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Phone: +1 646 783 7100 | Fax: +1 646 783 7161 | customerservice@law360.com

The Defining Pandemic Moments For Health And Life Sci Attys

By **Jeff Overley**

Law360 (March 11, 2021, 11:02 PM EST) -- The coronavirus pandemic's first year tested America's health care and life sciences systems in unprecedented ways and set the stage for profound and lasting changes. Here, attorneys share the moments and lessons that stand out — and what they'll be watching as the pandemic enters its second year.

Law360 solicited recollections from attorneys who advise health care providers, drug companies, health insurers and medical device makers in numerous legal areas that became both more prominent and more complex amid COVID-19. Those areas include enforcement, reimbursement, mergers and acquisitions, product approvals and manufacturing.

The remembrances start in March 2020, when the World Health Organization made the pandemic designation official and then-President Donald Trump declared a national emergency. They continue to the present, when rising vaccinations and declining infections are allowing lawyers to contemplate longer-term consequences of the crisis, as well as the prospect of returning to brick-and-mortar courtrooms.

Some of the memories explore high-profile developments involving pandemic politics and policy. Others are vignettes of canceled conferences and livestreamed lawyering — microcosms of how the virus kept attorneys apart.

They do not, of course, cover every big health and life sciences occurrence involving COVID-19. But they offer a sketch of life as a lawyer for industries that helped the nation endure a year like no other.

March 2020

The gravity of what was happening dawned on different lawyers in different ways.

Manatt Phelps & Phillips LLP partner Melinda J. Dutton remembers having been "on the road all week" in early March of last year. With the outbreak gaining steam, Dutton reluctantly decided to skip the global conference of the Healthcare Information and Management Systems Society, a buzzy annual affair that was anticipating 45,000 attendees in Orlando, Florida, and a keynote speech by Trump.

"I had just decided to cancel ... when HIMSS sent out a notice that they were calling it off for the first time in 58 years," Dutton recalled. "[That] is when the crisis became real to me."

George B. Breen, chair of Epstein Becker Green's health and life sciences steering committee, had his

moment of truth on March 16, when the U.S. Supreme Court postponed scheduled argument sessions for the first time since the 1918 influenza pandemic.

"That, to me, is when the reality of the situation truly set in," Breen recalled.

The same day saw an unsettling new reality sink in elsewhere. Many office buildings were empty. So were grocery store shelves. So was Times Square.

As much of America hunkered down, a public health plan was shaping up. On March 16 alone, the White House told Americans to avoid large gatherings, the U.S. Food and Drug Administration outlined "unprecedented" leeway for unapproved coronavirus tests, and the National Institutes of Health quietly announced an early clinical trial for a Moderna Inc. vaccine candidate that would eventually prove to be remarkably effective.

"March 16, 2020 was a huge day in terms of policy response to COVID," Hogan Lovells partner Cybil Roehrenbeck recalled.

The month of March also saw Trump — who in January had restricted travel from China — still focused on pulling up drawbridges in hopes of keeping the virus away from U.S. shores.

In an event that produced enduring images of the former president's pandemic response, Trump appeared at the Centers for Disease Control and Prevention in Atlanta. Wearing a red hat emblazoned with his "Keep America Great" slogan and standing between then-CDC Director Robert Redfield and then-Health and Human Services Secretary Alex Azar, Trump declared that a cruise ship carrying infected individuals shouldn't be allowed to dock.

"I don't need to have the numbers double because of one ship that wasn't our fault," Trump said.

Arnold & Porter partner Daniel A. Kracov told Law360 he thinks of that episode in conjunction with another event in March — his first discussion of rapid vaccine development with a client — as emblematic of key pandemic motifs.

"Those two moments sum up the paradoxes in this pandemic," Kracov said. "It has been a time of magical thinking and politics versus incredible science."

It was possible to see Trump embodying that paradox throughout the pandemic. He often deflected blame — China was a frequent target — and predicted the pandemic would simply "go away." But Trump also sent billions of taxpayer dollars to drug companies that ended up succeeding spectacularly in vaccine development.

April 2020

Early on, the Trump administration won bipartisan acclaim for dramatically expanding Medicare coverage of telehealth services. The move was meant to prevent viral spread by letting Americans visit doctors from home using the video cameras of computers or smartphones.

Morgan Lewis & Bockius LLP associate Jacob J. Harper told Law360 that the Centers for Medicare & Medicaid Services "deserves a lot of credit" for how swiftly it revamped the telehealth landscape.

"The interim final rules released in March and April 2020 were legendary," Harper said. "CMS packed years of telehealth changes into these rules."

The pandemic's early weeks also saw CMS advise health care providers to cancel nonemergency procedures in order to preserve staffing resources and personal protective equipment for COVID-19 care.

Douglas A. Grimm, health practice leader at Arent Fox LLP, told Law360 that the halting of elective procedures remains "one of the most significant industry actions" of the pandemic. He noted that it carried major implications for public health and slashed revenue for providers, prompting Congress to create a Provider Relief Fund with $175 billion that had many compliance strings attached.

James F. Segroves, a Reed Smith LLP partner, recalled that the first allocation from the Provider Relief Fund came "without warning" from HHS on April 10.

"Medicare providers throughout the country awoke to something strange: Significant amounts of money — in many cases several million dollars — had been deposited into their respective bank accounts with the description 'HHSPAYMENT,'" Segroves said.

The cash has kept providers afloat, but it has also kept them on edge. Appropriate use of the money is governed by an FAQ document that has grown to more than 60 pages, and scrutiny by the U.S. Department of Justice and whistleblowers is essentially guaranteed.

"For a provider community long conditioned to treat federal funds with the utmost care for compliance reasons, the money provided was a blessing and a curse," Segroves told Law360.

May 2020

By May, pandemic enforcement priorities had become crystal clear. Attorneys were forecasting a wave of False Claims Act investigations tied to pandemic relief dollars. The DOJ had established a task force on pandemic profiteering and charged people for allegedly hoarding enormous quantities of PPE, such as gloves, surgical gowns and N95 masks.

"I've seen a lot of new trends in the life sciences over the years, but this was the first time I have seen hoarding as an issue," Lowenstein Sandler LLP senior counsel James C. Shehan recalled.

At the same time, the pandemic's restrictions on large gatherings also meant that health fraud cases — like most other cases — were being litigated through Zoom and other digital platforms.

"As of May, I was participating in videotaped depositions as a matter of routine," Breen, the Epstein Becker attorney, recalled. "Mediations by videoconference became the rule rather than the exception."

June 2020

In June, the FDA revoked a controversial authorization for the use of malaria drugs hydroxychloroquine and chloroquine, which Trump had touted with scant evidence as potential cures for COVID-19.

Philip Katz, head of the pharma and biotech practice at Hogan Lovells, told Law360 that the initial authorization "showed that politics was having a real influence on FDA," and that the revocation helped restore the agency's reputation for rigorously following science.

"I thought the [authorization] was not FDA's finest moment," Katz said. "But I thought the revocation, in some ways, was a vindication of what the agency is always supposed to be about."

The episode was a microcosm of broader friction between the government's scientific establishment and Trump. And as the pandemic worsened and the presidential election drew nearer, that friction only appeared to intensify.

September 2020

During the pandemic's early months, lawyers handling M&A in health care saw a pause in deal-making amid financial uncertainty and the logistical challenges of traveling to meet with potential transaction partners.

But that lull subsided as the year wore on and the U.S. temporarily sustained a relatively low level of coronavirus cases and deaths in most of August, September and October.

M&A "came back with a vengeance in Q3-Q4 of 2020," Foley & Lardner LLP lawyer Christopher J. Donovan recalled.

The boom stemmed partly from bankers and private equity investors learning to love how Zoom allowed them to "visit four cities in one day" for meetings, Donovan said.

October 2020

Political fireworks between Trump and scientific agencies also came back with a vengeance around the same time. On his now-defunct Twitter account, Trump in late August accused "the deep state, or whoever, over at the FDA" of intentionally delaying a vaccine approval until after the Nov. 3 election.

Tensions escalated further on Oct. 6 when the FDA unveiled vaccine guidance that made pre-election vaccine clearance seem unlikely. Trump fired off a tweet that tagged then-FDA Commissioner Stephen Hahn and said, "New FDA Rules make it more difficult for them to speed up vaccines for approval before Election Day. Just another political hit job!"

The guidance probably didn't say much that the FDA hadn't already told top vaccine developers behind the scenes. But it was nonetheless a startling example of federal regulators seeming to publicly defy the wishes of the nation's commander in chief.

"It is another instance [where] the science triumphed over the politics," Hogan Lovells' Katz said.

November 2020

The pandemic quickly became intertwined with issues of race and class as it became clear that minorities and lower-income Americans were more susceptible to COVID-19. Potential factors included medical conditions, relatively crowded living and working environments, and limited access to high-quality health care.

Meena Datta, global co-leader of Sidley Austin LLP's health practice, singled out FDA guidance in November that advised drugmakers on approaches for "enhancing the diversity of clinical trial populations."

The guidance emerged around the same time that drugmakers were looking to diversify the populations, locations and professional directors of clinical trials, according to Datta, who predicted greater investment in equitable development of COVID-19 and non-COVID-19 treatments.

"This is an ethical issue in addition to a scientific issue," she told Law360.

On the enforcement front, Ropes & Gray LLP partner Kirsten Mayer spotlighted a special fraud alert in November from HHS' Office of Inspector General.

The alert, which was directed at drugmakers, seized on the cancellation of in-person speaker programs during the pandemic to urge a permanent end to such programs, which can facilitate illegal kickbacks in the form of sham speaker fees and lavish entertainment.

The alert was an example of government enforcers capitalizing on pandemic-prompted business changes. It was also important, Mayer said, because it identified potentially fraudulent characteristics of speaker programs. Kickback liability under the False Claims Act requires intentional wrongdoing, and FCA plaintiffs may wield the alert to show that drugmakers have been clearly put on notice of government concerns.

"I can say it's being used in litigation," Mayer said, declining to elaborate.

December 2020

Jaime L.M. Jones, global co-leader of Sidley's health practice, called attention to a December final rule from CMS, telling Law360 that it "significantly and permanently expands Medicare coverage for telehealth services for certain patients."

The rule builds on policies and pandemic waivers that fueled a surge in telehealth visits by Medicare beneficiaries and "a corresponding boom in for-profit telehealth providers," Jones said.

The regulatory moves can only go so far. Certain telehealth benefits, such as guaranteed coverage for audio-only visits or for people in urban areas, will likely expire after the pandemic without congressional action.

Jones told Law360 that "there is no going back to pre-2020" on telehealth, but that the Biden administration and Congress will be hard-pressed to ensure equitable access and find money for broad coverage of telehealth services.

January 2021

The FDA made Jan. 15 another important date in the pandemic's first year by moving to permanently exempt 84 medical devices from so-called 510(k) premarket notification, Morgan Lewis partner Dennis C. Gucciardo told Law360.

Companies use the 510(k) process to show that new devices are "substantially equivalent" to devices already proven safe and effective. Early in the pandemic, the FDA waived the process for certain products.

Gucciardo said that while permanent exemptions arguably make sense for some of the 84 devices, "it is unlikely" that the Biden administration's FDA will fully follow through on the plan.

The Jan. 15 proposal cited a lack of adverse event reports for the 84 devices. But that was based on data with "inherent limitations," and "the Biden administration may question the rationale" for using it, Gucciardo said.

In another FDA area, the U.S. Government Accountability Office on Jan. 28 unveiled an arresting assessment of the FDA's pandemic-inspired postponements of overseas inspections, Alston & Bird LLP partner Cathy L. Burgess noted.

From March to October 2020, the agency conducted only three "mission critical" inspections, compared to 600 inspections in comparable periods during each of the prior two years, the GAO found.

The decline occurred amid a yearslong trend of prescription drug production moving overseas and mounting concerns about quality control in India, China and other countries.

"This postponement of foreign inspections was unprecedented and came at a time when FDA had been facing pressure to increase its foreign facility inspections," Burgess told Law360.

February 2021

Hogan Lovells' Roehrenbeck cited Feb. 23 as a concrete example of the momentum behind expanded telehealth coverage, noting that a bipartisan group of lawmakers — Sens. Tim Scott, R-S.C., Brian Schatz, D-Hawaii, and Jeanne Shaheen, D-N.H. — introduced legislation to codify pandemic-era telehealth policies.

But she cautioned that enthusiasm won't be enough. Congress didn't widely expand telehealth before the pandemic because of concerns about spending, and that dynamic hasn't vanished just because video visits with physicians became popular during the past year.

A favorable cost estimate from the Congressional Budget Office would help, and supporters can also point out that "many employers and insurers have integrated telehealth into their platforms and plans because they saw the value" amid COVID-19, Roehrenbeck said.

The Present and Beyond

Optimism has been rising that the U.S. is close to extinguishing the threat of the novel coronavirus and its known variants. More than 10% of Americans have been fully vaccinated, and average daily cases have plummeted by 75% and deaths by 50% from their January peaks.

With brighter days on the horizon, attorneys are starting to peer ahead and envision what a post-pandemic future might look like. It's possible that the new normal will resemble the old normal, but be a bit better because of the lessons of the past year.

Some health care litigators, for example, miss being face-to-face with judges and witnesses. They say the switch to courtroom from "courtZoom" can't come soon enough, even if they acknowledge that some of the videoconferencing should probably stick around.

"You're going to have to always have the skill to do the remote situation, because I think that's going to continue [in] some form," said Breen of Epstein Becker. "But I'm ready to go back."

Lawyers who focus on health care delivery are getting back to advising traditional clients on traditional issues, but with new expectations for what's achievable.

Manatt's Dutton, who helps state Medicaid programs improve health outcomes, told Law360 that the nation learned hard lessons about "dramatic racial disparities in the health and economic consequences of COVID" and "how fragile our public health infrastructure had become."

She recognizes that America isn't out of the woods yet, and that taking full advantage of those lessons isn't possible at the moment.

"But I already see signs of real change," Dutton said. "And I am hopeful that as we emerge from this collective nightmare, there will be new will to turn these lessons into action."

--Editing by Jill Coffey and Breda Lund.