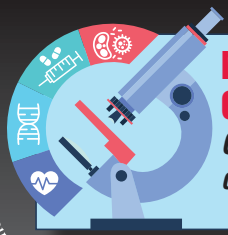
Volume XXXI, Number 5 Monday, April 8, 2024



Market Fragmentation Creates New Opportunities for Clinical Labs!

Consumer demand is driving the formation of new customized healthcare markets

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From the Desk of R. Lewis Dark...

THE DARK REPORT

RELIABLE BUSINESS INTELLIGENCE, EXCLUSIVELY FOR MEDICAL LAB CEOs / COOs / CFOs / PATHOLOGISTs

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COMMENTARY & OPINION by...

R. Lewis Dark

Founder & Publisher

Are Lab Leaders Ready for Artificial Intelligence?

WITH ASTONISHING SWIFTNESS, ARTIFICIAL INTELLIGENCE (AI) HAS BECOME PROBABLY THE SINGLE MOST IMPORTANT TECHNOLOGY discussed in corporate boardrooms and management meetings today. This is as true for clinical labs and pathology groups as it is for Fortune 100 corporations.

Almost daily, there are headlines about the inroads AI is making into different aspects of business and commerce. It should be recognized that these stories run the gamut from the good and the bad to the ugly.

On the good side, AI has improved how digital map programs interact with humans. They can display different routes to a destination and the time required to complete the trip. They can deliver real-time updates on traffic conditions and identify where wrecks and construction are slowing traffic.

On the bad side, in January, miscreants used AI to generate explicit images of pop music star Taylor Swift, which they then posted on social media platform **X** (previously known as **Twitter**). *BBC News* reported that these images went viral and were viewed millions of times by users of X before the platform purged the images.

On the ugly side, **Google** got a black eye when its Gemini chatbot was revealed to have been programmed to ignore white people. Consumers had a field day asking Gemini to generate and display Vikings, Nazis, Revolutionary War soldiers, and even George Washington, which Gemini composed as images of blacks, asians, and non-white people dressed in period-appropriate costumes and uniforms. Some users posted those Gemini-generated AI images on the Internet, which caused quite a stir.

The point is that AI is an evolving technology. It's clear that AI solutions often process input and then react in unintended ways. For this reason, clinical lab managers and pathologists should be cautious when considering the purchase and use of an AI-powered solution in their laboratories.

The explosion of interest in AI use in clinical labs and pathology groups is one reason why the *Executive War College* is offering an optional, one-day workshop on AI for lab leaders on May 2. This workshop will teach lab managers about the different technologies used in AI and the best ways to know when an AI-powered service can be trusted in daily operations. TDR

Lab Market Fragmenting, Creating New Opportunities

Goodbye to the mass market of yesteryear! Hello to customized markets demanded by consumers

CEO SUMMARY: Even as consolidation continues in the ownership of hospitals, health systems, office-based physicians, and clinical laboratories, there is a powerful trend of fragmentation quietly transforming the way providers—including clinical labs and pathology groups—serve patients and consumers who want specialized expertise and choice.

TODAY'S MARKET FOR CLINICAL LABORATORY TESTING SERVICES is fragmenting at a pace that is unrecognized by many pathologists and lab managers. This fragmentation will create new lab winners and new lab losers.

The lab winners will be those organizations guided by forward-looking lab administrators and pathologists. The lab losers will be the ones that are slow to adapt to the new realities of a different American healthcare system.

Two reasons make the strategic planning of a laboratory organization more challenging at this time. First, as noted above, several of the most powerful forces for change are subtle and not yet obvious to many lab professionals whose focus is on the daily delivery of accurate, timely test results.

Second, multiple factors are driving fragmentation in the delivery of lab testing services. That adds complexity to the strategic planning of lab owners and pathologist business leaders.

THE DARK REPORT has watched and analyzed the markets for clinical laboratory testing and anatomic pathology services across four decades. Never during this time has THE DARK REPORT seen so many market forces and new technologies in play simultaneously.

This intelligence briefing is the first in an ongoing series that will tackle the challenge of identifying these powerful market developments. The goal will be to provide clients and regular readers with facts, context, and analysis they can use to craft winning strategies to keep their labs at the cutting edge of clinical excellence in a financially-sustainable manner.

Today, our assessment centers upon the fragmentation occurring within the clinical laboratory and anatomic pathology sectors of laboratory medicine. This fragmentation is consistent with the

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THE DARK REPORT Intelligence Briefings for Laboratory CEOs, COOs, CFOs, and Pathologists are sent 17 times per year by The Dark Group, Inc., 21806 Briarcliff Drive, Spicewood, Texas, 78669, Voice 1.800.560.6363, Fax 512.264.0969. (ISSN 1097-2919.)

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SUBSCRIPTION TO THE DARK REPORT INTELLIGENCE SERVICE, which includes THE DARK REPORT plus timely briefings and private teleconferences, is $15.27 per week in the US, $15.27 per week in Canada, $16.05 per week elsewhere (billed semi-annually).

broader and long-established trend of fragmentation in every other sector of business and commerce.

The concept of "fragmentation" within a market sector can easily be described by going back to the days when companies looked at the United States as a mass market. Probably the last time when the mass market was dominant in this country was in the 1970s. The following examples demonstrate the dominance of the mass market and how it eventually fragmented.

Market Fragmentation Example 1
AUTOMOBILE INDUSTRY

In the 1970s, just three car companies dominated auto sales in the United States. They were **Ford**, **General Motors**, and **Chrysler-Plymouth**. During those years, the three companies collectively sold 80% to 90% of all new cars.

Contrast that with today's new car market in the United States. The fragmentation is obvious. More than 30 car manufacturers sell their products in the United States. Consumers have much greater choice when they are ready to purchase a new automobile today, compared to the 1970s.

Market Fragmentation Example 2
CONSUMER PRODUCTS

In the 1970s, companies sold uniform products in every region of the United States. **Procter & Gamble's** detergent brand Tide is a perfect example. In the 1970s, Tide made up 40% of all detergent sales. But, from coast to coast, Tide was only sold in one form—powdered detergent in a box.

Fast forward to the 2020s. Today, consumers can buy Tide in multiple forms. Visit *https://tide.com* and you will see 34 different versions of Tide that are available for purchase! This is fragmentation in the market.

Another useful example of fragmentation is **Nabisco's** Oreo cookie. A classic chocolate sandwich cookie with icing in the middle, the Oreo was trademarked in 1912 and sold in its original form until the last decade. Today, *https://www.oreo.com/oreo-cookies/oreo-flavors* offers consumers nine different flavors of Oreos!

Market Fragmentation Example 3
RECORDED MUSIC

During the decade of the 1970s, a handful of record companies controlled what music was recorded and how it was sold. During that decade, music aficionados could only acquire recorded music by purchasing a 45 single, a vinyl LP album, a tape cassette, or a reel-to-reel tape. (Yes, there were 4- and 8-track tape cassettes, but they were outmoded by the end of that decade.)

Today—in no small part because of **Napster's** success in 1999—the music industry is highly fragmented. Yes, CDs and vinyl LPs are still sold. But today, consumers have their choice of a growing number of music and content streaming services. Cable TV providers have streaming music channels. **Apple Music** and **Google Play** are options, as are services such as **Spotify**, **Pandora**, **Sirius/XM**, **iHeart Radio**, and **YouTube Music**.

Market Fragmentation Example 4
TELEVISION PROGRAMMING

During the 1950s, 1960s, and into the 1970s, consumers in the United States had a limited choice of television programming. **ABC**, **CBS**, and **NBC** were the three national networks. (And not all three networks had stations in the smaller cities.)

Television programming was truly a mass market. Adults and children watched the same programs and discussed them the next day at work and school. For example, it was national news when The Beatles made multiple appearances on the *Ed Sullivan Show* in 1964. During the 1970s, *Happy Days*, *Mash*, and *All in the Family* dominated the ratings, and there was often news coverage the next day in response to notable story lines.

Fragmentation of television programming commenced during the 1980s, when cable TV services hooked up millions of homes and offered them hundreds of channels to watch.

Today, the three networks still broadcast programming and millions of households continue to subscribe to the local cable TV providers. But the proliferation of streaming services has further fragmented and disrupted the classic way consumers watched television.

How fragmented is television watching today? There are probably 40 to 50 unique streaming content providers in the United States currently, including **Netflix**, **Amazon Prime**, **Hulu**, and **YouTube TV**.

Today, streaming services offer unlimited content, accessible 24/7 by television sets, personal computers, smartphones, and other devices that can access the internet.

In fact, along with streaming music services, streaming video/television services are the ultimate example of how a mass market in the United States has become fragmented due to changes in consumer preferences, enabled by new technologies.

Fragmentation, Consolidation

The examples provided above demonstrate that Baby Boomers and Gen X'ers are the last generations in the United States (during the 1970s) who were alive when companies looked at this country as a single mass market.

Lab managers and pathologist need to understand that fragmentation is happening in both healthcare and the clinical laboratory testing marketplace. Several market dynamics currently drive healthcare's fragmentation, including fragmentation within the clinical laboratory industry.

Before diving deeper into healthcare's fragmentation, it needs to be recognized that there is consolidation and integration going on within the U.S. healthcare system. One obvious example is how single hospitals were merged into multi-hospital health systems during the 1990s and 2000s.

In the past decade, it has become common for these integrated delivery networks (IDNs) to merge or acquire each other. It means fewer and larger health systems. Yet, there is fragmentation happening in how these IDNs organize themselves to serve the changing expectations of patients and consumers.

Office-based Physicians

Similarly, there has been consolidation in the ownership of office-based physicians. Regional and national organizations now employ and manage large numbers of doctors.

Consolidation has been ongoing within the clinical laboratory market and the anatomic pathology profession. Today, there are fewer independent clin-

Fragmentation, Trends at Executive War College

WHEN THE 29TH ANNUAL EXECUTIVE WAR COLLEGE CONVENES in New Orleans on April 30-May 1, there will be sessions devoted to current market trends, including fragmentation.

The market for clinical laboratory and anatomic pathology services is evolving rapidly. At the payer level, health insurers are becoming tougher in how they accept and process lab test claims. The federal **Food and Drug Administration's** proposed rule for the regulation of laboratory developed tests (LDTs) will be a major topic. The LDT market is highly fragmented and the LDT rule is widely viewed as disruptive.

Another topic for sessions is the demand for subspecialist pathologists that outstrips supply. The growth of subspecialization in pathology is another example of fragmentation.

ical lab companies and private practice pathology groups compared to 10 or 15 years ago. What is true of these consolidated labs and pathology groups is that they are, on average, much larger than the labs of two decades ago.

Three Primary Drivers

It is important to understand that fragmentation in the profession of laboratory medicine involves at least three primary drivers.

One driver is the ongoing advancement in the multiple enabling technologies used by clinical labs and pathology groups. Think about how automation alone has changed high-volume core chemistry, immunoassay, and hematology labs. More automation will arrive as companies further automate microbiology, histology, and other areas of lab testing.

A second driver is the recognized fact that more pathologists choose to specialize. When they finish residency, a larger proportion of pathologists go on to complete one or more fellowships to acquire specific expertise in one or more pathology subspecialties. One consequence of this is that—within the profession of pathology—there is more fragmentation of specialized expertise.

The third driver centers around the changed preferences of consumers and patients in how they access and use healthcare services, including lab tests. Today's consumers expect to have multiple choices when they are ready to buy a product or a service.

Telehealth Supports Choice

Telehealth and virtual office visits provide consumers with more choices of providers and enable them to easily consult with physicians locally or outside their region.

Similarly, it is already a fact in the clinical lab marketplace that physicians will use a specialty testing lab halfway across the nation if they want specialized tests for their patients.

These same office-based physicians are probably referring tests to several different specialty labs. This is fragmentation of the market, particularly compared to just a decade or two ago, when an office-based physician typically had one primary reference lab.

Today, when clinical labs and pathology groups do their market assessment as part of their strategic planning, they will want to articulate the different consequences that the trends of consolidation and fragmentation have on the local and regional healthcare markets they serve.

Consolidation means fewer—but larger—provider organizations. Fragmentation means that customers (physicians who order lab tests as well as patients and other healthcare consumers) want a service customized to their specific needs and interests.

Interesting Duality

This interesting duality of consolidation and fragmentation in healthcare and the clinical laboratory market creates a unique opportunity for savvy lab administrators and business-minded pathologists. The era of "we offer one service to everybody" is giving way to the era of "I know what I want and I'll find the physician and lab that can deliver it!"

Labs must use the newest digital services to increase their ability to deliver lab testing services closely tailored to the preferences of ordering physicians. The lab should do this in tandem with creating services that can be customized by individual patients and consumers.

When updating strategic plans, it is essential that lab administrators and pathologists study the forces reshaping how healthcare services are organized and delivered in the local and regional markets they serve. Consolidation can seem to be the major trend, but underneath consolidation, fragmentation is actively at work in response to consumers' desire for customized services. TDR

IVD Update

FDA Issues Memo to Reclassify Many High Risk IVD Assays

Some experts claim FDA would exceed its authority and that legal challenges will ensue

Was it an expected flood of applications to review laboratory developed tests (LDTs) that motivated the federal **Food and Drug Administration's** (FDA's) **Center for Devices and Radiological Health** (CDRH) to declare its intention "to initiate the reclassification process for most IVDs that are currently class III (high risk) into class II (moderate risk)" in a memo on Jan. 31?

Under this initiative, manufacturers could seek market clearance for tests through the 510(k) pathway, in which they demonstrate substantial equivalence to an existing test on the market.

"Such reclassifications may support the potential for more manufacturers to develop these tests, which can increase competition and increase access to these important tests," said CDRH Director Jeff Shuren, MD, JD.

New, novel tests that would otherwise warrant class III designation could be classified as class II through the agency's De Novo pathway, Shuren added. "Based on our experience, we believe that special controls could be developed, along with general controls, that could provide a reasonable assurance of safety and effectiveness for most future companion diagnostic and infectious disease IVDs. As such they would be regulated as class II devices."

The 510(k) and De Novo pathways are alternatives to the premarket approval pathway for class III tests.

The agency has already begun the process of reclassifying IVDs used to diagnose Hepatitis B virus, human parvovirus B19, and Mycobacterium tuberculosis infection, Shuren said. Previously, the agency reclassified antibody and RNA tests for Hepatitis C virus, he said.

Former FDA commissioner Scott Gottlieb, MD, praised the agency's move at a public meeting presented on Feb. 1 in Washington D.C. by **Friends of Cancer Research**.

"I think it was extremely forward-thinking," he said in response to a question from the audience. "I think it recognizes fundamentally that a test that is providing information to a treatment decision is fundamentally lower risk than a device that's being implanted in the patient [and] has to perform over 15 years."

Experts: It's All about LDTs

One legal expert who is also a pathologist told THE DARK REPORT that the move is likely connected to the FDA's efforts to regulate laboratory-developed tests (LDTs).

Last October, the agency released a proposed rule that would give it oversight of LDTs. This came after **Congress** failed to pass the VALID Act (Verifying Accurate Leading-edge IVCT Development Act), which would have provided a framework for the agency to regulate the tests.

"The FDA wants to make it easier for manufacturers to get their tests on the market, so that labs will use the manu-

factured kits rather than developing tests themselves," said Roger Klein, MD, JD. "I don't necessarily think that FDA's first priority is to make it easier for labs to submit tests for review."

Klein, a medical and legal consultant in Washington, D.C., was previously chief medical officer for **OmniSeq** and medical director for molecular oncology at **Cleveland Clinic**. He's been an outspoken critic of the FDA's moves regarding LDTs, contending that the tests should continue to fall within the jurisdiction of the federal **Centers for Medicare and Medicaid Services** (CMS) under the Clinical Laboratory Improvement Amendments (CLIA).

Attorneys Steven J. Gonzalez and Allyson B. Mullen of **Hyman, Phelps & McNamara, PC**, echoed Klein's point about the new reclassification initiative in a Feb. 2 post on *FDA Law Blog*.

"One can't help but read this announcement as an effort by FDA to prepare for (or at least give the appearance of preparing for) the deluge of IVD premarket submissions the agency expects it will receive following (the presumed) finalization of its proposed rule regulating LDTs," the attorneys wrote.

Even with the less-stringent regulatory pathways, the attorneys argued that the agency is ill-equipped for the workload likely to come its way. "FDA simply does not have the resources to handle the apocalyptic volume of premarket submissions it will have to review if it finalizes the LDT rule," they wrote. "We have yet to see the agency put forth a plan that would meaningfully change this calculation."

Class II vs Class III

"Historically, most diagnostic tests have been Class II, but companion diagnostic tests have been almost exclusively placed in Class III," Klein explained. "Those tests are used primarily to select patients for cancer therapies."

At present, he counts 169 companion diagnostic tests that have been approved or cleared for marketing and use with the associated cancer drug. Of these, "95%, or 162, went through premarket approval, so they're Class III," he said. "It's a determination of safety and effectiveness, and the manufacturer typically has to spend millions of dollars doing clinical trials."

That's not counting all the LDTs that would come under FDA jurisdiction if the new rule were finalized. Many LDTs, Klein said, are companion diagnostic tests.

Predicate Device

In a 510(k) clearance, he said, the agency determines if a new test is substantially equivalent to an existing test that's been cleared for marketing. The older test is known as the "predicate."

"FDA can be very liberal in terms of the predicate," he explained, and the agency can rely on a variety of approaches to determine substantial equivalence. For example, it could use a 'known methodology' approach, or one based on the clinical scenario. Regardless of the approach, the process is far less costly than a premarket approval.

In a Class II determination, the federal agency can also define "special controls" to mitigate risks associated with certain categories of tests, he said. These are special requirements or restrictions the manufacturer must follow to gain clearance.

So, how would reclassification work with companion diagnostic tests? "Until we see it in operation, we don't know how it will be implemented," Klein said. However, "I think FDA may end up down-classifying tests based on specific biomarkers." Therefore, a new test for a certain marker could be cleared if there's a predicate that tests for the same marker.

Even with a simpler regulatory pathway, he doubts that laboratories will find it cost-effective to get their tests cleared.

FDA's Final Rule on Lab Developed Tests Likely Coming Soon; Experts Expect Legal Challenge

FDA'S PROPOSED RULE TO GAIN OVERSIGHT of laboratory-developed tests (LDTs) is likely to be finalized in April, regulatory experts said, setting the stage for a possible legal challenge.

On **LinkedIn**, Scott Gottlieb, MD, wrote, "it's a shame Congress didn't pass the VALID Act. It was a much more efficient vehicle for regulating this field, giving FDA more tools to implement a risk-based framework. The VALID Act could also have served as a template for a least-burdensome approach to regulating AI medical devices. In time, I fear innovators across the space, as well as policy makers, will regret that the VALID Act didn't pass. Once this rule is implemented, it will be hard to get a second chance at the VALID Act."

In rebuttal to Gottlieb's post, Roger Klein, MD, JD, an outspoken critic of both the VALID Act and the FDA's proposed LDT rule, described the VALID Act as a "disaster for patients, treating physicians, and the molecular pathology field." He also predicted that a legal challenge to the LDT rule is likely, with a "decent chance" of an injunction that will prevent the final rule from taking effect.

Exceeds Legal Authority

"There could be circumstances under which FDA could regulate an LDT," Klein told THE DARK REPORT. "But I think, in general, what they're proposing exceeds their legal authority. I don't think there was any intention on the part of Congress, when it passed the medical device amendments, to grant authority to the FDA to regulate laboratories. They're prohibited from regulating services. They regulate devices. They're trying to take a service performed in a laboratory, break out a piece of it, and say, 'Well, that's actually manufacturing. And so it needs to be under us.'"

The VALID Act, he said, contained provisions that made it workable for large lab companies like **Quest** and **Labcorp** such as class approval and grandfathering of existing LDTs. "I think it would hurt their innovation tremendously, but I think they feel they can live with it," he said.

Klein said that the LDT rule, which lacks those exceptions, "would be viewed as an existential threat for laboratories of all sizes. The White House is determined to get this through. Their target is April. If they do it, I think laboratories will feel that they have no alternative but to challenge it."

In an article they wrote for *FDA Law Blog*, attorneys Jeffrey N. Gibbs, Allyson B. Mullen, and Gail H. Javitt of Washington D.C. law firm Hyman, Phelps & McNamara, PC, wrote, "[G]iven the large number of laboratories and clinicians that will be adversely affected, it would be very surprising if FDA were not sued by one or more plaintiffs."

What would happen at that point? Klein said that a court challenge could take two to four years to resolve. Plaintiffs would likely seek an immediate injunction. "I think there's a good chance they could succeed. It may depend on where the case is filed. A district court judge could issue a nationwide injunction. But some judges will probably be more deferential to FDA than others."

Presidential Politics

The outcome could also depend on the next Presidential election, he said. "A new administration could stop defending the rule in court, which would kill it. If the current administration stays in place, it will defend legal challenges to the rule. It could go through appeals to the federal Supreme Court."

FDA Final Rule on LDTs Moves Forward

FDA RELEASED THE PROPOSED LDT RULE IN OCTOBER following the failure of Congress to pass the VALID Act (Verifying Accurate Leading-edge IVCT Development Act), which would have provided a framework for FDA regulation of laboratory-developed tests (LDTS).

Since then, "the LDT rule has moved forward with astonishing speed," wrote attorneys Jeffrey N. Gibbs, Allyson B. Mullen, and Gail H. Javitt of Washington D.C. law firm Hyman, Phelps & McNamara, P.C. in *FDA Law Blog*.

The **U.S. Office of Management and Budget** received the draft final rule on March 1. "Given how fast it moved through HHS, the final [rule] is likely pretty close" to the draft version, wrote former FDA commissioner Scott Gottlieb in a post on **LinkedIn**.

If the rule does take effect, "clinical labs won't be submitting a lot of tests, not anything approaching the number of LDTs out there," predicted Roger Klein, MD, JD, a medical and legal consultant in Washington, D.C. "I think there would be a lot of non-compliance. I think many labs would ignore it or be unaware of the need to submit particular tests."

Under the Congressional Review Act (CRA), the White House has until May 22 to submit a copy of the final rule to Congress, Gottlieb observed. As a result, "the White House is likely to try and issue [the] final rule before that date. To reduce risk, it's subject to CRA review by the next Congress," he wrote.

"Most garden-variety laboratories do not have the resources, in my experience, to submit tests to the FDA," Klein noted. "Academic medical centers have financial constraints. In a hospital, for example, laboratories are typically cost centers."

Klein also believes that the paradigm of performing a companion diagnostic test for a single marker is largely outmoded given the emergence of next-generation sequencing, where a single test can search for multiple markers. "Some tests can go up to 500 or more genes," he said.

But even here, "hospitals are not doing these kinds of tests in high volumes" that would justify a costly regulatory submission, he added. "Looking at next generation sequencing, 30% to 40% of the testing is in lung cancer. There are something like 230,000 lung cancer cases in the United States each year, out of 330 million people. Most of the LDTs are performed for the smaller subset of advanced cases."

This is in contrast to infectious diseases, the other major category of tests covered by the new reclassification initiative, he said.

Infectious Diseases

"Infectious diseases are much higher volume, and they're recurrent," Klein explained. "People can get tested more than once. So, there are many more manufactured kits, unless it's a new disease like COVID, where initially most tests were LDTs. A laboratory can do lots of tests that are relatively low margin and still make money. In the cancer space, labs are still using mostly LDTs, and the tests are frequently money losers."

Going further, "I think even Class II of the medical device framework is too heavy for most lab tests," Klein said. Instead, he suggested that the way FDA evaluated Emergency Use Authorizations for COVID during the pandemic provides a better model. "I think it worked pretty well because you could get the test out faster. Asking for the analytical information and making sure the tests do what the companies say they do is a much better strategy." TDR

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Walgreens to Close 60 VillageMD Locations

Putting primary care clinics in retail drug stores proves to be more of a challenge than anticipated

CEO SUMMARY: Following substantial losses in fiscal 2023, Walgreens is working to cut costs and reduce overhead. One casualty in this effort will be the closure of 60 of the 360 primary care clinics in retail pharmacy stores built by Walgreens in recent years. These actions demonstrate that putting primary care clinics into drugs stores may be more challenging than expected.

At least one national pharmacy chain is rethinking its ambitious plans to incorporate primary care clinics into its retail pharmacies. **Walgreens Boots Alliance Inc.** recently disclosed it is closing dozens of **VillageMD** clinics located within its stores as part of a large-scale cost-cutting initiative.

In 2020, Walgreens invested $1 billion in VillageMD, a chain of primary care clinics that was created to provide healthcare services to individuals regardless of background or income. In 2021, Walgreens made an additional $5.4 billion investment in VillageMD and took a majority stake in the company.

This happened as other national retail pharmacy chains announced similar plans to build primary care clinics in their stores. This was true of **Walmart**, **Target**, and **CVS**. *(See TDR, "New Players May Reorder Who Buys and Who Orders Lab Tests," June 14, 2021.)*

There are several things to understand about the common strategy by the major retail pharmacy chains to add primary care services in their retail stores.

One is that the national pharmacy chains found themselves disintermediated from providing prescriptions to patients by pharmacy benefit management (PBM) companies. By 2021, PBMs had captured $484 billion of the total prescription drug spending of $576.9 billion. That meant PBMs controlled 84% of the prescription drug market! That caused retail pharmacies to look for new sources of revenue and primary care became an attractive option.

Filling Prescriptions

Delivering primary care in a retail pharmacy also came with another benefit. The odds were great that the patients—after visiting the primary care physicians—would choose to fill their prescriptions at that store's pharmacy. This would enable a national pharmacy chain to recapture some of the prescription volume and revenue it had lost to PBMs.

Additionally, should putting primary care clinics into retail pharmacies prove to be successful and widespread, it potentially could change the ways physicians and patients accessed the clinical laboratory tests they need for the care.

This would have a direct consequence on the clinical laboratory industry. Assuming the national retail pharmacy chains attracted substantial numbers of

patients, a large volume of lab tests would originate from these physicians and patients. Thus, hundreds or thousands of pharmacy-based primary clinics would represent a new class of customers for clinical laboratories.

The retail pharmacy chains would have two obvious paths to provide clinical lab testing services to these patients. First, if a pharmacy chain like Walgreens was operating hundreds of medical clinics nationally, might the company want to contract with a single national laboratory to provide the needed clinical lab tests?

This would mirror the national contracting practices of major health insurers, such as **UnitedHealthcare**, **Aetna**, **Cigna**, **Elevance** (formerly **Anthem**), and **Humana**. Over the past 25 years, these health insurers gave preference to national contracts with **Labcorp** and **Quest Diagnostics** over regional labs.

➤Establishing In-Store Labs?

Second, might the national pharmacy chain decide to set up its own in-house clinical laboratory services in these pharmacies? This could be done by either:

- Establishing physician office labs and near-patient testing capabilities in each pharmacy store with a primary care clinic; or,
- Setting up regional core clinical laboratories to support the testing needs of a cluster of the nearby drug store-based primary care clinics.

In either of these scenarios, local clinical labs would not be a favored choice to provide laboratory testing services to the patients served by the in-pharmacy primary care clinics.

The good news for clinical labs is that these developments are years away from happening. At the same time, it needs to be recognized that the national pharmacy chains have the resources to create hundreds of primary care clinics in their retail stores.

For example, Walgreens planned to open 500 to 700 VillageMD clinics in more than 30 US markets over five years, with the intent to build more. Even though the company fell short of that goal, it did manage to build 360 clinics at the beginning of this year, of which 211 clinics were attached to Walgreens stores and 149 were stand-alone clinics.

➤Financial Losses

But last year, Walgreens' healthcare division performed less than expected. It posted $1.73 billion in operating losses in 2023. That loss prompted Walgreens to reassess its expansion plans and alter its strategies to improve financial performance and increase profitability.

In October of last year, the company released a cost-cutting plan to reduce costs by $1 billion in expenses this year. The plan included cutting capital expenditures by around $600 million and closing 60 underperforming VillageMD clinics, exiting five healthcare markets entirely.

"I think we just have a lot of things going on, and we're trying to prioritize and figure out which models we'll focus on, and in which geographies we're focusing," said Sashi Moodley, MD, Walgreens' Chief Medical Officer, in an interview with *MobiHealthNews* at the *VIVE24 conference* in February.

"We also know there's a huge opportunity there to work with doctors that we don't necessarily employ, whether they're independent doctors, solo practitioners, medical groups, or even health systems," Moodley added. "There's much more we can do there. And so, I think, we're also going to, over time, scale some of those models."

➤Focus on Driving Growth

Following the financial losses in 2023, Walgreens acted swiftly. In January, the company shuttered three clinics in New Hampshire, 10 clinics in Jacksonville, Fla., and all 12 of its Indiana clinics.

In February, all 12 VillageMD clinics in Massachusetts also were closed. The company plans to close its remaining Florida clinics in March and its six Illinois clinics in April.

VillageMD has remained quiet about the closures and the last news release issued by the company was in October.

Walgreens said it will support patients of the closed VillageMD clinics by providing them with resources on where to seek care and instructions on how to access and transfer their medical records.

Getting the Footprint Right

It should be noted that VillageMD clinics are seeing growth elsewhere in the locations it operates. "VillageMD is driving patient panel growth and achieved 23% year-over-year growth in full risk lives, and 9% growth in fee-for-service volumes," Wentworth told *Forbes*. "Work is under way to implement targeted marketing efforts, leveraging Walgreens expertise and patient touchpoints, and we expect benefits over time as we learn and further develop our provider-based risk strategy."

Meanwhile, Walgreens is downsizing on other fronts. In the past six months, the company announced it would close 150 drug stores in the U.S., along with two distribution centers in Dayville, Conn. and Orlando, Florida.

Other national pharmacy chains are encountering similar financial challenges. In the last 12 months, **Rite Aid** filed bankruptcy and plans to close 900 of its 2,000 stores. **CVS** closed 244 stores between 2018 and 2020, followed by an announcement in 2021 that it planned to shutter another 900 stores by 2024. *(See TDR, "Hospitals, Pharmacies Struggle to be Profitable, Oct. 23. 2023.)*

The financial turmoil experienced by the national retail pharmacy chains is shared by the nation's hospital industry. Whenever there are sustained losses with an industry, a major restructuring occurs. Thus, clinical laboratory executives and pathologists will want to monitor the ongoing financial health of these two sectors of the U.S. healthcare system.

This is particularly true of the hospital sector because of its reliance on clinical laboratories and anatomic pathology groups.

These developments are also a timely flag that it would be wise for all labs to review their strategic assessment of the U.S. healthcare system and revise their business strategies in appropriate ways. TDR

Walgreens Posts Loss of $3.1 Billion in 2023

WHEN WALGREENS REPORTED ITS FOURTH QUARTER AND FULL YEAR EARNINGS for its fiscal year ending Aug. 31, 2023, it was not auspicious news for its corporate investors.

In its press release, Walgreens stated, "For the fiscal year 2023, sales were $139.1 billion, an increase of 4.8% from the year-ago period. The operating loss in fiscal 2023 was $6.9 billion compared to operating income of $1.4 billion in the year-ago period. The net loss in fiscal 2023 was $3.1 billion, compared with net earnings of $4.3 billion in the year-ago period."

The company has posted soft revenue projections for 2024. It plans to lay off 267 corporate employees or 5% of its workforce. Walgreens has also reduced its quarterly dividend payment to 25 cents/share to increase cash flow and free up capital.

In December, Walgreens Boots Alliance had its unsecured credit rating cut to junk by **Moody's Investors Service**. Moody's report cited the drugstore chain's high debt-to-earnings ratio and the various risks associated with its effort to add more healthcare services. Walgreens shares fell by as much as 2.9% after the downgrade. Moody's current outlook on Walgreens is stable.

Regulatory Update

Final Rule on AI Transparency Can Benefit Clinical Labs

Federal rule is intended to make AI algorithms transparent while supporting data interoperability

Artificial intelligence (AI) and machine learning are becoming ubiquitous in today's modern hospital systems and clinical laboratories. In response to these developments, federal officials issued a new rule that has major implications on how healthcare providers use artificial intelligence.

This article is the second part of a report by The Dark Report that discusses The Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) Final Rule, which was finalized in December. *(See TDR, "HHS Publishes Final Rule for Health IT Interoperability," February 26, 2024, for part one of this story.)*

The **U.S. Department of Health and Human Services** (HHS) **Office of the National Coordinator for Health Information Technology** (ONC) announced the new regulation as part of the 21st Century Cures Act. The new rule:

- Establishes algorithm transparency requirements;
- Adopts interoperability standards; and,
- Enhances information blocking requirements for the sharing of data between different healthcare entities to ensure the security of patients' protected health information.

The HTI-1 Final Rule establishes new transparency requirements for artificial intelligence (AI) and machine learning (ML) technology that supports decision making within the healthcare sector.

It also constitutes changes to Information Blocking Rules and the ONC's Health IT Certification Program and includes new provisions, as well as modifications to existing provisions, for promoting interoperability and enriching equity.

"Labs should pay close attention to the language about decision support intervention (DSI), specifically as it relates to the use of algorithms to analyze data and provide recommendations for treatment," stated Greg Stein, founder and Chief Executive Officer of **Shadowbox, Inc.**, a California-based company that specializes in healthcare automation, in an exclusive interview with The Dark Report.

Currently, labs provide test results to clinicians who determine the proper diagnosis and treatment protocols. The new regulations provide an opportunity for labs to provide clinical DSI as well, but that comes with challenges.

Opportunity for Labs

"I think this is a really complicated and challenging opportunity for labs in terms of wanting to provide AI-enabled services because I suspect there will be payer pushback—and to some extent clinician pushback—because labs are traditionally seen simply as service providers executing requests and returning results, not interpreting the treatment those results suggest," Stein explained.

"If labs are thinking about adding DSI tools to their results presentation, either through the lab results, portals or other software, they should be aware of these

rules and consider becoming certified health IT vendors themselves," he added.

The designers of the federal regulation appear to recognize that not every player is going to be enthusiastic about complying with the various provisions of HTI-1 and there are legitimate reasons for concern among the various actors. *(See sidebar on page 16.)*

"I recall looking at a particular EHR vendor's financial statements that reported approximately $700 million in services revenue," Stein said. "But at a 6% gross margin, it meant they were likely losing money on their services."

Moreover, there are still some bad actors among EHR vendors and Stein says labs know who they are. When those vendors engage in information blocking, they undermine the spirit of the Cures Act.

Diagnostic Information

All treatment decisions begin with some form of diagnostic, yet it is a tiny fraction of overall healthcare spending. When the government spends billions of dollars on integration and digitization, clinical laboratories are often left out of the process leading to frustration for lab personnel.

"Congress, ONC, and other agencies should figure out a way to enhance compliance, particularly for information blocking," Stein said. "My suggestion is that any healthcare reimbursed with federal money for a patient whose data resides within a non-certified health IT vendor triggers the requirement that the IT vendor must also comply with information-blocking rules.

"When the few EHR vendors choose not to certify as a way of side-stepping information-blocking rules, it is ultimately the patient who suffers. At the end of the day, [HTI-1] will dramatically reduce friction between clinical laboratories and patients," Stein noted. "Patients will be able to trust that they are getting information about themselves rapidly, effectively, and successfully."

Overall, Stein foresees many benefits for the role of AI in medicine and clinical laboratory testing. "AI represents the opportunity to empower fewer people to do more with less," he explained. "We have an aging population that receives costly therapeutics to extend and improve quality of life. This is juxtaposed with a static or even shrinking healthcare workforce here in the United States.

Uses of Artificial Intelligence

"This is why many people get excited about the potential for AI to detect disease faster, which is fantastic," Stein noted. "What gets me excited, however, is the opportunity to use AI to reduce clinician burnout and greatly reduce human error, minimizing mundane tasks that can be automated."

Stein went on to say that AI should help clinicians spend the majority of their time doing the patient care tasks they are trained to do versus paperwork, chart notes, form completion, and toggling between different applications.

"I think clinical laboratory managers and pathologists should be very careful to ensure that the artificial intelligence tool they deploy is more than something cool. It should truly be something that advances quality of care or operations," Stein suggested.

Support for Interoperability

"Advanced technologies should be embraced because these technologies enable EHR vendors to support interoperability without cost, while also enabling all vendors and providers to have access to patient data much more efficiently," Stein concluded.

Clinical laboratory managers should be aware of the federal government's new HTI-1 Final Rule and work with EHR vendors to find a solution that is beneficial to all parties and ensures the technology isn't a hindrance to patient care. **TDR**

Contact Greg Stein at greg@shadowbox.com.

How Clinical Labs Can Work with EHR Vendors to Reduce Fees and Prevent Information Blocking

SEVERAL CRITICAL ITEMS THE NEW HTI-1 RULE IS INTENDED TO RECTIFY include preventing electronic health record (EHR) vendors from charging excessive fees and taking too long to generate the interfaces that enable their platforms to communicate with physicians and with other vendors' EHR platforms.

"Labs need to have efficient access to clean, complete, and accurate patient data—both clinical, and demographic—so they can provide clinically-actionable results," said Greg Stein, founder and Chief Executive Officer of Shadowbox, Inc., in an interview with THE DARK REPORT. "Labs also need access to patient's insurance information so they can get paid for those services or else they go out of business."

Limited Resources

"If [EHR vendors] are required to build new interoperability solutions into their software to meet the federal rule, they are now allocating resources to help other vendors access data versus allocating resources to further enhance their own applications," Stein said. "It's easy to see how EHR vendors might perceive this to not be in their best interest."

From the EHR vendor's point of view, it's about limited resources and costs. This is the rationale behind why they charge so much money for their technology and why it takes so long to create interfaces, as many of the vendors simply do not have the staff to address all the requests.

In addition, some EHR vendors inaccurately view patient information as proprietary to them and are reluctant to share that proprietary information with other vendors.

"When an EHR vendor charges high fees or takes weeks or even years to create an interface, they're interfering with the access and delivery of critical healthcare services," Stein explained.

"Not only is this situation costly for the entire healthcare system, but it actually creates hardships for patients due to errors caused by manual workarounds like paper and fax, or simply the non-delivery of critical services that clinicians may want to access for their patients."

Information Blocking

Some EHR vendors may partake in soft blocking techniques—such as terms of service and contractual issues—while others are more aggressive. Stein sees the new HTI-1 interoperability guidelines as an opportunity for patients, clinicians, and vendors to support the government in improving healthcare.

"In terms of reducing or eliminating information blocking, if the government doesn't know about infractions, they can't act on them," Stein said. "I think labs and complementary vendors should collaborate and educate clinicians, patients, and others to support their efforts to make good software purchase decisions, which means migrating away from the bad actor EHRs. They need to report suspected information-blocking infractions through the easy access portals provided by both the ONC and the **U.S. Department of Health and Human Services, Office of the Inspector General**."

Stein believes the problem won't be solved until clinics migrate away from bad actor EHRs and toward EHRs that embrace these rules and the value they provide for all of the stakeholders.

"Labs," he says, "can support this migration by building relationships with EHR vendors that embrace these next-generation interface solutions."

Obituary

Pathologist Paul A. Brown, MD, MetPath Founder, Dies at 86

Brown sold MetPath to Corning for $140 million, in 1996, MetPath was renamed Quest Diagnostics

EARLIER THIS YEAR, THE PATHOLOGY PROFESSION LOST one of what some call "the two Lions of Pathology." On January 24, 2024, Paul A. Brown, MD, aged 85, died at his home in Palm Beach, Florida.

In 1967, Brown was the founder of **Metropolitan Pathology Laboratory, Inc.**, based in New York City and known as **MetPath**. After sustained growth and several ownership changes, MetPath became **Quest Diagnostics**.

Paul A. Brown, MD
1938-2024

Brown's peer—and the other Lion of Pathology—is James B. Powell, MD. In 1969, within a few years after graduating from his pathology residency, Powell founded **Biomedical Laboratories** in Burlington, N.C. Today, after several name changes, Biomedical Laboratories is now called **Labcorp**. After serving as CEO, Powell retired from Labcorp in 2000. Today, Powell is 85 years old and is reported to be in good health.

Remarkable Coincidence

It is a remarkable coincidence that two clinical pathologists graduated from their perspective residencies within a few years of each other, and then proceeded to found clinical laboratory companies that eventually grew into the nation's two largest laboratory testing corporations.

Paul Brown, MD, did his undergraduate studies at **Harvard University**. He then attended medical school at **Tufts-New England Medical Center** and completed his pathology residency at **Columbia Presbyterian Hospital** in New York.

NorthJersey.com reported, "Brown performed his pathology residency in **Englewood Hospital** where he first got the idea to create a diagnostic testing lab. After [starting] his first lab in [a] New York apartment, Brown moved the company to New Jersey to a storefront on Englewood Avenue in Teaneck. The company later moved to Hackensack and then to Teterboro where the largest lab is still today."

Under Brown's leadership, MetPath grew rapidly during the 1970s. The website *www.company-histories.com* has a detailed description of how Brown grew his lab company during that decade, writing:

> *Paul A. Brown, a pathologist who later said he was "amazed at the sky-high test prices charged by hospitals and clinics," founded what was originally Metropolitan Pathological Laboratory in 1967 with $500 and initially ran it out of his Manhattan apartment. Two years later he invested in a $55,000 device that automatically performed 12 common blood tests, charging $5.50, compared with more than $40 charged by hospitals and medical laboratories.*

In 1972 Brown spent more than $1 million on two AutoChemist units, which raised the number of blood tests MetPath could perform automatically to 25 and saved significantly on costly chemical reagents needed for analysis. The company began turning a profit in 1971 and, beginning in 1974, made money each year. ***Corning Glass Works*** *bought ten percent of its stock in 1973.*

By 1975 MetPath had one of the best equipped and largest medical laboratories in the world and was the largest U.S. company devoted entirely to clinical laboratory services. It was offering, in 11 cities, more than 600 laboratory tests to physicians, hospitals, and institutions and performing more than two million lab tests a month from specimens of more than 150,000 patients.

The tests were being processed at a highly automated central laboratory in Hackensack, New Jersey, with 80% of the results delivered to the client within 24 hours after collection of the specimen. Overall, MetPath's average billing per patient transaction was only $9.

MetPath was, by 1979, challenging ***Damon Corp.*** *for first place in the clinical laboratory testing field, which had grown into a $12-billion-a-year business. The company had net income of $3.8 million in fiscal 1978 (the year ended September 30, 1978) on revenues of $53.4 million.*

A new $25 million laboratory, easily the industry's largest and capable of analyzing up to 30,000 samples a day, was completed in Teterboro, New Jersey, in 1978. Fifty local offices made daily collections at doctors' offices and clinics, shipping them via same-day air freight to the laboratory. The results were transmitted to telecommunications terminals at each of the company's local offices. For a package of 29 common tests, MetPath was charging only $20.

As MetPath continued to be one of the largest and fastest-growing customers of **Corning Corporation's** laboratory glassware, the Corning board decided to acquire 100% of MetPath for $140 million in 1984.

Quest Diagnostics in 1996

Corning operated MetPath under that name until 1994, when the lab business was renamed **Corning Clinical Laboratories** (CCL). In 1996, Corning spun off CCL to create **Quest Diagnostics, Inc.**, which operates today under that name.

Meanwhile, after selling MetPath, Brown continued his entrepreneurial career. He founded a company called **HEARx** that provided services in hearing care. Under his leadership as Chairman and CEO, HEARx grew regularly and eventually had 200 company-owned centers. In 2011, **Siemens AG** purchased the assets of HEARx for $129 million.

Pathologists interested in how Brown developed his business and management skills might want to read the book Brown co-authored with Richard D. Hoffmann. It is "Success in the Business Jungle" and is still available on **Amazon** Kindle.

Remarkable Career

As a board-certified clinical pathologist, Brown had a remarkable career. He founded two companies that were sold for a combined total of $269 million.

There is an interesting footnote to Brown's laboratory career. Pathologist Raymond Gambino, MD, was Chief Pathologist at Englewood Hospital when Brown was completing his pathology residency. Gambino was also a Professor of Pathology at Columbia University's College of Physicians and Surgeons.

The professional relationship between Brown and Gambino led to Gambino joining MetPath as Chief Medical Officer in 1983. Gambino continued at Quest Diagnostics until retirement in 2014. He died in 2017 at the age of 95. TDR

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

UnitedHealth Group stated that the cyberattack against **Change Healthcare**, a business unit of UnitedHealth's **Optum** division, disrupted processing of approximately $14 billion in claims. The company discovered the cyberattack on Feb. 21 and said it disconnected the data systems targeted in the attack. UnitedHealth also stated that its software system for preparing medical claims, named Assurance, was back online as of March 25. UnitedHealth extended $3.5 billion in advanced payments to aid those healthcare providers that experienced financial disruption as a result of the cyberattack.

MORE ON: *Change Healthcare Cyberattack*

Clinical labs and pathology groups submitting claims through the Change Healthcare claims clearinghouse saw little disruption in the processing of those claims. That's because the cyberattack targeted the data systems that enabled the transmission of prescription orders from providers to pharmacies, along with remittance from those prescription orders. The cyberattack against Change Healthcare can be considered a warning that all providers—including clinical labs and pathology groups—would benefit from reviewing their cybersecurity protections with the goal of strengthening them using the latest generation of data security tools.

SONIC HEALTHCARE BUYS SWISS LABS

Last month, **Sonic Healthcare, Ltd**, of Sydney, Australia, announced its acquisition of the **Dr. Risch Laboratory Group**, based in Aarau, Aargau Switzerland. Dr. Risch generates annual revenue of approximately US$113 million and operates 14 labs in Switzerland and Liechtenstein. Sonic will integrate Dr. Risch labs into its existing Swiss operations. Sonic is the world's largest, multi-national clinical lab company, with labs in eight countries in the continents of Australia, North America, and Europe.

TRANSITIONS

- Jannalee Johnson launched **Canyon Bio Science Consulting, LLC**, in Phoenix in June of 2023. Johnson's prior positions were with **XiFin, Inc.**, **Inform Diagnostics**, **Leica Biosystems**, **Abbott Laboratories**, **TriCore Reference Laboratories**, **Avero Diagnostics**, and **Bostwick Laboratories**.
- Eric Reynolds is now CEO at **Healthcare Direct** of Branson, Missouri. He formerly held positions at **MTM, Inc.**, **Change Healthcare**, **Atlas Development Corporation**, **MITEM Corporation**, **Healtheon/WebMD**, and **SmithKline Beecham Clinical Laboratories.**
- **HealthEC, LLC** of Edison, N.J., selected Brian Zinkil as Vice President of Sales. His prior positions were with **Midmark**, **Ronco**, **Viewics**, **Aperio**, **Dako**, and **Abbott Diagnostics**.

That's all the insider intelligence for this report. Look for the next briefing on Monday, April 29, 2024.

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SPECIAL SESSION

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Michael Laposata, MD, PhD

Chair of Pathology, Univ. of Texas Medical Branch–Galveston
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UPCOMING...

- ***Dept. of Justice to probe UnitedHealth Group over possible antitrust violations.***
- ***Labcorp acquires select business assets of OPKO's BioReference Laboratories division.***
- ***Is digital pathology poised for wider adoption in the United States? Experts offer their predictions.***