting that in big Pharma's reaction to the Trump administration's statements and they generally took that approach as well.

Which was: yeah, it cost us a lot of money and it takes us a long time, but that's probably necessary. One of the reasons for that is the insurance formularies. Even if you get past the FDA, you don't get a dime if someone's not going to reimburse for the product. Not only do you have to prove that it's safe and effective to get on the formulary, you have to prove that it's better than what they're currently doing and usually at a more cost-effective level.<sup>42</sup> So it is very difficult. So that's to say that all of that analysis that they gathered during the FDA approval process, they're going to need anyway when they get to the formulary and the insurance company level.

One thing that, based on the conversation here, I think a lot of us would probably agree is at a state level, you need to start looking at your insurance rates and maybe look at how exclusive you should or should not be, and what other alternatives that should be available to the patients rather than pushing money to a specific big manufacturer or developer of drugs.

But to get to the patent issue specifically, there are animal trials first, then there are phase one through four human trials. There are serious adverse event trials, there are data gathering trials, there are all these trials that have to be conducted in order to bring a product to approval.<sup>43</sup> For every success where they do finally achieve approval, you can take my word for it, there are many failures. That same kind of effort was put in up to a certain level and then they met a road block and a stop.

And of course, the patent process, the reason that's there, the reason patent process protection even exists is to allow, in my case, the drug manufacturer or drug developer to recoup that cost.<sup>44</sup> So

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<sup>42</sup> Gordon D. Schiff et al., *A Prescription for Improving Drug Formulary Decision Making*, PLOS MEDICINE, <http://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1001220> (last visited July 27, 2018)(The efficacy and safety requirements entail questioning the "quality and strength of the evidence" and the formulary studies, as well as searching for safe "administration and preparation" of the drug and the "adequacy of the experience with the drug.").

<sup>43</sup> 21 U.S.C. § 355(b) (2012).

<sup>44</sup> 35 U.S.C. § 154 (2012).

the government has looked at that and said that they think 20 years is probably a reasonable time to be able to recoup that cost.<sup>45</sup> It's not really 20 years, it's 20 years from the time you filed the application.<sup>46</sup> And most of the time you want to protect your product pretty early on during that trial phase. So, you've lost several years in the process of actually bringing it to approval, which shortens your time.

**Ms. Looney:** The only thing is I think that when it comes time to price the drug, it's not necessarily priced on recouping the money over that time period. I mean a lot of times the drugs, especially the ones that are new and very effective and are going to be prescribed, are priced based on what the market will bear. I'm not saying that's necessarily a bad thing, but I think that you have to account for recouping the money on all those other products that didn't make it.

But I remember reading about Revlimid, which is now on the market, but it was experimental for a while.<sup>47</sup> [...] The price of it--because what it was replacing was blood transfusions--so if the blood transfusions cost, and they were expensive, I will say they were 50, 60, 70 grand a year depending on how often you had to have them, the drug company priced Revlimid at about 20 percent less than that.<sup>48</sup> So it was comparable. You're still talking about 50 grand at year for a drug, you know, but a very effective drug. It's working so I would say okay, 20 years may be the right amount of time, and I don't think it's anything that you can look... you can't do a cost benefit analysis for each particular drug for that 20 years. I think that you have to take into consideration all the ones that don't work.

**Ms. Lampley:** That's right. And the unknowns, right? The future risk of something going wrong once it gets on the market. When there's a big class action advertisement on one of the big news channels saying during every break, "call us if something's happened," it really is a potential cost that at the time that you price the product and the time of your patent expires, you don't even know that it's out there. It can happen anytime, but that's all to say: there is that legitimate reason for having the patent there and not shortening it, but with respect to extensions, of course any game can be played and any program can be abused.

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<sup>45</sup> *Id.*

<sup>46</sup> *Id.*

<sup>47</sup> DRUGS.COM, *Revlimid Approval History*, <https://www.drugs.com/history/revlimid.html> (last visited July 20, 2018).

<sup>48</sup> DRUGS.COM, *Revlimid Prices, Coupons, and Patient Assistance Programs*, <https://www.drugs.com/price-guide/revlimid> (last visited July 20, 2018).

One of the changes that I would suggest, and I think it would be a very good one, is to really look more carefully when a company wants to file an extension on a patent that's about to expire. In some cases there really is a change. It's a significant change and it's protectable, but in some cases it may be just a way to extend the patent further.<sup>49</sup> Of course, the generic drugs are the ones that are most angry when that happens because it delays their ability to introduce some competitor in the market. But another change that I think would be helpful in addition to looking at extensions more carefully than we might already be doing, is to allow generics to really come on quick. I do think that's a place where the FDA process could be shortened as much as possible because the safety and the effectiveness has already been proven. It's just a small change in the generic world.

We also have biosimilars and I won't get into that, but that's a whole other world that we have to consider too as competing products that may necessarily have to wait until the patent expires.<sup>50</sup>

With advertisements—that's incredibly expensive for pharmaceutical companies and it's a trend of "well, they're doing that so we have to do it, too" and it's all about being an informed patient. A patient now wants to go in and know what they're asking for and sometimes demand a certain product. It costs Pharma companies a lot of money to have that visibility. So I think that's another way we could look, at the state level, at cost of advertisement and the actual effect on the price of the drug in having that advertisement. One more thing, I think what we really need to do is to provide more leniency under anti-kickback and other restrictions to drug companies because the ones that I represent are very passionate about helping patients, waiver of copays, waiver of deductibles, charitable care, giving the drug away to the population that needs it.

But because our federal restrictions are sometimes so prohibitive, we're unable to do really everything that we would like

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<sup>49</sup> See *Ortho-McNeil Pharm., Inc. v. Lupin Pharms., Inc.*, 603 F.3d 1377 (Fed. Cir. 2010) (after a drug manufacturer made slight changes to a successful drug formula, the court gave a patent extension to Ortho-McNeil); see also Himanshu Gupta et al., *Patent Protection Strategies*, J. OF PHARMACY AND BIOALLIED SCIENCES, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3146086/?report=reader> (last visited July 20, 2018).

<sup>50</sup> Joe Nocera, *Why the Biosimilar Drug Revolution Hasn't Arrived*, BLOOMBERG, <https://www.bloomberg.com/view/articles/2017-09-07/why-the-biosimilar-drug-revolution-hasn-t-arrived> (last visited July 20, 2018).

to do as a pharma company.<sup>51</sup> So I think that's another area that we really need to step back and let people take care of patients as they would like to do.

**Mr. Stewart:** I think this is an interesting topic. I'm going to freeze the conversation and get to the audience in our last couple of minutes. Does anybody have any questions that they wanted us to address before we have to disappear?

**Audience Member:** I have to say that the pharmacy ads irritate me to death, you know, we're, we're past the time that we're not going to do it. But when we say things like, "tell your physician if you had a kidney transplant," well give me a break. Why should the physician prescribe something just because a patient walks in and demands it? But the question is: it must be an effective tool, or Pharma wouldn't do it, but on the back side, you know, the consumer or the physicians, do you get any backlash? And I'm all for information, you know, for patients that have certain conditions when you do that lengthy side effects thing, which I think is really good, but some of these drugs just seem inappropriate for a patient to go in and say, I saw this on TV and I want this drug.

**Mr. Hardcastle:** That was exactly the argument that the Pfizer Guy in France was saying. You're stirring up demand where none exists, but you know, the counterpart to that is that, about 10 years ago, we started to hear the phrase "consumer driven healthcare" and that's, you know, information-driven and the ads do provide some information. Sideline: my wife rescues dogs--copious amounts of dogs-- and they come to us with either no names or just really stupid names. I mean, I don't how many Jack Russell terriers you can name Jack Daniels, but anyway, I found that the drug, we have Otesla now, currently the drugs provide nice names for the rescue dogs and some other things. Yasmin, Otesla daschhunds.

**Ms. Lampley:** I agree about the informed patient. I think it puts probably undue pressure on a lot of physicians and I think another result is it puts perhaps warranted pressure on insurance drug formularies, and those who are putting them together, because of

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<sup>51</sup> Andria Jacobs, *Waiving Copay and Deductibles Waves a Red Flag*, AM. J. OF MANAGED CARE, <https://www.ajmc.com/contributor/andria-jacobs-m-ms-cen-cphq/2015/07/waiving-copays-and-deductibles-waves-a-red-flag> (last visited July 20, 2018); see 42 U.S.C. § 1320a-7b (2012) (The Anti-Kickback Statute restricts healthcare providers from accepting bribes to gain referrals for items the government reimburses.); see also 31 U.S.C. § 3729 (2012) (The False Claims Act restricts companies from defrauding governmental healthcare programs by holding them responsible for their fraudulent actions.).



patient demand. There are a lot of different aspects to it, but to me, it could easily interfere with physician judgment and patient satisfaction with their physician for really very unwarranted reasons.

**Audience Member:** Julie. But the same is true of all that unwanted advertising that people see on tv and they think, oh, because some plaintiffs' ad that's been made into an infomercial says if you take this drug, you may be entitled to compensation also has and is building up the cost of drugs.

**Mr. McDonald:** Just two things that were brought to mind when you talked about granted in a class action suit, the oversight is not as great by the courts, but you still have the litigation standpoint with a single person writing a script and then prescribing the drug. That ultimately resulted in either the acceptance of the claim or denial of the claim.

On the second part, I mean there is, there is obviously a place for consumer information and consumer guidance that has been kind of called a war for advertising for quite some time, but fundamentally wasn't that the job of the physician? Doesn't the advertising actually spur kind of a hypochondriac mentality on the part of the consumers rather than giving an honest and detailed account of, of their particular symptoms? They're focused on whatever symptoms correspond to the publicly available information. So that, you know, I see that I have a, you know, kind of a burning sensation in my hand so it must be this particular ailment. So that everything that I was going to talk about is going to be focused on that particular ailment and that creates kind of an information chasm between the physician and the consumer rather than a bridge.

**Ms. Looney:** It's not giving the physician the opportunity to diagnose you, basically, because you come in saying, I know this is what I have and this is a drug I want. And I think Julie touched on a really important point because it is going to pay, you know, pay for value, kind of point, physician satisfaction. And what your patients think about the physicians is a really important metric that is being measured.<sup>52</sup>

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<sup>52</sup> Erin E. Sullivan & Andy Ellner, *Strong Patient-Provider Relationships Drive Healthier Outcomes*, Harv. Bus. Rev., <https://hbr.org/2015/10/strong-patient-provider-relationships-drive-healthier-outcomes> (last visited July 20, 2018); see also CMS, *Consumer Assessment of Healthcare Providers & Systems*, <https://www.cms.gov/Research-Statistics-Data-and-Systems/Research/CAHPS/> (last visited July 28, 2018).

And so if your doctor doesn't give you the drug you want or ticks you off, then you're not going to evaluate them very well. And that could be an excellent doctor who says you're just fine on the drugs you're on, which are generics that have been around forever. They're controlling your symptoms. You don't need this nice new Humira or whatever. You see all these things that--I have rheumatoid arthritis, so I see those all the time and I'm not, I'm on Methotrexate, Prednisone, all of which have been around forever that are really cheap. But you know, it's interesting because it's something that's important and you know, I get you do want information. I do think it's good.

I think part of it--because your drug reps are allowed to take information, but your doctors don't really sit around getting information and you can't take them to breakfast and lunch and all those things they used to do anymore when you might get 15 minutes of the doctor's time. So you know, we've kind of ratcheted it back one way and so then, now you have all those direct to consumer ads and they are very annoying ads. Because if you can't get the drug reps to be able to get the doctor, she's got to get to the patient and the doctors are watching these ads too, so you've got to get to them.

**Audience Member 2:** I've got a couple of questions about tort reform and its effect on say, I guess, cost of care and whether or not it's having the intended effect. And also on the legal profession; how are you seeing it in your professional practices day in, day out?

**Ms. Looney:** I think that for us probably in particular, it's not so much affecting what we do, but I think tort reform can be good. If you can cut back on the cost that the drug companies are having to pay for the lawsuits and frivolous lawsuits then it means, you know, they don't have to charge \$50,000 for the drug.

**Ms. Lampley:** That's right. The reserves they have to set aside for the potential liability moving forward. That all goes into the pricing and then if some states have tort reform and others don't, obviously then you have the forum shopping that goes on. I think it's a need. Things have to be controlled.

**Mr. Hardcastle:** Yeah. I will offer a slightly different viewpoint. Slightly different. I think that tort reform in Tennessee as it applies to medical malpractice claims against physicians has, with various caps, reduced the likelihood of people bringing a suit. So I think it has had the intended effect. It's just not worth it to a lot of plaintiffs' lawyers to take suits without essentially catastrophic damages and

ways around the caps. I don't know that it's had any effect on, and Mark may know from his prior life, had any effect on malpractice premiums, practice patterns... I mean, there's some possibility that all it's done is left some people out in the cold.

**Ms. Looney:** I think that's the point. There are some lawsuits that need to be brought. There are some plaintiffs who have truly been injured and truly suffered and it's just kind of balancing all that with throwing it all out and figuring out what's best.

**Mr. Hardcastle:** Yeah. And having been in this business for a long time, of course, probably most people in here have a sort of a negative bias against plaintiff lawsuits, but they have a reason and I remember traveling once and crossing, like, an ancient Roman aqueduct covered with tourists with about a 400 foot drop and no guard rails and all I could think of was "this country needs more plaintiffs' lawyers."

**Audience Member 3:** What the savvy plaintiff lawyer has done is shift those claims to the manufacturer of the drug. So what we often see will be a case where it is medical malpractice and, of course, the companies we represent, we don't place blame on the doctors. So what it's done is it's decreased [audio interference] but it's increased it in the type of clients. And some of the judgments are astronomical, astronomical. We have a client at a \$720,000,000 verdict in California or something that I think is one of the most ridiculous things I've ever seen.

**Mr. Hardcastle:** So preparing for this, I started thinking about this idea of all these absolutes out there and how they have constrained development and it reminded me of something I read as an undergraduate and I threw away a bunch of books and somehow I saved this.

So this is a commentary from a famous legal scholar named Alexander Bickel who died in 1974, young, but he was counting on Edmund Burke, who was an Irish political philosopher whose whole theory was you should not have these absolutes, you should take all these things and put them in a blender and this is what Bickel said about Burke:

"There are no absolutes that a complex society can live with in its law. There is only the computing principle that Burke spoke of--adding, subtracting, multiplying, dividing. It is the most enduring instinct of our legal order, which is more Burkean than some care to acknowledge, to resist the assertion of absolute claims

and, therefore, a waste of breath to make them. Even absolute rights that the legal orders seems, absentmindedly, to create (anti-trust or anti-kickback, whatever), if very rarely, do not endure. Circumstances erode them. Better to recognize from the first that the computing principle is all there is, ought to be, or can be.”<sup>53</sup>

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<sup>53</sup> Alexander M. Bickel, *The Morality of Consent* 88, (Yale U. Press) (1977).