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The promise of direct-to-consumer COVID-19 testing: ethical and regulatory issues

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ABSTRACT

Widespread diagnostic and serological (antibody) testing is one key to mitigating the COVID-19 pandemic. While at first, the majority of COVID-19 diagnostic testing in the USA took place in healthcare settings, quickly a direct-to-consumer (DTC) testing market also emerged. In these DTC provision models, the test is initiated by a consumer and the sample collection occurs at home or in a commercial laboratory. Although the provision of DTC tests has potential benefits—such as expanding access to testing and reducing the risk of exposure for consumers and medical personnel—it also raises significant ethical and regulatory concerns. This article reviews these challenges and shows how they parallel and also diverge from prior concerns raised in the DTC health testing arena. The first part of this paper provides an overview of the landscape of diagnostic and serological tests for COVID-19, anticipating how provision models are likely to evolve in the future. The second part discusses five primary issues for DTC COVID-19 tests: test accuracy; potential misinterpretation of results; misleading claims and other misinformation; privacy concerns; and fair allocation of scarce resources. We conclude with recommendations for regulators and companies that aim to ensure ethically marketed DTC COVID-19 tests.

KEYWORDS: Diagnostic COVID-19 tests, direct-to-consumer tests, misinformation, privacy, regulation, serological COVID-19 tests

INTRODUCTION

In the wake of the COVID-19 pandemic, widespread diagnostic and serological (immunity) testing is considered key in containing the spread of the disease, as well as in easing stay-at-home measures and informing policies for restarting the economy.[1] Most tests, whether diagnostic or serological, are currently offered by healthcare providers who interface with the healthcare system.

However, a number of companies[2] have begun to offer COVID-19 testing on a direct-to-consumer (DTC) basis[3]: that is, the test is initiated by a consumer—not a healthcare professional—typically via the company's website. While a healthcare professional may be involved at some stage of the process that involvement may be as minimal as a brief review of a questionnaire that the consumer has completed as part of the purchasing process. As such, the consumer may have no direct contact with a healthcare professional (although some companies offer the option of post-test consultations in the case of positive results). In addition, the results of DTC tests do not necessarily become part of patients' health records, as the companies offering such tests operate independently of the healthcare system.

The acquisition of the sample in DTC tests may occur in one of two ways: via at-home collection or in-laboratory collection. In the former, individuals order and receive an at-home collection kit, where they acquire the sample and mail it back to the company (or a lab that processes the results on behalf of the company). For in-laboratory collection, individuals make an appointment to visit a commercial laboratory where their sample is collected. Both models of DTC COVID-19 tests—at-home or in-laboratory collection—are distinguishable from those offered by hospitals and

1 Patrice A. Harris, *We Must Expand COVID-19 Testing Capacity Before Restarting the Economy*, American Medical Association, https://www.ama-assn.org/about/leadership/we-must-expand-covid-19-testing-capacity-restarting-economy (accessed May 19, 2020); World Health Organization, *WHO Director-General's Opening Remarks at the Media Briefing on COVID-19—16 March 2020*, World Health Organization, https://www.who.int/dg/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19—16-march-2020 (accessed May 19, 2020).

2 See for example: Hims, *COVID-19 Saliva Test,* https://www.forhims.com/covid-test (accessed May 19, 2020); Vault Health, *COVID-19 Test Kit,* https://www.vaulthealth.com/covid (accessed May 19, 2020); 1health.io, *Zero Contact*™, https://1health.io/ (accessed May 19, 2020); Everlywell, *Everlywell: Home Health Testing Made Easy,* https://www.everlywell.com/ (accessed May 19, 2020); LetsGetChecked, *Coronavirus Test (COVID-19),* https://www.letsgetchecked.com/us/en/home-coronavirus-test/ (accessed July 21, 2020); Phosphorus, *COVID-19 Testing,* https://www.phosphorus.com/covid-19 (accessed July 21, 2020); Quest Diagnostics, *COVID-19 Immune Response*, https://questdirect.questdiagnostics.com/products/covid-19-immune-response/b580e541-78a5-48a6-b17b-7bad949dcb57?utm_source=GetQuestTest.com&utm_medium=referral&utm_campaign=quest-direct-covid-pr (accessed May 19, 2020).

3 The term DTC testing has been used in the literature to describe different provision models of health products. For the purposes of this article, our key criteria for considering a test to be DTC are (a) that it is promoted directly to consumers; (b) the testing process is initiated by consumers, who order the test online or by phone and/or book an appointment to a commercial lab in order to have their sample taken; (c) it requires little to no involvement of a healthcare provider, and whatever involvement does occur is usually not in person. See: Stuart Hogarth, Gail Javitt & David Melzer, *The Current Landscape for Direct-to-Consumer Genetic Testing: Legal, Ethical, and Policy Issues*, 9 Annu Rev Genom Hum G 161–182 (2008); Heidi Carmen Howard & Pascal Borry, *Is There a Doctor in the House?: The Presence of Physicians in the Direct-to-Consumer Genetic Testing Context*, 3 J Community Genet 105–12 (2012); Henry Curtis & Joseph Milner, *Ethical Concerns With Online Direct-to-Consumer Pharmaceutical Companies,* 46 J Med Ethics 168–171 (2020).

health clinics, as it is the consumer who initiates the order and completes the testing process with little to no interaction with a healthcare professional.

Even though the COVID-19 pandemic has changed the way much healthcare is delivered by increasing the use of telemedicine to minimize in-person visits, the doctor–patient relationship remains central. In this regard, the DTC testing model is distinct. Although healthcare professionals employed by DTC companies may authorize the ordering of laboratory tests, they have little, and usually no direct contact with the consumer. Indeed, from the perspective of the consumer, the process of ordering a DTC COVID-19 test may feel similar to purchasing other goods or services. For example, to order the LabCorp COVID-19 diagnostic test, an individual must click through a brief questionnaire, after which they can input their credit card information, click 'order,' and thereafter receive shipping updates via email.

The DTC provision of COVID-19 tests by private companies may expand access to testing and contribute to the mitigation of the present public health crisis. In particular, there are potential benefits to at-home testing, which eliminates the risks of exposure that individuals and medical personnel collecting samples may incur. In addition, at-home testing reduces the demand for personal protective equipment required by sample collectors and decreases the testing burden for the healthcare system as a whole.

However, DTC tests also raise significant ethical concerns and pose regulatory challenges. Although the regulatory environment for COVID-19 tests is not identical to that for other types of DTC health tests (such as currently marketed genetic or hormone tests),[4] many of the concerns raised by DTC COVID-19 tests parallel those wrought by other types of DTC health tests. At the same time, there are important contextual differences that make concerns over DTC COVID-19 tests particularly urgent, such as the global population affected, the infectious nature of SARS-CoV-2, and the historic challenges to the healthcare system and economy during the pandemic.

As widening the provision of diagnostic and serological COVID-19 tests may be crucial to containing the pandemic, it is important to critically consider the key issues that might lie ahead for DTC COVID-19 testing. In this article, we examine the main ethical and regulatory challenges of DTC diagnostic and serological tests, focusing on the US context. The first part of this article provides an overview of the landscape of diagnostic and serological tests for COVID-19, anticipating how their provision models could evolve in the future. The second part identifies five primary ethical and regulatory issues for DTC COVID-19 tests: uncertainty over the accuracy of test results; potential misinterpretation of test results by users; misleading product promotion and misinformation; privacy concerns; and fair allocation of scarce resources. Each of these issues parallels prior concerns raised in the DTC health testing arena, but also diverges from them in important ways. We conclude with recommendations for regulators, companies, and other relevant stakeholders that can help ensure high-quality, accurate, and equitably distributed COVID-19 tests, and inform the ethical provision of DTC health tests during public health crises.

4 For example, in times of public health emergency, FDA may use its "emergency use authorization" authority—a pathway to market that is not available for "standard" DTC health tests. *See* 21 U.S.C. § 360bbb-3. *Cf.* Y. Tony Yang & Patricia J. Zettler, *Food and Drug Administration's Regulatory Shift on Direct-to-Consumer Genetic Tests for Cancer Risk*, 125 Cancer 12 (2019) (describing the regulatory history for DTC tests for genetic health risks).

THE LANDSCAPE OF COVID-19 TESTING

Diagnostic Tests

COVID-19 diagnostic tests aim to determine whether a person is currently infected with SARS-CoV-2, the virus that causes COVID-19. The most commonly used diagnostic tests during the COVID-19 pandemic are polymerase chain reaction (PCR) tests.[5] For the purposes of testing, a swab is taken from the patient and tested in a lab for the genetic material of the virus. Although the typical sample used in these tests is obtained by a nasopharyngeal swab that reaches deep into the nose, the FDA recently issued Emergency Use Authorizations (EUAs) for diagnostic PCR tests using samples collected from shallow nasal swabs and saliva.[6]

While PCR is considered to be the 'gold standard' of molecular testing due to its high reliability,[7] this high accuracy may not be applicable to certain rapid point-of-care PCR tests, which according to a recent preprint study, may miss up to 48% of infections.[8] At present, the only non-PCR diagnostic test that has received an EUA is an antigen test used on shallow nasal swabs can rapidly detect fragments of the virus.[9] However, these antigen tests have a higher probability of producing false-negative results than PCR tests, as they cannot detect all active infections.[10]

Although at first, the majority of COVID-19 diagnostic testing in the USA took place in healthcare settings, a DTC testing market quickly emerged: first with companies marketing at-home tests without FDA authorization, and more recently, with such tests authorized by the FDA. Specifically, in March 2020, companies such as Nurx, Everlywell and Carbon Health began marketing at-home collection kits directly to consumers.[11] The provision of tests by these companies involved healthcare professionals to various degrees (i.e. to review an eligibility questionnaire), although typically only after the consumer had initiated or completed the purchase of the test.[12]

The marketing of such tests largely coincided with the release of an FDA guidance explaining that the agency would permit laboratories and commercial manufacturers to develop and offer COVID-19 diagnostic tests as long as they notified FDA that their assays had been validated and submitted an EUA. This policy, however, did not apply to at-home sample collection, which instead required that FDA

5 Joseph Hadaya, Max Schumm & Edward H. Livingston, *Testing Individuals for Coronavirus Disease 2019 (COVID-19)*, 323 JAMA 1981 (2020).

6 Denise M. Hinton, *LabCorp COVID-19 RT-PCR Letter of Authorization*, https://www.fda.gov/media/136148/download (accessed May 21, 2020); U.S. Food and Drug Administration, *Accelerated Emergency Use Authorization (EUA) Summary; SARS-CoV-2 Assay (Rutgers Clinical Genomics Laboratory)*, https://www.fda.gov/media/136875/download (accessed May 19, 2020).

7 Alireza Tahamtan & Abdollah Ardebili, *Real-time RT-PCR in COVID-19 Detection: Issues Affecting the Results*, 20 EXPERT REV MOL DIAGN 1–2 (2020).

8 Atreyee Basu et al., *Performance of the Rapid Nucleic Acid Amplification by Abbott ID NOW COVID-19 in Nasopharyngeal Swabs Transported in Viral Media and Dry Nasal Swabs, in a New York City academic institution*, BIORXIV 2020.05.11.089896 (2020).

9 U.S. Food and Drug Administration, *Sofia 2 SARS Antigen FIA*, https://www.fda.gov/media/137886/download (accessed May 19, 2020).

10 Andrew Jacobs, *F.D.A. Approves First Antigen Test for Detecting the Coronavirus*, NEW YORK TIMES, https://www.nytimes.com/2020/05/09/health/antigen-testing-fda-coronavirus.html (accessed May 19, 2020).

11 Jamie Ducharme, *Your Doctor's Appointment Has Been Cancelled. Are At-HomeI Tests a Good Solution?* TIME, https://time.com/5809606/covid-19-at-home-testing/ (accessed May 19, 2020).

12 *Id.*

issue an EUA before marketing. After FDA clarified this policy in an update to its guidance document,[13] some companies pulled their at-home collection kits from the market.[14] At least one other did so only after facing enforcement action from local authorities.[15]

DTC at-home collection kits, however, are rapidly reemerging with FDA authorization. In April 2020, Pixel by LabCorp received an EUA for the first COVID-19 diagnostic test with at-home collection (via a shallow nasal swab kit).[16] Currently, consumers can purchase this kit for $119 after completing a brief online survey that assesses symptom level (severe, mild or none); potential exposure to coronavirus; and whether an individual is low- or high-risk.[17] One month later, a second diagnostic at-home kit that utilizes saliva samples was issued an EUA.[18] At present (August 2020), there are approximately a dozen companies, including Everlywell, LetsGetChecked, Phosphorus, Hims, Vault Health, and 1Health.io, offering authorized at-home COVID-19 diagnostic tests that involve nasal swab or saliva collection.[19] Notably, some of these companies have previously faced criticisms outside the COVID-19 context. More specifically, commentators have raised ethical concerns about companies such as Hims, whose business model permits consumers to order prescription drugs without interfacing directly with a healthcare professional.[20] Others have raised validity

13 U.S. Food and Drug Administration, *Coronavirus (COVID-19) Update: FDA Alerts Consumers About Unauthorized Fraudulent COVID-19 Test Kits*, Food and Drug Administration, March 20, 2020; U.S. Food and Drug Administration, *Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised): Immediately in Effect Guidance for Clinical Laboratories, Commercial Manufacturers, and Food and Drug Administration Staff*, Food and Drug Administration, May 11, 2020.

14 Although outside the COVID-19 context FDA has distinguished DTC tests from laboratory-developed tests (LDTs), it is worth noting that concerns have been raised about FDA requiring labs to submit EUAs before marketing COVID-19 tests that are LDTs. Barbara Evans and Ellen Wright Clayton have argued that FDA lacks clear statutory authority over LDTs, its oversight does not add much to what is already required under the Clinical Laboratories Improvement Amendments (CLIA), and has unnecessarily limited availability of tests in the USA. See Barbara J. Evans & Ellen Wright Clayton, *Deadly Delay: The FDA's Role in America's COVID-Testing Debacle*, 130 Yale L. J. Forum (2020). *But see* Patricia J. Zettler, *Pharmaceutical Federalism*, 92 Ind. L.J. 845, 890 (2017) (raising questions about certain arguments that FDA lacks authority over LDTs).

15 For example, in Los Angeles, local authorities filed a civil action against the company Yikon Genomics Inc., for illegally selling at-home COVID-19 tests and falsely claiming that their tests were approved by FDA. Tom Dreisbach, *Los Angeles Authorities Sue Company For "Illegally Selling" At-Home COVID-19 Test*, NPR, https://www.npr.org/sections/coronavirus-live-updates/2020/04/06/828174323/los-angeles-authorities-sue-company-for-illegally-selling-at-home-covid-19-test (accessed May 19, 2020).

16 U.S. Food and Drug Administration, *Coronavirus (COVID-19) Update: FDA Authorizes First Test for Patient At-Home Sample Collection*, https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-first-test-patient-home-sample-collection (accessed July 21, 2020).

17 Pixel by LabCorp, *COVID-19 At-Home Test Kit Survey*, https://www.pixel.labcorp.com/covid-19-survey (accessed May 19, 2020).

18 U.S. Food and Drug Administration, *Coronavirus (COVID-19) Update: FDA Authorizes First Diagnostic Test Using At-Home Collection of Saliva Specimens*, https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-first-diagnostic-test-using-home-collection-saliva (accessed July 21, 2020).

19 Hims, Vault Health, 1health.io, Everlywell, LetsGetChecked, Phosphorus, Quest Diagnostics, *supra* note 2.

20 Henry Curtis & Joseph Milner, *Ethical Concerns With Online Direct-to-Consumer Pharmaceutical Companies*, 46 J Med Ethics 168–171 (2019); Natasha Singer & Katie Thomas, *Drug Sites Upend Doctor-Patient Relations: 'It's Restaurant-Menu Medicine,'* New York Times, https://www.nytimes.com/2019/04/02/technology/for-him-for-hers-get-roman.html (accessed May 19, 2020).

concerns about Everywell's DTC tests measuring the immune response to food in order to determine food sensitivity.[21]

Serological Tests

While diagnostic tests aim to detect an active infection, serological tests aim to detect antibodies in the blood, indicating that a person had been infected and recovered from COVID-19. The presence of such antibodies could potentially indicate that the individual has developed some level of immunity against the virus. The blood sample for these tests is usually obtained through a finger prick. The sample can be collected by an individual and sent to be analyzed in a lab, or be analyzed with laboratory equipment available at a point-of-care location (e.g. in a pharmacy or physician's office) that can deliver results within a few minutes. Although the accuracy of these tests for COVID-19 antibodies is not well established,[22] they are at present widely available through numerous laboratories with or without a referral, often in a DTC context that requires consumers to initiate the testing process outside the healthcare system.

The widespread availability of serological testing was made possible from a regulatory perspective because, until recently, FDA exercised its discretion not to enforce requirements for laboratories and commercial manufacturers operating without an EUA, as long as they provided a disclaimer that the tests had not been reviewed by FDA and that results should not be used as the sole basis for confirming that someone has the disease.[23] Following concerns about the quality of many tests on the market, in May 2020 FDA changed its approach, aligning its policy for serological tests with that for diagnostic tests.[24] This means that like with COVID-19 diagnostic tests, companies distributing at-home serological tests must obtain an EUA before marketing their products. In addition, later the same month, FDA published a list of serological tests that could no longer be marketed or distributed.[25] This was because while the manufacturers of these tests had notified FDA that they intended to seek an EUA, eventually they either voluntarily withdrew their tests from the notification list or failed to apply for an EUA.

Currently, at least two companies offer DTC COVID-19 serological tests.[26] As opposed to at-home collection kits, in this context, consumers initiate the test by

21 Thierry Hurlimann et al., *Ethical Considerations in the Implementation of Nutrigenetics/Nutrigenomics.*, 14 Pers Med 75–83 (2016); Lesley McClurg, *Do DIY Medical Tests Promise More Than They Can Deliver?*, NPR, https://www.npr.org/sections/health-shots/2018/05/28/614125270/do-diy-medical-tests-promise-more-than-they-can-deliver (accessed May 21, 2020); American Academy of Allergy, Asthma & Immunology, *The Myth of IgG Food Panel Testing*, https://www.aaaai.org/conditions-and-treatments/library/allergy-library/IgG-food-test (accessed May 21, 2020).

22 World Health Organization, *"Immunity passports" in the Context of COVID-19*, World Health Organization, https://www.who.int/news-room/commentaries/detail/immunity-passports-in-the-context-of-covid-19 (accessed May 19, 2020).

23 U.S. Food and Drug Administration, supra note 13.

24 *Id.*

25 U.S. Food and Drug Administration, *Coronavirus (COVID-19) Update: FDA Provides Promised Transparency for Antibody Tests,* https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-provides-promised-transparency-antibody-tests (accessed July 21, 2020).

26 HealthLabs.com, *COVID-19 Antibody Test,* https://www.healthlabs.com/covid-19-antibody-test (accessed July 21, 2020); Quest Diagnostics, *supra* note 2.

making an appointment and having their sample collected in a lab. For example, the Quest Diagnostics serological test can be purchased online for $119 after individuals complete a brief questionnaire that assesses whether an individual is currently symptomatic for COVID-19.[27] Other companies offer tests specifically to employers interested in testing their employees for COVID-19 antibodies.[28] Although to-date there are no strictly at-home serological tests, these may be on the horizon: for example, Scanwell together with Lemonaid Health are reportedly developing an at-home antibody test that will require consumers to extract a blood sample and share a picture of the blood testing stick with a healthcare provider, who would interpret the results in a subsequent consultation.[29]

Looking Ahead

In the future, it is possible that COVID-19 diagnostic and serological tests will become increasingly available both on an at-home and consumer-initiated basis, for a number of reasons. First, there is consumer demand, which provides financial incentives for companies to offer such tests. Second, there are public health benefits in expanding at-home testing capacity—this type of testing may allow for more individuals to get tested without exposing themselves and others to the risk of infection. Third, FDA has recently expressed its explicit support for at-home COVID-19 testing, clarifying that such tests may be issued an EUA as long as manufacturers provide adequate data and scientific evidence supporting the safety and accuracy of such tests.[30] However, the development of such a market raises ethical concerns and regulatory challenges, which need to be addressed in order to reap the full potential of DTC testing.

ETHICAL CONCERNS AND REGULATORY CHALLENGES

Although COVID-19 testing in general—even when not provided on a DTC basis—may raise many ethical and regulatory issues, the five main concerns discussed in this section are particularly pronounced in the DTC space. More specifically, the at-home COVID-19 diagnostic testing model presents heightened challenges regarding the accuracy of tests compared to testing that involves sample collection from a healthcare provider. In addition, the absence (or minimal involvement) of a healthcare provider and, potentially of adequate information accompanying the tests, intensifies concerns about the possible misinterpretation of test results. Furthermore, to-date, there has been a number of misleading claims made by companies advertising DTC COVID-19 tests (and misinformation from other sources), as well as numerous cases of marketing of fraudulent DTC tests. Privacy concerns are also more pronounced in

27 Quest Diagnostics, *supra* note 2.

28 HealthLabs.com, *Bulk COVID-19 Antibody Screening*, https://www.healthlabs.com/covid-19-antibody-test (accessed July 21, 2020)

29 Lemonaid Health and Scanwell, *At-home Antibody Test for the Novel Coronavirus (SARS-CoV-2)*, https://www.lemonxscan.com/ (accessed May 19, 2020); Alice Park, *An At-Home Coronavirus Test May Be on the Way in the U.S.*, TIME, https://time.com/5809753/at-home-coronavirus-test/ (accessed May 19, 2020).

30 U.S. Food and Drug Administration, *FAQs on Testing for SARS-CoV-2, Q: Can I offer my test for self-collection of a specimen at home and shipping to a laboratory for testing under the policies outlined in the Policy for Coronavirus Disease-2019 Tests?* (Updated 5/8) https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-testing-sars-cov-2 (accessed May 19, 2020); Ultimately, the availability of at-home COVID-19 tests will depend on specific state laws and regulations, in addition to federal ones.

the DTC context, since some companies may not be covered by the Health Insurance Portability and Accountability Act (HIPAA). Finally, the provision of DTC tests by commercial providers may exacerbate inequalities in access to testing at the expense of communities that are disproportionately affected by COVID-19.

Accuracy of Test Results

The major ethical and regulatory concerns that surround the actual processes of DTC testing for both active COVID-19 infection and serological testing mirror existing concerns about DTC health monitoring and disease evaluation tests already widely available in the USA. Many of these existing tests, such as HIV tests or the monitoring of HbAC levels for diabetes management, have proven track records in medical treatment. However, many others—such as food sensitivity tests and genetic tests for susceptibility to multifactorial disorders—are of uncertain quality, particularly because of their inconclusive clinical validity (i.e. the ability of a test to correctly identify that a particular variant is correlated with increased risk of disease or condition)[31] and unproven clinical utility (i.e. the ability of the test to inform clinical management of a patient).[32]

In the COVID-19 context, the public health value of accurate COVID-19 tests is clear. However, there remain questions regarding the accuracy of DTC tests, which is dependent on various factors, including the quality of the sample collected, proper shipment, and stability of the specimen, as well as the sensitivity and specificity of the test. Indeed, FDA has recently acknowledged that COVID-19 tests involving at-home sample collection may present unique issues regarding accuracy, and in recognition of these challenges it recently published an EUA template to help provide guidance to manufacturers of such tests.[33]

Regarding the quality of the sample, although many diagnostic COVID-19 tests in the healthcare setting utilize nasopharyngeal swabs—which may be difficult for individuals to obtain themselves—such tests seem unlikely to come to the US DTC market. The currently available DTC at-home tests utilize shallow nasal swabs or saliva samples, which are easier for individuals to obtain. Early studies have indicated that nasal swabs and saliva samples—even when self-collected—can effectively and reliably identify infections of the SARS-CoV-2 virus,[34] and the results of one preprint study

31 Kathy Hudson et al., *ASHG Statement on Direct-to-Consumer Genetic Testing in the United States*, 81 American Journal of Human Genetics 635–637 (2007).

32 Martina C Cornel, Carla G van El & Pascal Borry, *The Challenge of Implementing Genetic Tests With Clinical Utility While Avoiding Unsound Applications.*, 5 J Community Genetics 7–12 (2012).

33 U.S. Food and Drug Administration, *Coronavirus (COVID-19) Update: FDA Takes Steps to Streamline Development of Tests With At-Home Sample Collection,* https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-takes-steps-streamline-development-tests-home-sample-collection (accessed July 21, 2020).

34 JonathanAltamirano, Prasanthi Govindarajan & Andra L. Blomkalns, *Assessment of Sensitivity and Specificity of Patient-Collected Lower Nasal Specimens for Severe Acute Respiratory Syndrome Coronavirus 2 Testing*, 3 Jama Netw Open e2012005 (2020); Kelvin Kai-Wang To, Owen Tak-Yin Tsang, Cyril Chik-Yan Yip, et al., *Consistent Detection of 2019 Novel Coronavirus in Saliva*, Clin Infect Dis (2020); Sumio Iwasaki, Shinichi Fujisawa, Sho Nakakubo, et al., *Comparison of SARS-CoV-2 Detection in Nasopharyngeal Swab and Saliva*, J Infect (2020); Lorenzo Azzi, Giulio Carcano, Francesco Gianfagna, et al., *Saliva is a Reliable Tool to Detect SARS-CoV-2*, 81 J Infect e45-e50 (2020).

suggested that saliva may actually be more sensitive than nasopharyngeal swabs.[35] Thus, while further research in this field is necessary, at-present, quality for self-collected shallow nasal swabs and saliva samples does not appear to be a primary concern.

With regard to the shipment and stability of sample, FDA has noted that at-home tests may raise particular concerns due to the time lapse between the collection and the analysis. In addition, samples may be subject to conditions during shipment (e.g. high temperatures) that may compromise them.[36] However, for some nasal swabs (foam or polyester) shipped in certain ways (in a dry tube or in saline solution), FDA has recently indicated that preliminary data suggest that the samples appear to be stable.[37] Thus, at present, samples collected and shipped using these methods appear to alleviate stability concerns, although questions remain regarding stability for other forms of samples and shipment methods.

In addition, the sensitivity (i.e. the ability of the test to detect the presence of the virus or antibodies) and specificity (i.e. the ability of the test to detect the absence of the virus or antibodies) of the test itself are also crucial for the reliability of results. While the PCR tests currently used in COVID-19 diagnostic testing are considered to be of high accuracy, there is always a risk of false-positive or false-negative results, and those risks may depend on factors such as testing outside the diagnostic window, and the use of inadequately validated assays.[38] In the case of serological tests for COVID-19, such concerns are more pressing, as their accuracy has not been well-established and the chance of such tests producing false-positive results may be high, especially in low prevalence populations.[39] A recent preprint study performed by a consortium of laboratories in California found that of the 12 antibody tests studied, one test produced false-positive results over 15% of the time, and three other tests more than 10% of the time.[40] Given that until recently there has been only limited oversight of these tests, the reliability of serological tests remains an important concern.[41]

Although DTC COVID tests are reviewed by FDA before they enter the market this does not eliminate concerns about their accuracy. Issues of unproven quality are potentially inherent to those tests that are marketed under an EUA, as all FDA-authorized COVID-19 tests currently are. For FDA to issue an EUA for a test, the Federal Food, Drug, and Cosmetic Act requires, among other things, that FDA conclude it is 'reasonable to believe' that the test 'may be effective in diagnosing' the disease.[42]

35 Anne Louise Wyllie, John Fournier, Arnau Casanovas-Massana et al., *Saliva is More Sensitive for SARS-CoV-2 Detection in COVID-19 Patients Than Nasopharyngeal Swabs,* medRxiv (2020).

36 U.S. Food and Drug Administration, supra note 30.

37 *Id.*

38 Giuseppe Lippi, Ana-Maria Simundic & Mario Plebani, *Potential Preanalytical and Analytical Vulnerabilities in the Laboratory Diagnosis of Coronavirus Disease 2019 (COVID-19)*, Clin Chem Lab Med (2020).

39 U.S. Food and Drug Administration, *EUA Authorized Serology Test Performance,* https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/eua-authorized-serology-test-performance (accessed August 4, 2020).

40 Jeffrey D. Whitman et al., *Test Performance Evaluation of SARS-CoV-2 Serological Assays*, Medrxiv 2020.04.25.20074856 (2020).

41 Hannah Hagemann, *Antibody Tests Go to Market Largely Unregulated, Warns House Subcommittee Chair*, NPR, https://www.npr.org/sections/coronavirus-live-updates/2020/04/26/845164212/antibody-tests-go-to-market-largely-unregulated-warns-house-subcommittee-chair (accessed May 21, 2020).

42 21 U.S.C. § 360bbb–3(c).

Consistent with this statutory language, FDA has explained that the standard for a product being issued an EUA requires 'a lower level of evidence than the 'effectiveness' standard that FDA uses for [standard] product approvals.'[43]

Concerns about test quality have intensified following the US Department of Health and Human Services's (HHS) August 2020 statement that FDA will not require premarket review for laboratory developed tests (LDTs), including for COVID-19 LDTs, unless the agency first goes through notice-and-comment rulemaking to do so.[44] FDA describes LDTs as tests that are "designed, manufactured and used in a single laboratory," and historically has exercised its discretion not to enforce premarket review requirements for many LDTs.[45] But FDA also has enforced such requirements for DTC tests (even when they may meet the definition of an LDT),[46] and HHS's statement did not explain whether it was intended to apply to DTC products that may meet the definition of an LDT. It, thus, is unclear what HHS intended its statement to cover and how FDA will treat DTC LDTs going forward.[47] It is possible that FDA will allow some DTC COVID-19 tests that are considered LDTs to be offered without an EUA.[48] As a result, more tests of uncertain quality may enter the market in the near future.

In addition, issues regarding the quality of DTC COVID-19 tests may be heightened because of the widespread, historic nature of the pandemic and the urgent need for expanding testing capacity—and accompanying political pressure. At the same time, however, it is critical that regulators, industry, and the public recognize the need to ensure high-quality standards.[49]

43 U.S. Food and Drug Administration, *Emergency Use Authorization of Medical Products and Related Authorities,* https://www.fda.gov/media/97321/download (accessed May 21, 2020).

44 U.S. Department of Health and Human Services, *Rescission of Guidances and Other Informal Issuances Concerning Premarket Review of Laboratory Developed Tests*, https://www.hhs.gov/coronavirus/testing/recission-guidances-informal-issuances-premarket-review-lab-tests/index.html (accessed August 28, 2020). There may be questions about the legal effect of some aspects of the HHS statement (for example, whether a paragraph-long statement on HHS's website is sufficient to withdraw existing FDA guidances). But, as a practical matter, FDA is an agency within HHS and we should expect FDA to follow HHS's statement on LDTs.

45 U.S. Food and Drug Administration, *Laboratory Developed Tests* https://www.fda.gov/medical-devices/vitro-diagnostics/laboratory-developed-tests (accessed August 28, 2020).

46 See U.S. Food Drug Administration, *Draft Guidance for Industry, Food and Drug Administration Staff, and Clinical Laboratories: Framework for Regulatory Oversight of Laboratory Developed Tests (LDTs)* (2014) https://www.fda.gov/media/89841/download (accessed August 28, 2020).

47 The HHS statement did make clear that LDTs for which FDA has already issued an EUA are unaffected by the change in policy.

48 It is worth noting that the definition of DTC test that FDA has used is narrower than the one we set out in this article. We use the term to describe consumer-initiated tests with minimal involvement of a health care provider. FDA has defined DTC tests as those tests "marketed directly to consumers without the involvement of a health care provider" (See: U.S. Food and Drug Administration, *Direct-to-Consumer Tests*, https://www.fda.gov/medical-devices/vitro-diagnostics/direct-consumer-tests (accessed August 28, 2020). Thus, even if FDA continues to enforce premarket review requirements for DTC tests that meet this narrower definition, some of the tests we discuss-those that minimally involve a health care and are considered to be LDTs-may no longer require an EUA.

49 Alex John London & Jonathan Kimmelman, *Against Pandemic Research Exceptionalism*, 368 Science 476–477 (2020).

Potential Misinterpretation of Results

For all DTC health testing, the absence of a healthcare professional and, potentially of adequate information regarding the potential limitations of these products, has raised concerns about the risk of misinterpretation of results and of potentially inappropriate subsequent healthcare decision making. These concerns apply even for those tests that have met relevant quality standards.

Moreover, such concerns are particularly salient for COVID-19 testing. For diagnostic testing, false-negative results could create a false sense of security and contribute to further spread of the virus, while false-positive test results could keep people out of work, school, or childcare, exacerbating economic and educational harms. Additionally, although the interpretation of COVID-19 diagnostic testing is relatively straightforward—indicating whether an individual has an acute manifestation of the infection—serological testing is far more difficult to interpret. For example, while preliminary data suggest that recovery from COVID-19 might confer immunity to subsequent infection, it is still uncertain how protective such immunity is and how long it may last.[50] In addition, while many manufacturers claim that their serological tests are of high sensitivity and specificity, many have not released any data supporting their claims.[51]

Considering the potential unreliability of currently available serological tests and the uncertainty over the meaning of COVID-19 immunity, it is of concern that several companies are marketing serological tests to employers interested in testing their employees, as such results could be used to make decisions about employees going back to work. Misinterpreting or overestimating test results could expose individuals to risks of reinfection and could undermine public health mitigation efforts.[52]

In this regard, DTC COVID-19 tests, whether diagnostic or serological, should be accompanied by clear guidance and information about their potential and limitations. During the pandemic, with millions of individuals fearful of being sick, but also desperate to resume work, the scale, and immediacy of the adverse impact of misinterpreting COVID-19 test results are far greater than other commercially available DTC health-related tests.

Misleading Product Promotion and Misinformation

Many concerns that have been previously raised regarding DTC promotion of health-related tests—such as misleading or inaccurate claims, exaggeration of benefits and minimization of risks[53]—are relevant in the case of COVID-19 tests. Amidst the

50 World Health Organization, *supra* note 22; Robert D Kirkcaldy, Brian A King & John T Brooks, *COVID-19 and Postinfection Immunity: Limited Evidence, Many Remaining Questions*, 323 Jama (2020).

51 Jennifer Abbasi, *The Promise and Peril of Antibody Testing for COVID-19*, 323 Jama 1881 (2020).

52 Henry Greely, *Covid-19 'immunity certificates': practical and ethical conundrums*, STAT, https://www.statnews.com/2020/04/10/immunity-certificates-covid-19-practical-ethical-conundrums/, (accessed May 21, 2020). *Cf.* Hrefna D Gunnarsdottir, Michael S. Sinha, Sara Gerke & Timo Minssen, *Applying the Proportionality Principle to COVID-19 Antibody Testing*, J.L. Biosci. (published online 2020), https://academic.oup.com/jlb/article/doi/10.1093/jlb/lsaa058/5878809 ("Though ethical issues remain . . . [COVID-19] antibody testing may be part of a long-term strategy for international travel or employment, particularly between nations with disparate disease prevalence rates.").

53 Louiza Kalokairinou, Pascal Borry & Heidi Carmen Howard, *Regulating the Advertising of Genetic Tests in Europe: a Balancing Act*, 54 J Med Genet 651–656 (2017).

pandemic, the market has been flooded by companies making unsubstantiated and often fraudulent claims, such as falsely stating that their tests have been approved by FDA[54] or that their serological tests can diagnose the disease.[55] To-date, several state and local regulators have issued cease-and-desist orders to individuals and companies on the grounds that they have been illegally promoting and offering COVID-19 tests.[56] At a federal level, both FDA and Federal Trade Commission (FTC) have warned companies to stop making misleading claims, including about treating and preventing the coronavirus.[57]

In addition to misleading information coming from companies themselves, the public has been receiving an overwhelming amount of misleading information about serological testing from other sources. Politicians in the USA and abroad have exaggerated the potential of such tests, touting widespread serological testing as a 'game changer'[58] and a key to restarting the economy. Some governments have reportedly considered issuing 'immunity passports' based on positive serological tests results.[59] Additionally, in a May 2020 statement, the Governor of New York stated that detecting COVID-19 antibodies means that, 'You can get to work, you can go back to school, you can do whatever you want.'[60] Yet, as explained above, it is still uncertain what positive serological test results mean for functional immunity, how protective any immunity is, and how long it may last.

Misinformation about COVID-19 tests, whether from companies or other sources, is particularly concerning.[61] Misleading product promotion capitalizes on widespread anxiety caused by the pandemic and preys on the vulnerability of consumers, many of whom are likely concerned about their health. The massive amount of information (and misinformation) about COVID-19, and the quickly changing landscape, may make it particularly challenging for consumers to differentiate between legitimate tests and fraudulent products (which might mislead consumers about their COVID-19 health

54 Matthew Ormseth, *An FDA-Approved Coronavirus Home Test Kit? That's False, L.A. authorities say*, Los Angeles Times, https://www.latimes.com/california/story/2020-04-05/coronavirus-home-test-fda-los-angeles-city-attorney-settlement (accessed May 21, 2020).

55 Stephanie M. Lee, *Everyone Wants to Know If They Already Had the Coronavirus. Some People May Be Preying on That.*, Buzzfeed News, https://www.buzzfeednews.com/article/stephaniemlee/coronavirus-antibody-tests-cease-and-desist (accessed May 19, 2020).

56 *Id.*

57 Johnny Diaz, *F.T.C. Warns 10 Companies About Virus-Related Health and Business Claims*, New York Times, https://www.nytimes.com/2020/04/25/us/ftc-mlm-coronavirus-claims.html, (accessed May 19, 2020); U.S. Federal Trade Commission, *FTC Coronavirus Warning Letters to Companies*, https://www.ftc.gov/coronavirus/enforcement/warning-letters (accessed May 19, 2020); U.S. Federal Trade Commission, *FTC Sends 45 More Letters Warning Marketers To Stop Making Unsupported Claims That Their Products And Therapies Can Effectively Prevent Or Treat COVID-19*, https://www.ftc.gov/news-events/press-releases/2020/05/ftc-sends-45-more-letters-warning-marketers-stop-making (accessed May 19, 2020); U.S. Food and Drug Administration, *Coronavirus (COVID-19) Update: FDA Issues Warning Letters to Companies Inappropriately Marketing Antibody Tests, Potentially Placing Public Health at Risks*, https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-issues-warning-letters-companies-inappropriately-marketing-antibody (accessed August 4, 2020).

58 Smriti Mallapaty, *Will Antibody Tests for the Coronavirus Really Change Everything?*, 580 Nature 571 (2020).

59 *Id.*

60 Beckie Strum, *New York Governor Looks to Antibody Testing as a Potential Means to Get People Back to Work*, MarketWatch, https://www.marketwatch.com/story/new-york-governor-looks-to-antibody-testing-as-a-potential-means-to-get-people-back-to-work-2020-04-07, (accessed May 19, 2020).

61 See, e.g., Timothy Caufield, *Pseudoscience and COVID-19—We've Had Enough Already*, Nature (2020).

status). Moreover, misinformation regarding the potential benefits and limitations of the tests could lead individuals to misunderstand their COVID-19 health status—even if companies selling the tests are not themselves providing misleading information.

Privacy Concerns

DTC testing by private companies in the realm of genetics has raised important questions regarding privacy and confidentiality of personal data.[62] In the USA, companies may not be subject to laws intended to protect the privacy of health information, such as the HIPAA.[63] Thus, the protection of personal data, including the duration of storage and the third party access to them, is largely determined by terms of service created by the companies themselves.[64] Similarly, many of the companies offering at-home COVID-19 tests, whether diagnostic or serological, may not be covered by HIPAA and the protection of personal data may, therefore, depend on companies' individual policies.

In the COVID-19 context, consumers may erroneously assume, in some cases, that privacy rules governing data in the healthcare setting (such as HIPAA) and doctor–patient confidentiality also apply to DTC companies, giving them a false sense of security.[65] Furthermore, consumers may not realize that for infectious diseases, the limits of confidentiality may be narrower as compared to other types of tests. More specifically, companies may need to comply with relevant local and state regulations regarding the reporting of positive test results to authorities and may need to disclose protected health information without obtaining prior permission from the consumer.[66] Currently, several state and county health departments require healthcare practitioners and medical laboratories to report COVID-19 cases, providing, amongst other information, the name and address of the patient.[67]

While the policies of some companies are more transparent than others, it is likely that consumers will click 'I Agree' to terms and conditions without ever reading them. This may be especially the case with individuals ordering diagnostic tests, as it is likely that such tests will be purchased under conditions of urgency and anxiety that may not

62 Timothy Caulfield & Amy L. McGuire, *Direct-to-Consumer Genetic Testing: Perceptions, Problems, and Policy Responses*, 63 Annu Rev Med 23–33 (2012); Linnea I. Laestadius, Jennifer R. Rich & Paul L. Auer, *All Your Data (effectively) Belong to us: Data Practices Among Direct-to-Consumer Genetic Testing Firms*, 19 Genet Med 513–520 (2017); Henry T. Greely, *The Future of DTC Genomics and the Law*, 48 J Law Medicine Ethics 151–160 (2020).

63 I. Glenn Cohen & Michelle M. Mello, *HIPAA and Protecting Health Information in the 21st Century.*, 320 Jama 231 (2018); W. Nicholson Price & I. Glenn Cohen, *Privacy in the Age of Medical Big Data*, 25 Nat Med 37–43 (2019).

64 Andelka M Phillips, *Genomic Privacy and Direct-to-Consumer Genetics: Big Consumer Genetic Data—What's in that Contract?*, 2015 Ieee Secur Priv Work 60–64 (2015).

65 Amy L. McGuire & Wylie Burke, *Health System Implications of Direct-to-Consumer Personal Genome Testing*, 14 Public Health Genomi 53–58 (2010).

66 U.S. Department of Health & Human Services (HHS), *HIPAA for Professionals: FAQ*, https://www.hhs.gov/hipaa/for-professionals/faq/294/must-a-health-care-provider-obtain-permission-to-notify-public-health-authorities/index.html (accessed May 19, 2020).

67 Minnesota Department of Health, *Reporting COVID-19/SARS-CoV-2 Infections*, https://www.health.state.mn.us/diseases/coronavirus/hcp/report.html#how (accessed May 19, 2020); California Department of Public Health, *Local Health Departments Communicable Disease Contact Information*, https://www.cdph.ca.gov/Programs/CCLHO/Pages/LHD-Communicable-Disease-Contact-List.aspx (accessed May 19, 2020).

allow for careful review of the relevant contracts. In addition, given the scarcity of tests, some people may not feel that they have the option to refuse.

Policies regarding third-party access to data are particularly relevant, especially in view of risks of discrimination in the context of employment. More specifically, it is possible that employers may be interested in accessing serological test results, especially when they are the ones initiating the testing. This is because confirming that employees have immunity could be relevant for recruitment decisions.[68] For these reasons, it is important for consumers to understand the limits of confidentiality of their health information and the risks of a privacy breach.

Fair Allocation of Scarce Resources

In recent years, DTC health testing has been marketed to consumers as an opportunity to access a wide range of health information directly, often completely bypassing the mainstream healthcare setting. By offering consumers information on genetic susceptibility to multifactorial disorders, carrier status, reproductive health, and infectious diseases, many DTC companies have presented themselves as expanding access to testing and enabling consumers to take control of their health. However, there have been longstanding concerns that such testing could eventually lead consumers back to the mainstream healthcare system for consultations regarding their test results, creating downstream costs and using resources that, in some settings, may be scarce.[69]

For COVID-19 tests, competition over scarce resources may be more direct and tangible. Currently, there are shortages of basic elements of diagnostic tests, such as swabs and reagents, both in the USA and worldwide. Such shortages are partly responsible for the inadequate testing capacity in the USA.[70] Despite an increase in the number of tests performed daily since the first month of the pandemic, testing is still not scaled up sufficiently to meet public health needs or consumer demand.[71] In this regard, companies offering DTC COVID-19 testing could provide an alternative for individuals and expand access to testing. However, given the scarcity of resources, they could also be in direct competition with other healthcare providers, such as hospitals.

The use of scarce resources by companies offering DTC testing during a global pandemic could also raise concerns over fair allocation of such resources. Previous research has indicated that consumers who purchase DTC health testing tend to be of higher socioeconomic status. For example, empirical studies of DTC genetic testing have shown that the majority of the consumer base is white, highly educated, and has a higher

68 Natasha Singer, *Employers Rush to Adopt Virus Screening. The Tools May Not Help Much.*, New York Times, https://www.nytimes.com/2020/05/11/technology/coronavirus-worker-testing-privacy.html (accessed May 19, 2020).

69 Caulfield & McGuire, *supra* note 65.

70 Sheryl Gay Stolberg, Farah Stockman & Sharon LaFraniere, *Testing Remains Scarce as Governors Weigh Reopening States*, New York Times, https://www.nytimes.com/2020/04/25/us/politics/virus-testing-shortages-states-trump.html (accessed May 19, 2020); Chirs Canipe & Travis Hartman, *The COVID-19 Testing Challenge: Why It's so Hard to Overcome Testing Shortages in the United States*, Reuters, https://graphics.reuters.com/HEALTH-CORONAVIRUS/TESTING/azgvomklmvd/ (accessed May 19, 2020).

71 Alexis C. Madrigal & Robinson Meyer, *A Dire Warning From COVID-19 Test Providers*, The Atlantic, https://www.theatlantic.com/science/archive/2020/06/us-coronavirus-testing-could-fail-again/613675/ (accessed July 21, 2020); Sarah Mervosh & Manny Fernandez, *Months Into Virus Crisis, U.S. Cities Still Lack Testing Capacity*, The New York Times, https://www.nytimes.com/2020/07/06/us/coronavirus-test-shortage.html, (accessed July 21, 2020).

than average household income.[72] Consistent with such findings, in the context of COVID-19, it is possible that poor and marginalized communities will have less access to DTC tests, because of inadequate financial resources, limited information about the availability of such tests, companies' marketing strategies, or other reasons. This is particularly concerning given that racial and ethnic minority groups have been disproportionately affected by the pandemic.[73] Currently, several state and county health departments are expanding testing capacity by launching testing sites in underserved communities.[74] In order to avoid two-tiered access to testing based on socioeconomic status or race, it is important that efforts to provide free testing to low-income communities, as well as to communities of color, are sustained and expanded across the USA.

Currently, issues of fair access to COVID-19 testing are more pressing for diagnostic tests, as they have clear clinical utility and are considered more reliable compared to serological tests. However, considering the ongoing policy discussions in some countries regarding using serological test results as an 'immunity passport' that would allow individuals to return to work,[75] ensuring equitable access to serological testing may become crucial in the near future.

CONCLUSION

As this article highlights, many of the concerns surrounding DTC COVID-19 parallel those surrounding other DTC health tests that are widely available in the USA. However, the scale of the present pandemic lends an increased urgency to existing issues. Given the fast-changing landscape of the COVID-19 pandemic, this article cannot predict or address all issues associated with DTC COVID-19 testing that are likely to arise. There are, however, several recommendations that can help inform the ethical provision of DTC health tests during this public health crisis.

First, consistent with its obligations under the Federal Food, Drug, and Cosmetic Act,[76] FDA should reassess its EUAs and remove authorization for tests that are found to be of low quality. Enabling testing to reach the market as quickly as possible is, of course, an important goal. But testing is not useful if consumers, healthcare

72 Sarah E. Gollust et al., *Consumer Perspectives on Access to Direct-to-Consumer Genetic Testing: Role of Demographic Factors and the Testing Experience: Consumer Perspectives on Access to Direct-to-Consumer Genetic Testing*, 95 Milbank Q 291–318 (2017); Deanna Alexis Carere et al., *Design, Methods, and Participant Characteristics of the Impact of Personal Genomics (PGen) Study, a Prospective Cohort Study of Direct-to-Consumer Personal Genomic Testing Customers.*, 6 Genome Med 96 (2014).

73 Neeta Kantamneni, *The Impact of the COVID-19 Pandemic on Marginalized Populations in the United States: A Research Agenda*, 119 J Vocat Behav (2020); Abi Rimmer, *Covid-19: Disproportionate Impact on Ethnic Minority Healthcare Workers will be Explored by Government*, 369 BMJ (2020); Centers for Disease Control and Prevention, *COVID-19 in Racial and Ethnic Minority Groups*, https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/racial-ethnic-minorities.html (accessed July 21, 2020).

74 Governor Andrew M. Cuomo, *Amid Ongoing COVID-19 Pandemic, Governor Cuomo Launches New Initiative to Expand Access to Testing in Low-Income Communities and Communities of Color*, https://www.governor.ny.gov/news/amid-ongoing-covid-19-pandemic-governor-cuomo-launches-new-initiative-expand-access-testing-low (accessed July 21, 2020); Conor McCue, *Denver Launching Coronavirus Testing To Help Communities Of Color*, CBS Denver, https://denver.cbslocal.com/2020/06/09/denver-community-coronavirus-testing/, (accessed July 21, 2020); Colleen Shalby, *L.A. County Expands Coronavirus Testing in Hard-Hit Black, Latino communities*, Los Angeles Times, https://www.latimes.com/california/story/2020-07-16/la-county-expands-testing-in-vulnerable-communities (accessed July 21, 2020).

75 Mallapaty, *supra* note 58.

76 21 U.S.C. 360bbb-3(g)(1).

professionals, and public health regulators cannot be confident in the results. Ultimately, FDA must ensure progress in studying and developing high-quality testing continues, and assure available testing meets the conventional—rather the lower, EUA—standards.

Second, all stakeholders should be working to educate policymakers and the public with accurate, non-misleading information about the limits and potential benefits of DTC testing. For example, companies should provide consumers adequate and clear information regarding their tests, in both communications about how to interpret test results and in promotional materials. FTC and states should continuously monitor the market and take action when necessary to protect consumers and ensure they have accurate and non-misleading information. In addition, for companies that are marketing DTC tests under an EUA and that make misleading claims that have a negative public health impact, FDA should make clear it will consider withdrawing the EUA.[77]

Third, with regard to privacy, it is crucial that companies provide transparent and easy-to-comprehend privacy policies that are not buried amongst other terms and conditions. Considering the vulnerability of consumers and the ongoing public health crisis, the FTC should monitor the practices of such companies closely to ensure that such terms are not disproportionate and safeguard the rights of consumers to privacy.

Fourth, equitable access to high-quality DTC tests is critical. At a minimum, companies should make clear whether their tests are covered by health insurance and whether they provide options for individuals who cannot afford standard prices, whether or not they are insured. But more is likely to be needed—and if mechanisms for equitable access for COVID-19 testing are successfully developed, they can inform models of access for other kinds of potentially beneficial DTC testing.

Ensuring a market of accurate and ethically marketed DTC COVID-19 tests presents significant challenges for regulators and requires the buy-in of all stakeholders, including industry. At the same time, regulators and industry may be well-equipped to address many of these challenges, drawing on past experience regulating other DTC tests. Regulators, industry, and the public also have an opportunity to think carefully about the risks and benefits of different models of DTC testing, and ultimately use the lessons learned from COVID-19 to improve the DTC testing market.

DISCLOSURES

Patricia J. Zettler reports serving as an expert witness retained by the Direct Purchaser Class Plaintiffs in In re Suboxone Antitrust Litigation, No. 2:13-MD-2445 (E.D. Pa), as an expert witness retained by the Direct Purchaser Class, End Payor Class, and Retailer Plaintiffs in In re Opana Antitrust Litigation, No. 14cv-10150 (N.D. Ill.), and as a consultant to Georgia State University on tobacco and nicotine research funded by FDA and NIH.

77 21 U.S.C. 360bbb-3(g)(2)(C).

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