Welcome to the fourth installment of Arnold & Porter's Virtual and Digital Health Digest. This edition primarily covers January 2023 highlights across the virtual and digital health space. This digest focuses on key virtual and digital health and telehealth-related developments in the United States, United Kingdom, and European Union in the healthcare, regulatory, intellectual property, and privacy spaces.

In this issue, you will find the following:

US News

EU and UK News

US News

FDA REGULATORY UPDATES

FDA Names New Digital Health Center Director. In January, the FDA tapped former Oracle executive Troy Tazbaz to lead the Digital Health Center of Excellence within the Center for Devices and Radiological Health (CDRH). The CDRH management directory as updated on January 14 now identifies Tazbaz as the division director. Brendan O'Leary, who had been the acting director since the February 2022 departure of Bakul Patel, is now listed as the acting deputy division director. According to trade press, Tazbaz most recently spent 11 years at Oracle spearheading the company's cloud transformation efforts. Fierce Healthcare reports that in an email statement, an FDA spokesperson stated, "Troy will lead the Digital Health Center of Excellence in its next phase, which is focused on continued growth and improvement of building and sustaining capacity for strategic partnerships, innovating regulatory frameworks for digital health and continued harmonization with other regulators."

CDRH Releases 2022 Annual Report with Overview of Digital Health Accomplishments. On January 26, the CDRH released its 2022 Annual Report, which provides an overview of center's achievements in 2022. The report opens with a message from the CDRH director, in which he notes that digital health technologies "will continue to remain a high priority for CDRH in 2023 and beyond." Highlighted digital health-focused accomplishments discussed in the report include the following:

- Issuing final guidance on "Clinical Decision Support Software" clarifying the scope of the FDA's oversight of CDS software intended for healthcare professionals (HCPs).
- Launching the "Digital Health Policy Navigator," an interactive tool that helps developers assess whether a particular software function meets the device definition, and if so, whether it is the focus of the FDA's oversight as a device.
- Concluding the software precertification pilot program (and issuing the report "The Software Precertification (Pre-Cert) Pilot Program: Tailored Total Product Lifecycle Approaches and Key Findings)."
- Launching a list of Augmented Reality/Virtual Reality medical devices legally marketed in the United States to increase transparency and access to information on AR/VR devices.
- Participating in the publication of the final document "Machine Learning-enabled Medical Devices: Key Terms and Definitions" by the International Medical Device Regulators Forum (IMDRF).
- Releasing "Spotlight: Digital Health Regulatory Science Research

Opportunities," highlighting common digital health interest areas (e.g., patient-generated health data, artificial intelligence and machine learning, cybersecurity, and interoperability).

- Issuing draft guidance titled "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions."
- Co-chairing the Medical Device Cybersecurity Guide working group of the International Medical Device Regulators Forum (IMDRF), which released two draft documents in 2022 for public consultation: "Principles and Practices for the Cybersecurity of Legacy Medical Devices" and "Principles and Practices for Software Bill of Materials for Medical Device Cybersecurity."
- Updating the Medical Device Cybersecurity Regional Incident Preparedness and Response Playbook in conjunction with MITRE.

Analysis of many of these CDHR digital health-focused updates can be found in the November 2022, December 2022, and January 2023 issues of Arnold & Porter's Virtual and Digital Health Digest.

FDA Finalizes Several Digital Health-Related Device Classifications. In the January issue of our Virtual and Digital Health Digest, we highlighted several recent software-related device classifications finalized by FDA. Since then, FDA has finalized several additional software-related device classifications for product types that were reviewed through the agency's de novo classification process. The de novo process can be used by sponsors to request that FDA classify novel devices that lack a predicate device, including novel digital health devices, into Class II (moderate risk) or Class I (low risk). After issuance of a de novo classification order, FDA will follow up with a final order codifying the classification in regulations. The recently codified device classifications include the ones listed below. All of these devices were classified into Class II (special controls).

- Software Algorithm Device to Assist Users in Digital Pathology
- Software for Optical Camera-based Measurement of Pulse Rate, Heart Rate, Breathing Rate, and/or Respiratory Rate
- Computerized Behavioral Therapy Device for Treating Symptoms of Gastrointestinal Conditions

FDA Announces Workshop on Digital Health Technologies in Clinical Trials. On March 28 and 29, FDA will host a virtual public workshop entitled "Understanding Priorities for the Development of Digital Health Technologies to Support Clinical Trials for Drug Development and Review" in collaboration with the Duke-Robert J. Margolis, MD Center for Health Policy. As described in the *Federal Register* notice, "the purpose of the public workshop is to understand the priorities for the development of Digital Health Technologies (DHTs) to support clinical drug trials, including accessibility, diversity, and clinical outcome measures using DHTs." The workshop also fulfills a Prescription Drug User Fee Amendments (PDUFA VII) commitment to hold the first of a series of public workshops to gather input into issues related to the use of DHTs in regulatory decision-making by the end of the second quarter, fiscal year 2023. Information about registration is available in the notice.

FDA Hosts Conference on Artificial Intelligence and Machine Learning. On February 17, FDA hosted a conference entitled "Application of Artificial Intelligence and Machine Learning for Precision Medicine" in collaboration with the University of Maryland Center of Excellence in Regulatory Science and Innovation (M-CERSI). The conference objectives included examining progress made from implementing artificial intelligence and machine learning in drug development and precision medicine; discussing methodologies and best practices currently used; and discussing technical challenges and how they can be addressed (e.g., bias,

generalizability, and opacity). The agenda can be found here. Stay tuned for a summary of the conference to be included in our next newsletter once FDA posts additional meeting materials.

The Clinical Decision Support Coalition Submits Citizen Petition Requesting Rescission of CDS Guidance. On February 6, the Clinical Decision Support Coalition ("CDS Coalition") submitted a citizen petition requesting that FDA rescind the final "Clinical Decision Support Software" guidance issued in September 2022 ("Final CDS Guidance") and repropose the guidance to follow the statutory language of the 21st Century Cures Act ("Cures Act"). As further detailed in Arnold & Porter's October 17 advisory, the Final CDS Guidance differs significantly from the prior 2019 draft guidance, including that FDA clarified that to meet Cures Act Criterion 3 (intended for the purpose of "supporting or providing recommendations to a health care professional about prevention, diagnosis, or treatment of a disease or condition"), a non-device CDS software function's outputs or recommendations should not be directive or specific to a particular treatment or diagnosis but rather should provide options for an HCP to consider. The Final CDS Guidance also identifies the time-critical nature of the HCP decision-making as a factor to take into consideration when evaluating Criterion 3.

The CDS Coalition's citizen petition takes issue with the updated FDA guidance around Criterion 3, with the Coalition requesting that FDA "clarify that CDS software can indeed recommend a single diagnosis or single treatment pathway, and that the time critical nature of the decision-making is not a bar under Criterion 3 of the Cures Act requirements for CDS . . . but rather a factor to be considered under Criterion 4 of the Cures Act." Among other points, the CDS Coalition asserts that "FDA violated the FD&C Act by publishing the CDS Guidance without an adequate notice that gave the public a legitimate opportunity to comment" and "by disregarding the plain language of the statute, and instead inventing its own interpretation that flies in the face of congressional intent." Under FDA regulations, the agency has 180 days to respond to the petition, although that response could be a tentative response explaining the agency has been unable to reach a decision on the petition and is still considering the issues. Comments on the petition can be submitted to the docket, available here.

HEALTHCARE FRAUD AND ABUSE UPDATES

Seven Sentenced in Kickback Conspiracy to Defraud Federal Health Insurance Programs. On January 25, multiple individuals pled guilty for their roles in a kickback conspiracy scheme to submit false and/or fraudulent claims to federal healthcare programs through a network of durable medicine equipment (DME) companies, marketing companies, and telemedicine providers. Marketing companies and/or call centers allegedly obtained leads by entering into agreements for prescriptions from telemedicine companies. DME companies allegedly entered into agreements with marketing companies and/or call centers to purchase leads on prescriber product orders, which included patient information and signed prescriptions for durable medical equipment. The DME companies would pay the marketing companies and/or other call centers on a per-prescription basis. The marketing companies and/or call centers sent invoices to the DME companies that disguised the kickbacks to the DME companies. To further disguise the false or fraudulent orders, the DME companies used drop ship companies to process the orders and ship the DME products to the beneficiaries. The individuals sentenced were involved in the kickback conspiracy as owners of the marketing companies or call centers, owners of the dropship companies, telemedicine physicians, or owners of the DME companies billing the federal health insurance programs. Four individuals—Harry Barton, David Tsui, Jeffrey Hoffman, and Steve Lowell—received prison sentences for their involvement.

Two Florida Doctors Convicted in $31 Million Medicare Fraud Scheme On January 30, two Florida doctors were convicted for their roles in a scheme to defraud Medicare for millions of dollars. Dean Zusmer owned one of four DME companies that submitted over $31 million for medically unnecessary DME to Medicare. Zusmer and his co-conspirators obtained signed doctors notes and patient referrals through kickback payments made to marketers. These marketers, in turn, used overseas call centers to solicit patients and telemedicine companies to acquire prescriptions for unnecessary braces for these patients. Zusmer co-conspired with Jeremy Waxman—sentenced to over 15 years in prison for his role in the scheme—and Lawrence Alexander—an orthopedic surgeon who owned a DME company with Waxman and concealed his and Waxman's role in the scheme by putting the DME company in the name of one of Alexander's family members. Zusmer faces a maximum penalty of 10 years in prison for conspiracy to commit healthcare fraud, healthcare fraud, and paying illegal healthcare kickbacks.

PROVIDER REIMBURSEMENT UPDATES

COVID-19 Public Health Emergency Expected to end on May 11. On January 30, the White House issued a statement on administrative policy in response to House actions H.R. 382 and H.J. Res. 7, which collectively seek to immediately end the COVID-19 national emergency and public health emergency (PHE) and accompanying flexibilities for healthcare and healthcare administration. In its statement, the White House announced that the Biden Administration intends to extend the emergency declarations to May 11. This continuation, according to the White House, will not impose any new restrictions related to COVID-19, including masking mandates. But ending the emergency declarations immediately, it said, would lead to highly significant impacts on the U.S. healthcare system and government operations by causing wide-ranging "chaos and uncertainty." On February 9, Department of Health and Human Services (HHS) Secretary Xavier Becerra informed U.S. governors that he was renewing the PHE an additional 90 days to May 11—one month past its current expiration date of April 11. HHS intends for this to be the final renewal of the COVID-19 PHE.

According to the White House statement, if the PHE is ended immediately—instead of through the orderly wind down enacted by Congress in December 2022—millions of Americans would abruptly lose Medicaid coverage, state budgets would become over encumbered, hospitals and nursing homes that rely on flexibilities created by the emergency declaration would not have time to retain staff and reform billing processes, and those who rely on telehealth services, including veterans, would suddenly lose access to critical health care.

Contemplating the loss of access for veterans and others who rely on telehealth services for prescription drugs, lobbyists have called on the Drug Enforcement Agency (DEA) to initiate regulations that would ensure the continuation of some telehealth services. Under the Ryan Haight Act, practitioners are required to conduct an in-person evaluation of a patient before they can prescribe controlled substances over the internet. The in-person requirement under the act was waived during the pandemic but will resume when the PHE ends without further action by government officials. Previously proposed rules by DEA would implement Special Registrations for Telemedicine, which would allow providers to prescribe controlled substances remotely, but advocates have called for updated rules to support telemedicine.

Recently, a DEA official indicated that the agency plans to shortly propose new regulations that would allow telehealth providers to continue to prescribe controlled substances after the COVID-19 PHE ends, which, as noted, the Biden Administration expects to extend by an additional month to May 11. In DEA's Fall 2022 Unified Agenda, the agency expressed its commitment to carrying out certain policy initiatives, including ensuring access to a three-day supply of buprenorphine and, in addition, publishing a rule to enable certain physicians to prescribe that medication through audio-only communication systems. DEA also indicated that it intended to publish a rule regarding telemedicine registrations and define the circumstances in which they can be obtained. Telehealth lobbyists signaled concern that the end of the PHE would harm certain patients who face barriers to receiving in-person care, including veterans and individuals prescribed buprenorphine for opioid use disorder.

Some states are responding to the eventual end of the emergency declaration flexibilities through state bills that would permanently continue some services established during the pandemic. For example, on January 25, Montana State Senator Walt Sales introduced a bill (Montana Senate Bill 196 - Require Payment Parity in Insurance Coverage of Telehealth Services) in the Montana Senate that would mandate health insurers to reimburse telehealth services at the same rate that those insurers would reimburse a provider for services delivered in person. The proposed bill would disallow insurance companies from denying or limiting

reimbursement based only on the technology used to deliver healthcare services—as long as the equipment meets certain requirements and is appropriate for use in the services provided.

Further, and in anticipation of changes that will result following termination of the PHE, on February 6, the Centers for Medicare & Medicare Services (CMS) issued a Public Health Emergency Resource Update. In its update, CMS announced materials to aid providers and ensure a smooth transition as flexibilities related to the PHE end, including provider-specific information fact sheets about the PHE waivers, a waiver and flexibility request form, and information regarding acute hospital care at home.

PRIVACY UPDATES

FTC Targets GoodRx In First Action Under Health Breach Notification Rule

On February 1, the Federal Trade Commission filed its first complaint under the agency's Health Breach Notification Rule (HBNR), which was promulgated more than a decade ago pursuant to the Health Information Technology for Economic and Clinical Health Act (HITECH Act). The complaint, filed against prescription drug discount provider GoodRx Holdings, Inc., alleges that GoodRx violated both the HBNR, which requires vendors of personal health records (PHRs) to notify affected individuals and the FTC if there is any breach in the security of unsecured individually identifiable health information held in such records and Section 5 of the FTC Act, which prohibits deceptive and unfair conduct that harms consumers. According to the FTC, GoodRx, which operates a digital health platform offering health services such as telehealth visits and prescription drug discounts, shared individually identifiable health information of patients without their knowledge, including with social media companies such as Facebook, and made claims to a be "HIPAA Secure" when in fact GoodRx is not a HIPAA covered entity. With respect to the HBNR, the FTC alleged that GoodRx's sharing of individually identifiable health information without authorization constituted a "breach" and that GoodRx violated the HBNR by failing to report the breach to the FTC and the individuals to whom the information pertains. Under a proposed order, GoodRx will pay a $1.5 million civil penalty and will be prohibited from sharing its users' individually identifiable health data with any third parties for advertising purposes. For additional details on this FTC action, see our blog here.

EU and UK News

REGULATORY UPDATES

Extension to MDR transition period published. As mentioned in the January digest, on January 6, the European Commission published a proposal for a Regulation extending the transitional periods under the Medical Devices Regulation (MDR). The proposal was accompanied by a press release and a Q&A. Under the proposal, certificates issued by Notified Bodies from May 25, 2017, under the old regime, valid on May 26, 2021, and not withdrawn since, will remain valid after the period indicated on the certificate until the following dates and the provided conditions are met:

- **31 December 2027**: Class III and Class IIb implantable (with exceptions).
- **31 December 2028**: Class IIb (with exceptions), Class IIa and Class I sterile or measuring.
- **31 December 2028**: Devices which did not require Notified Body involvement under the old regime, for which the declaration of conformity was drawn up prior to 26 May 2021, and do require Notified Body involvement under the MDR.

Certificates that expire before the regulations come into force shall be considered valid until the above dates if certain conditions are met. In addition, the proposal removes the "sell-off" deadline, by when devices already placed on the EU market by the end of the applicable transitional period could remain in the supply chain and made available in the EU without having to be taken off the market. This amendment applies to both the MDR and the In Vitro Diagnostic Regulation.

The Commission held a one-week consultation on the proposal and now the proposal is in the process of being adopted by the Council and the European Parliament under an accelerated co-decision procedure. On January 25, the Council agreed on the text in the proposal without amendments, and it is expected that the European Parliament will vote on the text during the plenary session on February 13-16.

OECD Report on the Future of Telemedicine. On January 17, the Organization for Economic Co-operation and Development (OECD) published a report reflecting on how the use of telemedicine in OECD countries increased as a result of the COVID-19 pandemic. The report also discussed how telemedicine will continue to be used going forward. According to the report, while patients are reported to generally be very satisfied with using telemedicine services, physicians appear to be more split in their opinions. Furthermore, a key uncertainty is whether telemedicine represents good value for money from the perspective of healthcare systems. The report highlights three policy priorities:

i) Understand who is using remote care services, why they are using them, and what happens after they have used them.

ii) Collect and analyze cost and utilization data to understand whether payment arrangements for telemedicine services encourage effective use of such services.

iii) Consider how to create a coordinated and integrated health system with both remote and in-person services.

Guidance on the Use of Social Media from UK PMCPA. On January 26, the U.K. Prescription Medicines Code of Practice Authority (PMCPA) published new guidance on the use of social media by pharmaceutical

companies. The guidance covers both corporate social media channels and employees' professional and personal use of such channels. The PMPCA helpfully sets out key questions to consider before carrying out any social media activity and reminds companies to monitor their posts for pharmacovigilance purposes and compliance with other legislation, guidance, and codes on the promotion of medicines. Fourteen activities are considered in detail, including the use of links, corporate announcements, patient support, signposting meetings, and clinical trial recruitment. Within these activities, key PMCPA cases are pointed to or examples of activity that might be considered acceptable are provided. See our recent blog for more details, as well as a list of key takeaways from the new guidance.

Merger between UK NHS England and NHS Digital. On February 1, the U.K.'s NHS Digital merged with NHS England. This means that NHS England will now assume responsibility for data collection, analysis and dissemination, and the general implementation of digital technology into the NHS. Any U.K. law contracts (including data sharing agreements) with NHS Digital, and approvals from the Research Ethics Committee or Confidentiality Advisory Group will automatically transfer to NHS England, but public-facing materials, such as privacy notices or participant information sheets that mention NHS Digital, are advised to be updated. The Department of Health and Social Care also published on January 23 draft guidance on how NHS England will protect patient data following the transfer of NHS Digital's functions.

PRIVACY UPDATES

ICO Report Considering Privacy in the Context of Consumer Healthtech
In December 2022, the U.K.'s Information Commissioner's Office (ICO) published its first annual Tech Horizons Report, which considers the implications of new technology on data privacy. The ICO identifies three main issues within healthtech:

i) Some devices are generating special category data, which requires additional privacy safeguards.

ii) Users need to have transparency and control over the processing of their personal information.

iii) Some devices are producing inaccurate and biased data.

The ICO advises that healthcare organizations should have clear privacy policies, consider whether they are processing special category data, and ensure that AI processing is accurate and free from systematic bias.

DIGITALEUROPE Position Paper on EHDS Proposal. On January 19, DIGITALEUROPE published its position paper on the European Health Data Space (EHDS) proposal. While supporting the objectives of the EHDS,

DIGTALEUROPE suggests a number of recommendations to improve the European Commission's proposal, including (i) clarifying the general conditions and mechanisms for secondary use of electronic health data; (ii) removing the proposed additional restrictions relating to access to and transfers of non-personal data outside the EU; and (iii) alignment across the various legislation regulating data (e.g., General Data Protection Regulation, the Medical Devices Regulation, the AI Act, the Cyber Resilience Act).

REIMBURSEMENT UPDATES

European Frameworks for Evaluating Digital Medical Technologies On January 13, the Belgian Health Care Knowledge Centre (KCE) published its report on the evaluation of digital medical technologies (DMTs) for reimbursement. The report assessed the current Belgian framework for evaluating DMTs as well as frameworks in various European countries (Austria, England, France, Finland, Germany, and the Netherlands). The report aims to inform recommendations to the Belgian health authorities to be considered in a future Belgian framework to support a clearer and more transparent process for the evaluation of DMTs. Key topics discussed in the report include, for example, evidence requirements for DMTs to demonstrate value and temporary reimbursement pathways.

PRODUCT LIABILITY UPDATES

EESC Publishes Opinions on the New Product Liability Directive and AI Directive. On January 25, the European Economic Social Committee (EESC) published its opinion on the European Commission's proposal for a revised Product Liability Directive (revised PLD) and its opinion on the proposed Artificial Intelligence Directive (AI Directive). With respect to the revised PLD, the EESC acknowledges that the regime needs to adapt to address digital challenges and supports the Commission's decision to include AI through a no-fault liability regime in the revised PLD and a fault-based liability regime in the AI Directive. The EESC calls for the EU legislators to take into account the other legislation aimed at regulating digital technologies (e.g. the AI Directive, the AI Act, and the NIS 2 Directive) so there is coherence and consistency between the overlapping regimes. In its opinion on the AI Directive, the EESC expresses concern that a directive could lead to divergent interpretations by stakeholders in the supply chain and courts and calls for clear definitions (e.g., a decision made by machines using AI) and expertise in those applying the new laws. The EESC also recommends that the Commission closely monitors the availability and extent of insurance covering AI liability (to assess whether to make insurance for AI products mandatory) and that a review of the AI Directive should take place after three years (rather than the proposed five years) given the speed of technological developments.

INTELLECTUAL PROPERTY UPDATES

Getty Images and AI Copyright Filing. On January 16, Getty Images filed copyright infringement proceedings against Stability AI before the U.K. High Court of Justice. Stability AI is the open-source AI company behind Stable Diffusion, a text-to-image generator that was launched in August 2022 and has attracted millions of users and significant media interest. Specifically, Getty Images alleges that "Stability AI has unlawfully copied and processed millions of images protected by copyright and the associated metadata owned or represented by Getty Images absent a license to benefit Stability AI's commercial interests and to the detriment of the content creators." This illustrates potential IP infringement liability for companies developing AI platforms that source their platform's training data from third parties. If the data is protected by copyright (as is the case with

photographs, images, and scientific publications) and appropriate licensing arrangements with the IP rights holders have not been sought, then companies may be liable for infringement. This liability may extend to customers using such AI platforms depending on the output from the use of such platforms.

EUIPO Intellectual Property Infringement and Enforcement Tech Watch Discussion Paper 2023. The European Union Intellectual Property Office updated its 2020 paper on IP in emerging technologies. The paper considers nine emerging technologies: robotics, 3D printing, nanotech, spatial computing, AI, blockchain and distributed ledger technology, 5G and 6G mobile networking, and quantum computing. It recognizes that these technologies are rapidly evolving and have not yet reached their full potential, and therefore their impact on IP has yet to be fully understood. With respect to digital and virtual health, the report notes that AI and connected devices are recognized technologies with potential positive impacts for human health. The paper also highlights that all the emerging technologies, often in combination, can be used to facilitate the future production, marketing, and distribution of counterfeit goods (e.g., by using 3D printing facilities to copy IP protected products and avoid custom checks). The technologies may also be used to infringe on IP in new ways (e.g., copyright infringement in virtual applications). In the future, further important and emerging technologies will be considered, and the contributions will continue to assist the EUIPO develop tools and promote best practices to enhance IP protection.

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