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Contributing Editor:
Roger Kuan
Norton Rose Fulbright

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59 Tanner Street
London SE1 3PL
United Kingdom
+44 207 367 0720
info@glgroup.co.uk
www.iclg.com

Production Editor
Jane Simmons

Publisher
James Strode

Senior Editor
Sam Friend

Head of Production
Suzie Levy

Chief Media Officer
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Introductory Chapters

Expert Analysis Chapters

Q&A Chapters

The Rise of Digital Therapeutics and Corresponding Legal, Regulatory, and Policy Landscape


Jason Novak


René Quashie

Norton Rose Fulbright
Consumer Technology Association (CTA)

Digital therapeutics, of DTx, is a subset of digital health that, as defined by the Digital Therapeutics alliance [Digital Therapeutics Alliance; https://dtxalliance.org (2020)] focuses on "evidence-based therapeutic interventions driven by high-quality software programs to prevent, manage, or treat a medical disorder or disease". Over the past few years, DTx has quickly grown as a new platform for addressing the treatment, management, and/or prevention of various diseases. Technological advancements, to go along with the focus on multi-modal and data-driven solutions, has quickly elevated DTx into mainstream Healthcare discussion.

As with any emerging technology, particularly in healthcare, legal and regulatory policy issues often follow the emergence. However, DTx is an example of a "convergence industry" in that DTx is not the child of one industry, healthcare, but two, healthcare and tech.

As we have discussed in previous articles, digital health is a convergence of typically disparate industries: tech; and healthcare. Each industry encounters issues unique to their industry, particularly in the areas of intellectual property, data rights, and regulatory. Beyond unique issues, perspectives on these areas are different for each industry as well. Take open-source (OS) software as one of many examples. In tech, OS is often revered as the industry standard by which to operate, which has in turn strongly impacted the developers that create software solutions. In healthcare, not so much. But why?

In tech, the "how" something works is not as important as "what" it does. In healthcare, both the "how" and the "what" are fundamental to customer adoption, particularly with the regulatory underbelly that permeates healthcare innovation. That cultural difference can and has impacted perspectives in these disparate industries when applied to OS strategy.

As such, given that digital health is a combination of both tech and healthcare, it is often the case that almost all entities in the digital health world will have strategic (often legal) "blind spots" based on their experience leading up to the endeavour.

DTx is no different, especially as it applies to intellectual property, data, and regulatory considerations. As such, we will focus on those considerations in the world of DTx, and introduce some points to keep in mind as you consider your overall development strategy.

Legal Considerations

The legal considerations for DTx development are numerous and varied. Some of those considerations are standard fare for any innovation and will not be discussed. Others are industry-unique. Below, we will focus on a couple of unique considerations: intellectual property (IP); and data.

Intellectual property

IP strategy is industry specific. It is industry specific because markers exist within each industry that add up to a corresponding impact on IP strategy. Moreover, IP strategy is company specific. It is company specific because markers exist within each company that add up to a corresponding impact on IP strategy. Essentially, this means that IP strategy is *ad hoc*, not formulaic. As such, areas such as invention harvesting and invention protection must necessarily differ for each industry, and each company inside each industry. Anything less may result in a less sophisticated and insufficiently curated strategy than the specific DTx business or entity deserves.

Invention harvesting

Invention harvesting is the process by which IP experts interact with innovators to identify potential inventive ideas, and develop a strategy by which to protect them. In mature industries, such processes can be more formulaic because, for example, developers have been regularly educated on what to look for, and have had more experience capturing and defining those innovations. In growth industries, such processes are a bit less formulaic because, for example, developers have received little or no education on what to look for and, therefore, have less experience capturing and defining those innovations. In convergence growth industries (i.e., DTx), the issues become even more acute. Beyond the reality that the process is not formulaic at all, developers have received little or no education, and developers have nearly no innovation capture experience, the IP experts in these convergence spaces are few and far between. What can result is a situation of the blind leading the blind. Moreover, the developers often come from either side of the convergence. Therefore, beyond lacking the understanding of IP capture in the convergence space, many developers are biased by previous learnings and experiences on one or the other side (tech or traditional healthcare), making the task more difficult by having to educate while also breaking defined habits of traditional thinking. Again, think open source (OS) in a healthcare context. If you are a developer from traditional tech, what is your philosophy about OS? Now compound that by having leadership primarily having experience in traditional healthcare. Now compound that by placing these divergent philosophies and experiences in a DTx company, one for which neither has substantial experience. How would OS strategy be defined with those voices in the room?

So how does the tech *vs.* healthcare dichotomy affect invention harvesting? A better way to define the problem is to think

of a car. The hood of the car covers features of the car from public viewing. Those features above the hood are clear for all to see. Those features under the hood are not. Those features above the hood equate to features that may be, for example, customer facing, patentable at least to a degree depending on individual national IP laws, or have strategic value in the market if patented instead of maintained as confidential. Those features under the hood, by contrast, may be, for example, non-customer facing, non-patentable in key countries, or have strategic value in the market if maintained as confidential or a trade secret. Is that "hood line" always in the same place? Absolutely not. Can that "hood line" vary considerably? Absolutely. One of the big reasons is the industry of focus. So, let's look at this "hood line" in the context of traditional tech and healthcare.

As discussed above, traditional tech customers are generally concerned with "what" a product does, whereas traditional healthcare customers are generally concerned with both "what" a product does and "how" a produce works. Moreover, tech products are typically very transient, with innovation advancing rapidly, though often very iteratively, in most cases quicker than patent filings can be prosecuted to issued patents.

Healthcare, by contrast, often innovates and builds products for the long term, which is essentially necessary as the time to market for healthcare products are longer, and the accompanying and difficult regulatory approval requirements making iterative innovation less of a focus. As such, the timing for prosecuting patent applications more aligns with product life and feature stability.

Accordingly, in tech, less of a focus on "how" keeps many features under the hood. For example, with phone apps, customer expectations are geared around what an app does, not why it works. As such, typical public disclosure requirements are minimal. Add to that the transient nature of product development, and one can see why the "hood line" in tech is very high, with more under the hood than over it.

By contrast, the culture in healthcare substantially lowers that "hood line". In healthcare, there is a significant focus on the "how", not only from a customer expectation standpoint, but from a regulatory requirements standpoint as well. Thus, healthcare products are less transient. Add to that the publication-first culture of healthcare innovators in private companies, universities, research institutes, and hospital systems alike, public disclosure requirements and customer expectations are substantially higher. As a result, the "hood line" drops greatly relative to tech, resulting in more publicly facing features in healthcare products than tech products and a greater need to proactively secure rights to those features.

How does this affect the convergent DTx industry? First, as stated before, DTX companies often include both traditional tech and traditional healthcare leadership, bringing with them these traditional philosophies. Second, in our shrinking and increasingly connected world, these employees come from various territories around the world that have IP laws that can differ, sometimes widely, from each other. Third, the "ratio" of tech innovation to healthcare innovation is unique to each DTx company. The result is a "hood line" that often sits between these two traditional industries, in a gray zone for which neither is familiar. Therefore, counselling in the DTx space is essential to educate all these parties in an effort to define that line in the most appropriate and sophisticated way.

Finally, another increasingly influential variable is artificial intelligence/machine learning (AI/ML). AI/ML is a great example of technological advancement in one traditional industry (tech) heavily influencing healthcare. While AI/ML has conceptually existed for years, overall technological advancement of underlying software innovation and the digital marketplace has brought AI/ML to the forefront in healthcare as a feasible feature to generate unique insights never before possible. However, this only reinforces the dichotomy. While this discussion is complex enough to deserve its own article, it can be boiled down to a fundamental problem: tech's traditional view on IP protection for AI/ML likely will not align with the needs and opportunities in a DTx framework. For example, while traditional Tech may view the IP strategy as a patent *or* trade secret approach, DTx offers the opportunity at both patent *and* trade secret protection for these AI/ML-based solutions. Again, as stated above, sophisticated counselling in the DTx space is needed to understand AI/ML's impact on the corresponding "hood line".

Data considerations

As is apparent in recent months and years, DTx will continue manifesting throughout the healthcare industry. If the COVID-19 pandemic has taught us anything, it is that companies, healthcare providers, and health systems that have figured out how to maintain a digital infrastructure are more nimble and more capable of adapting to changes in healthcare delivery while driving adoption for the same. Given that reality, regardless of how complex our constantly evolving healthcare industry may seem to get, there is a common theme: data is king and the proper generation, acquisition, maintenance, transaction and/or use of data is essential to a successful DTx endeavour. As a result, to continue being relevant and adapting to the new operating reality, companies must focus on establishing a well-developed data strategy to execute a DTx endeavour. While there are many considerations, we will touch on only three in detail.

1. First Consideration: Know your industry and corresponding "blind spots"! As we have discussed previously, the convergence of typically disparate industries – tech and healthcare – to form DTx, converges issues unique to each industry. For example, tech can deal with data transactions, data privacy, and cybersecurity on a regular basis. Healthcare traditionally has not, at least not until digitisation brought about the concept of using and transacting with personal health information under HIPAA and other laws. Healthcare must contemplate FDA oversight and reimbursement considerations on a regular basis, while tech traditionally does not. Therefore, these industries have historically functioned in parallel: tech, focusing on moving fast to create the best, most innovative products; while healthcare, which is highly regulated and appropriately risk averse, concentrates on assessing every potential consideration before implementing a change.

   Recognising the disparate nature of this convergence will give DTx leaders the ability to recognise the strategic (often legal) "blind spots" based on their experience leading up to the endeavour. Knowing what you do not know is the first step to "cleaning up your house" as it relates to data strategy.
2. Second Consideration: Understand use/consent requirements! Healthcare data is exceptionally valuable to both the patient and the data-procuring company. Given its value and heavy regulated nature of that data, one must have permission to use healthcare data for a desired purpose. Regardless of whether the healthcare data is generated or acquired by the data user, the data user must have the consent of the data's ultimate owner, i.e., the patient, to use that healthcare data. In the cases where healthcare data is acquired from a third party, the data user must also have the consent of the third party to use the healthcare data for a desired purpose. Often, consent from a third party

(e.g., a healthcare data warehouse or aggregator) comes via a data transaction, where the data user can compensate, in some form, the third party to acquire the healthcare data for the desired purpose. Of course, the consent between data owner and data user will come via the data owner providing consent to this third party to transact the data to parties such as the data user. It is worth noting that a healthcare data warehouse or aggregator does not solely mean data mines such as personal genomics companies 23andMe and Ancestry. It also includes traditional entities such as hospitals and hospital systems, universities, research institutes and pharmaceutical companies. For simplicity, we will refer to these types of entities as Healthcare Data Aggregators (HDAs). Consent can come in a variety of ways, but it is critical to be able to demonstrate such consent for any downstream data use.

3. Third Consideration: Understand the true playing field when transacting with sophisticated entities! HDAs, through a data transaction, look to benefit from their held healthcare data. A benefit to a HDA can be in the form of, for example, direct remuneration, royalties from data user revenue, milestone payments (commercial and revenue milestones), equity in data user's company, and access to data user's analytical results. In cases where both parties are subject to some form of collaboration, joint venture or co-development agreement, profit can also include some ownership of co-developed intellectual property with the data user.

Moreover, given that most HDAs are likely to be large and traditionally sophisticated, negotiation leverage can be skewed in the HDA's favour. However, given the convergent nature of digital health, and DTx by extension, depending on the type of HDA, that sophistication may not carry to data rights transactions. The digitisation of healthcare has been rapid for everyone, and often the larger the entity, the less nimble it can be to the rapid industry changes. To a degree, that is why the start-up model works and has been successful over the years to introduce innovative technology to the healthcare industry, if not all industries.

Consider a personal genomics HDA that builds its business model around these transactions. Its sophistication and experience with these data transactions can be somewhat assumed. In fact, some may have fairly set data transaction terms determined over time and experience, therefore leaving little room for negotiation.

By contrast, some traditional entities (e.g., hospital systems, universities, research institutes, big pharma) may have general sophistication, but that may not stretch to data transactions. For example, being a sophisticated healthcare research institute does not inherently mean that said institute has any deep experience in healthcare data transactions. Additionally (and noteworthy), these sophisticated entities often operate amidst internal silos, where the portion of the organisation generating data may not be the same group that understands its value, understands what parameters exist around these data (e.g., consent limitations), and has business acumen to transact on these data. Since digital health is a convergence of typically disparate industries, as discussed above, "blind spots" can exist for even the most "sophisticated" entities.

Do note that while we discuss "blind spots", use/consent, and sophisticated entities as considerations, more considerations definitely exist. One example includes multiple data transactions, the requisite time and cost, and the impact one bad transaction can have on the entire platform. Another is the regulated nature of healthcare, discussed more below. The take-away here is that a data strategy needs to be formed early, before entering discussions and building products. The viral impact of a spotty data strategy can set back companies for years. As such, if the experience and resources do not exist in-house, you should seek help from outside resources.

Regulatory Considerations

The U.S. healthcare regulatory environment for DTx is evolving. From pathways to market to insurance coverage and reimbursement to privacy, federal regulators are wrestling with ways to regulate DTx.

Food and Drug Administration (FDA)

Digital therapeutics are generally regulated as software by the FDA under the agency's software-as-a-medical-device (SaMD) category and are subject to regulatory obligations much like conventional medical devices. In that sense, DTx is no different than other digital health solutions whose regulatory paradigm is largely based on the framework governing medical devices. As defined under FDA law, a medical device is an "instrument, apparatus, implement, machine, contrivance . . . or other similar or related article, including any component, part, or accessory" which, among other things, is intended for use in the diagnosis, treatment, cure, mitigation, or prevention of a disease or condition, or intended to affect the structure or function of the body.[1] Section 3060 of the Cures Act excludes from the definition of "device" software functions intended for activities such as healthcare facility administrative support, healthy lifestyle maintenance, or serving as electronic patient records, so long as the function is not intended to interpret or analyse them for the purpose of condition diagnosis, cure, mitigation or treatment.

When analysing software, there are a few questions for consideration:

- Is the solution intended for use in diagnosis, treatment, medical care, or disease prevention?
- If yes, is the solution exempt from the definition of a medical device under Section 3060 of the Cures Act? If so, then the solution is not considered a medical device.
- If not exempt under Section 3060, is the solution subject to "enforcement discretion"[2] under an applicable FDA guidance or policy? If yes, medical device obligations do not apply. If not, the solution may be regulated as a medical device.

If the software is considered a medical device, manufacturers must then determine a regulatory pathway to market. A 510(k) approval pathway, for example, applies to low/moderate risk devices (Class I or II), thus allowing for an abbreviated approval pathway, provided the applicant provide a predicate device to which the software is "substantially equivalent". A Premarket Approval (PMA) pathway, by comparison, has no predicate device, applies to the highest risk (Class III) of devices, and therefore requires clinical studies. *De Novo* Classification (*De Novo* 510(k)) provides the opportunity to classify novel medical devices that provide reasonable assurance of safety and effectiveness for the intended use, but for which there is no legally marketed predicate device. The *De Novo* 510(k) applies a risk-based classification process. Devices that are classified into Class I or Class II through the *De Novo* pathway may be marketed and used as predicates for future 510(k) submissions.

The pandemic saw the FDA relax some of its requirements allowing conditional approval of mental health-related DTx solutions during the public health emergency. As noted by the agency, this approach helps "expand the availability of digital health therapeutic devices for psychiatric disorders to facilitate

consumer and patient use while reducing user and healthcare provider contact and potential exposure to COVID-19 during this pandemic". For example, the FDA approved marketing of the first game-based digital therapeutic solution to improve function in children with attention deficit hyperactivity disorder.[3] The agency also approved a DTx designed to reduce sleep disturbance related to nightmares in adults who suffer from nightmare disorder or have nightmares from post-traumatic stress disorder.

According to data from the FDA, almost 65 DTx solutions have been approved by the agency with almost half of those approved after 2017. Most of the solutions were via the 510(k) pathway, with a much smaller subset coming through the *De Novo* or PMA pathways.[4] Some DTx have also received so-called Breakthrough Device designations, a programme designed to expedite the development and review of breakthrough technologies, while preserving the regulatory standards for the pathways discussed above.[5]

The FDA has recognised that its traditional regulatory paradigm was not designed for the kinds of software products on the market today. In response, the agency launched the Software Precertification (Pre-Cert) Pilot Program to help the agency develop a regulatory model for oversight of software-based medical devices that reflects current realities.[6] Under Pre-Cert, instead of evaluating individual SaMD products, the FDA is proposing to certify a company and its software development process for conformance to certain principles of excellence such as patient safety, product quality, and cybersecurity responsibility.

To the extent DTx solutions include AI/ML components, we note that the FDA recognises that AI/ML is fundamentally different from other SaMDs. The agency is in the process of developing a new regulatory paradigm specifically with AI/ML in mind. Under the traditional regulatory regime, products driven by AI/ML require repeated premarket review for software modifications – an unrealistic requirement given how frequently these modifications occur. Last year, the agency published an AI/ML action plan detailing the steps it will take in regulating the space, including supporting regulatory science efforts to develop methodology for the evaluation and improvement of ML algorithms, and advancing real-world performance pilots to provide additional clarity on what a real-world evidence generation programme would look like for AI/ML-based SaMDs.[7]

Insurance coverage of DTx

The Centers for Medicare and Medicaid Services (CMS), has not developed guidance regarding coverage and reimbursement of DTx, although the agency recognises a few reimbursement codes addressing collaborative care models that involve use of apps. Because CMS tends to be a market leader in terms of coverage and reimbursement, it is an important bellwether regarding if and how other insurance providers will cover emerging health technology like DTx.

The issue is that DTx does not fall under an existing Medicare benefit category. In other words, if a product or service cannot be placed in an established benefit category, Medicare will not cover and pay for that product or service. Some believe DTx can be shoehorned into one of the existing categories. For example, some have argued that DTx could fit into the durable medical equipment category, which among other things, requires an item to demonstrate it can withstand repeated use, has an expected life of at least three years, and is appropriate for use in the home.[8] The problem, however, is that DTx may not be able to meet the three-year expected life requirement, using just one counterpoint. Ultimately, these coverage debates underscore the issues with fitting 21st century technology into a coverage framework built for another time.

As reimbursement experts have noted "a CMS coverage pathway for DTx will require reimbursement rules for the time a clinician spends on remote monitoring of DTx data, akin to payment for a medical service, and the DTx product itself, akin to payment for a medical device or pharmaceutical".[9] There is hope on the horizon. Some have called for establishing a specific Medicare benefit category for DTx which would require an act of Congress. Difficult as that may seem, it has been done before as we can see in the examples of home infusion therapy and opioid use disorder treatment services. Medicare Advantage (the managed care portion of the Medicare programme) also allows plans far more flexibility to cover solutions such as DTx that do not yet have a benefit category through supplemental benefits.

On the private market side, the two largest pharmacy benefit managers in the U.S. established first-in-kind digital health formularies two years ago that provides a pathway for greater DTx adoption.

Security and privacy

Given that DTx solutions store and transmit patient data, privacy and security are key regulatory considerations for the category. Increasingly, cybersecurity issues are front and centre when it comes to connected or software-enabled devices. The FDA requires medical device manufacturers to comply with federal requirements to address risks, including cybersecurity. In acknowledging the increasing use of wireless and network-connected devices and the electronic exchange of medical device-related health information, the FDA published draft guidance in 2018 taking a tiered approach regarding cybersecurity risk.[10] Tier 1 devices (higher cybersecurity risks) are those capable of connecting (e.g., wired, wirelessly) to another medical or non-medical product, to a network, or to the Internet – and a cybersecurity incident affecting the device could directly result in patient harm for multiple patients. Tier 2 devices (standard cybersecurity risks) are medical devices for which the criteria for a Tier 1 device are not met.[11] The agency recommends that premarket submissions for Tier 1 devices include documentation showing how the device design and risk assessment incorporate certain design controls. For Tier 2 devices, the FDA recommends that manufacturers include documentation in their premarket submissions that either shows they have incorporated certain specific design features or provide a risk-based rationale for why design controls are not appropriate.

While the FDA has issued guidance regarding various aspects of cybersecurity including device design and the required documentation for premarket submissions, the agency does not require premarket security audits for medical devices.

Issues are just as complicated when it comes to privacy. The U.S. has a sectoral approach to privacy laws at the federal level unlike many jurisdictions around the world. This means that the privacy regulations that apply to data collected in the U.S. depend on the type and context of the data collected. The most well-known federal privacy law in the healthcare sector is the Health Insurance Portability and Accountability Act of 1996 (HIPAA), which applies to "covered entities" and their "business associates". "Covered entities" consist of health insurance providers, healthcare clearinghouses (entities that assist the submission of claims to health insurance providers), and healthcare providers. "Business associates" are third parties that create, receive, maintain, or transmit protected health information (PHI) on behalf of covered entities. Many stakeholders, however (including DTx manufacturers), that collect and use PHI may not be covered under HIPAA's scope.

For those organisations, the Federal Trade Commission (FTC) is the primary federal regulator in data privacy and has broad jurisdiction over the data privacy and security practices of for-profit entities. The FTC gets its primary authority from Section 5 of the FTC Act, which prohibits "unfair or deceptive acts or practices in or affecting commerce". The agency has used this broad jurisdiction to pursue enforcement actions against companies for engaging in "deceptive" practices by not complying with their own privacy policies, privacy settings, or other representations to consumers. The agency is particularly focused on organisations that use personal data not consistent with a consumer's reasonable expectations, including failing to implement reasonable security measures – which could be considered an "unfair" trade practice. The FTC also enforces the Health Breach Notification Rule that requires certain businesses not covered under HIPAA to notify their customers and others if there has been a breach of unsecured individually identifiable electronic health information. If all of the foregoing is not complicated enough, DTx stakeholders may also have to navigate a patchwork of state privacy laws that have been passed in the last few years.

Conclusion

Digital therapeutics is a wonderful example of innovation allowing for the convergence of disparate technologies that facilitate new frontiers of insights into our health. By synergising data streams from unique sources to produce novel insights, digital therapeutics solutions will provide the opportunity to look at health issues in a myriad of different ways as we seek new insights and potential solutions to existing diseases. But with that convergence comes greater opportunity for problems, legal and regulatory, from the start. As such, getting your legal and regulatory strategy right is essential to put you on the path to success.

Endnotes

1. 21 U.S.C. § 321(h).
2. An FDA policy in which even if a solution meets the definition of a medical device, the FDA chooses to not enforce its requirements because it has determined that the risk to patients of using the product is low.
3. https://www.fda.gov/news-events/press-announcements/fda-permits-marketing-first-game-based-digital-therapeutic-improve-attention-function-children-adhd.
4. https://journals.plos.org/digitalhealth/articlefigure?id=10.1371/journal.pdig.0000008.t001.
5. https://www.fda.gov/medical-devices/how-study-and-market-your-device/breakthrough-devices-program.
6. https://www.fda.gov/medical-devices/digital-health-center-excellence/digital-health-software-precertification-pre-cert-program.
7. https://www.fda.gov/media/145022/download.
8. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c20.pdf.
9. https://www.healthaffairs.org/do/10.1377/forefront.20210510.303135/full/.
10 https://www.fda.gov/media/119933/download.
11. *Id.*

Jason Novak is a Partner in Norton Rose Fulbright's Precision Medicine and Digital Health Practice Group, where he focuses on advising entities, both large and small, on the various legal issues that can arise with emerging technologies in the healthcare and life sciences industries. Tech and biotech are traditionally disparate technologies that, when blended together to form many of our most exciting new technologies, bring forth a combination of unique and interrelated legal issues. Jason has extensive experience in IP strategy and patent portfolio management, preparation and prosecution, oppositions, counselling, licensing and technology transactions, in and out-licensing, freedom-to-operate, various types of due diligence, IP training, risk recognition and management, and dispute resolution. Prior to starting this practice, Jason was an IP Director for Thermo Fisher Scientific, where he managed worldwide IP needs in genetic sciences instrumentation and software.

Norton Rose Fulbright
555 California Street
Suite 3300
San Francisco, 94104
California
USA

Tel: +1 628 231 6800
Email: jason.novak@nortonrosefulbright.com
URL: www.nortonrosefulbright.com

René Quashie is the first-ever Vice President of Policy & Regulatory Affairs, Digital Health at the Consumer Technology Association (CTA), the largest technology trade association in the U.S. with 2,000 member companies. Quashie provides guidance on key technical, legal and regulatory issues relating to digital health technology products, services, software and apps. Quashie also works on behalf of CTA's Health Division, which supports the health technology industry through advocacy, education, research, standards work, policy initiatives and more. Prior to CTA, Quashie was in private law practice at several national firms for two decades focusing his work on digital health and privacy. He earned his law degree from George Washington University.

Consumer Technology Association (CTA)
1919 S. Eads Street
Arlington
VA 22202
USA

Tel: +1 703 907 7600
Email: rquashie@cta.tech
URL: www.cta.tech

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