Journal of Law and the Biosciences, 1–10
doi:10.1093/jlb/lsaa053
Essay

Covid-19, single-sourced diagnostic tests, and innovation policy

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I. INTRODUCTION

At the heart of the United States, disastrous response to the Covid-19 pandemic is a failure of diagnostic testing. That something so fundamental to medical care could be so botched evokes incredulity. From primary care offices to critical care settings, every patient encounter begins with a diagnostic workup. Diagnostic testing tools are key parts of the physician's toolkit, and confirmatory testing is essential. But in the greatest public health challenge of the 21st century, the failures of diagnostic testing have been laid entirely bare.

The story of this failure in diagnostic testing has been told in detail and will be unpacked for years to come. Briefly, the U.S. pandemic response lacked high-quality diagnostics, failed to deliver tests in sufficient quantity, and was too slow in deploying developed tests when initially needed.[1] This lack of appropriate testing resulted in inaccurate patient identification and poor epidemiological characterization of viral spread.[2] From there, the errors further multiplied and rendered the rest of the governmental pandemic response similarly sluggish and ineffective.

This article seeks to highlight an implication of the failure that applies broadly to diagnostic testing in general: the problems inherent in relying on a sole source for a diagnostic test. Though we focus on the question of single-sourcing in this exploration, we do not claim this factor as the only failure characterizing U.S. Covid-19 testing

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1 Michael D. Shear et al., *The Lost Month: How a Failure to Test Blinded the U.S. to Covid-19*, The New York Times, https://www.nytimes.com/2020/03/28/us/testing-coronavirus-pandemic.html (accessed Mar. 28, 2020).

2 *Id.*

policy.[3] Beyond single-sourcing, the FDA stumbled through a series of missteps around its application of Emergency Use Authorization (EUA) strictures and its issuance of EUAs.[4] Nationwide testing further suffered from the CDC's initial promotion of stringent criteria (e.g., travel history, symptom severity, etc.) to determine whether patients should even be allowed to receive tests. The constellation of these factors resulted in fewer patients being tested and rapid spread of the virus.[5] On the other end of the spectrum, the FDA's antibody-testing policy was likely too lax for SARS-CoV-2 serology tests (designed to determine viral antibody presence in blood), leading to too many poor-quality marketed tests that could lead individuals to falsely believe that they were immune to COVID-19.[6] By April 30, 2020, more than 170 serology tests had been marketed without FDA approval.[7]

Put bluntly, errors abounded in the COVID-19 testing landscape. But, reliance on single-sourcing for diagnostics was an early, central, and crucial error.

To be sure, Covid-19 testing had a sole source for a different reason than is typical for most tests. In the initial phase of the pandemic, the Food and Drug Administration (FDA) exclusively authorized the Centers for Disease Control (CDC) to conduct tests for SARS-CoV-2, the virus causing Covid-19, thereby granting an effective testing monopoly to the agency.[8] The CDC's test monopoly proved problematic for multiple reasons, including poor test quality and slow analysis of test results, as well as supply chain limitations preventing manufacturing scale.[9]

The test generated a high proportion of false positives due to initial development with faulty reagents.[10] Beyond quality control issues, the diagnostic test further suffered from a slow reporting of results as clinicians had to send samples back to labs beyond the clinical practice setting for analysis.[11] These shortcomings exacerbated the pandemic's toll by preventing quick containment of the virus.

Crisis may have been averted had there been any alternatives to the CDC's test, but under the FDA's restrictions, there were no other approved tests available to perform any confirmatory testing and receive second opinions. Labs were left to sit powerless until other tests were at long-last approved. This *de facto* diagnostic test monopoly proved critical and pushed back pandemic control efforts by several weeks.[12] Even

3 David Willman, *Contamination at CDC lab delayed rollout of coronavirus tests*, Washington Post, https://www.washingtonpost.com/investigations/contamination-at-cdc-lab-delayed-rollout-of-coronavirus-tests/2020/04/18/fd7d3824-7139-11ea-aa80-c2470c6b2034_story.html (accessed Apr. 18, 2020).

4 *Id.*

5 *Id.*

6 Steve Eder, Megan Twohey & Apoorva Mandavilli, *Antibody Test, Seen as Key to Reopening Country, Does Not Yet Deliver*, The New York Times, https://www.nytimes.com/2020/04/19/us/coronavirus-antibody-tests.html (accessed Apr. 19, 2020).

7 Nicholson Price et al., *How is regulatory policy influencing the development and marketing of antibody testing for COVID-19*, Written Description, https://writtendescription.blogspot.com/2020/05/how-is-regulatory-policy-influencing.html (accessed May 4, 2020).

8 Christopher Weaver et al., *America Needed Coronavirus Tests. The Government Failed.*, J., https://www.wsj.com/articles/how-washington-failed-to-build-a-robust-coronavirus-testing-system-11584552147 (accessed Mar. 19, 2020).

9 *Id.*

10 *Id.*

11 *Id.*

12 *Id.*

after the FDA permitted other labs to conduct testing, they were all required to follow the CDC's chemical formulation.[13] Non-CDC labs all required the same reagents, effectively rendering the additional approvals useless because the small reagent manufacturer could not keep up with the instantaneous jump in demand. The approval of several competing tests earlier in the pandemic response that are not chemically identical, such as the Roche SARS-CoV-2 test,[14] could have also alleviated some of the initial supply chain pressure and underscores the need to prevent monopoly testing. Of course, single-sourcing does not always lead to problems; the SARS-CoV-2 test adopted by the World Health Organization has worked well in the countries that used it.[15] But, single-sourcing sharply raises the possibility of problems leading to catastrophic failure down the line.

The problems with single-sourcing, though, are not limited to pandemics. Diagnostic tests are crucial to quotidian clinical practice. And within that practice, the abilities to access high-quality diagnostics rapidly and to perform confirmatory testing are crucial. Single-sourcing diagnostic tests jeopardize the ability to confirm test results but also may impact innovative efforts to develop new diagnostics based on old tools, supply robustness, and cost-effective development.[16] An appropriate model for diagnostic testing development, including innovation incentives, should go beyond simply discouraging test monopolies and promoting confirmatory testing, by also allowing for low R&D costs for test development and yielding fast delivery of high-quality tests—preventing the errors highlighted in the Covid-19 testing response from occurring in both emergency and non-emergency situations.

Unfortunately, policy efforts ongoing since before the pandemic are pointing exactly the wrong direction. After an 8-year stretch of unpatentability for certain diagnostics, efforts are afoot to change the law: recent legislative action would allow such tests to be patented again,[17] raising concerns about limitations on initial use and confirmatory testing.[18]

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13 *Id.*

14 Carrie Arnold, *Why the U.S. coronavirus testing failures were inevitable*, National Geographic, https://www.nationalgeographic.com/science/2020/03/why-united-states-coronavirus-testing-failures-were-inevitable/ (accessed Mar. 30, 2020).

15 *Id.*

16 Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 Science 698, 699 (1998) (discussing development cost inefficiencies that arise when individual genes are patented, resulting in the ownership of concurrent fragments that can prevent the development of any one test). This danger was later realized, leading to several major research universities endorsing 'In the Public Interest: Nine Points to Consider in Licensing University Technology' in part to protect academic research and development of diagnostics. Nevertheless, the Nine Points were entirely voluntarily, with important institutions such as Johns Hopkins University not signing on and with no repercussions for signatories that violated the guidelines. AUTM Board of Directors, *In the Public Interest: Nine Points to Consider in Licensing University Technology*, https://www.autm.net/AUTMMain/media/Advocacy/Documents/Points_to_Consider.pdf (accessed Mar. 6, 2007).

17 Stuart P. Meyer, *Still No Shortage of Viewpoints as Eligibility Debate Moves to the Hill*, Bilski Blog, https://www.bilskiblog.com/2019/06/still-no-shortage-of-viewpoints-as-eligibility-debate-moves-to-the-hill/ (accessed June 27, 2019).

18 In the past, diagnostic and gene method patents, often with overly broad language, have been used to block more scientifically accurate and cost effective alternatives. *See* Declaration of Ellen Matloff at 4, Ass'n for Molecular Pathology, 702 F. Supp. 2d 181 (No. 09–4515 RWS) ('Myriad's continuous and systematic assertion of its BRCA patents [had] resulted in the elimination of other genetic testing options available to [her] and

In this paper, we first consider how to address the problems with single-sourcing diagnostic tests in emergency medical contexts such as the ongoing Covid-19 pandemic. We then turn to applying those lessons for standard diagnostic test development, in particular considering how we can create adequate incentives for development without relying on a problematic single-source or quasi-monopoly model.

II. DIAGNOSTIC TEST GOVERNANCE AND SOURCING DURING A PUBLIC HEALTH EMERGENCY

The key diagnostic testing roadblock during the Covid-19 pandemic response in the USA appears to have been the FDA's decision to permit only the CDC to offer diagnostic testing for SARS-CoV-2. Without approval to test, none of the many other potential testing providers could offer confirmatory testing when the CDC's test offered ambiguous results, provide testing to make up for the CDC's breathtaking shortfall in testing volume, or offer innovative advances on the basic test to improve the substantial time required to get results back from the CDC.[19] Though the FDA ultimately did relax its regulatory structure in approving diagnostic tests, [20] the policy-driven delay had profound consequences.

Accordingly, the most straightforward intervention would involve updates to the FDA's EUA process. The 2013 Pandemic and All-Hazards Preparedness Reauthorization Act passed under the Obama administration contemplated a pandemic but focused primarily on streamlining the administrative process necessary for the FDA to start issuing EUAs of unapproved medical countermeasures (MCM) and expanding the emergency uses of already FDA-approved MCMs.[21]

We suggest updating the EUA model so that safety and efficacy of novel diagnostic tests can be established as quickly as possible. One criticism of the FDA's response during the Covid-19 outbreak was that the agency required EUAs for SARS-Cov-2 tests developed and conducted by individual labs authorized under the Clinical Laboratory Improvement Amendments (CLIA).[22] This yielded an unnecessary roadblock for development that disincentivized early testing, as these labs are normally only regulated by the Centers for Medicare and Medicaid Services (CMS); the FDA typically exercises enforcement discretion over laboratory-developed tests that are created and run in a single location.[23] Dueling draft bills in Congress, the VALID and VITAL Acts, seek

[her] patients that could [have been] cheaper, better and more appropriate'); *see infra* note 43 and accompanying text discussing the verification of Long QT Syndrome tests. Myriad's stifling of competition via patent litigation, even after their BRCA1/2 gene patents were invalidated, occurred despite public pledges of support for research and access to second opinions and confirmatory testing. Myriad, *The Myriad Pledge,* https://myriad.com/about-myriad/myriad-cares-2/the-myriad-pledge/; Susan Decker, *Myriad Genetics Sues Ambry to Thwart Breast Cancer Test,* Bloomberg, https://www.bloomberg.com/news/articles/2013-07-09/myriad-genetics-sues-ambry-to-thwart-rival-cancer-test (accessed July 10, 2013).

19 Weaver et al., *supra* note 8.

20 Weaver et al., *supra* note 8.

21 Brooke Courtney, U.S. Food & Drug Admin., Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (PAHPRA) Medical Countermeasure (MCM) Authorities: FDA Questions and Answers for Public Health Preparedness and Response Stakeholders 4-9, 11–13 (2014).

22 Arnold, *supra* note 14.

23 Food and Drug Administration, *Draft Guidance for Industry, Food and Drug Administration Staff, and Clinical Laboratories*, https://www.fda.gov/media/89841/download (accessed Oct. 3, 2014).

to clarify when the FDA should regulate LDTs.[24] While the VALID Act seeks to stratify tests by risk in order to determine regulation pathways and concentrate power to the FDA, the VITAL Act aims to focus on emergency situations and position CLIA regulations more prominently than FDA authority.[25] But neither bill is law; the FDA could have continued to exercise enforcement discretion with respect to SARS-CoV-2 LDTs. It chose not to.

Experiences at Stanford University and the University of Washington exemplify the substantial burden labs faced in filing EUAs for their LDTs. Stanford University created one of the first non-CDC SARS-CoV-2 diagnostics but delayed the deployment of the test because the EUA application was too difficult.[26] Instead of opting to complete the application, the university waited for a more lenient regulatory framework to begin using their tests.[27] At the University of Washington, researchers filed EUAs for tests developed in January, only to face similar administrative difficulties.[28] The strict application criteria included filing documents physically on CDs or thumb drives—unreasonable expectations in the context of a pandemic and a driving need to hasten test availability.[29]

Thus, in order to facilitate early deployment of multiple tests in a pandemic scenario, we suggest considering whether the EUA model be updated to: (i) streamline the EUA application process, perhaps through an alternative, temporary route administered through CMS, a regulatory body that CLIA-approved labs are already familiar with; (ii) make the regulatory regime more flexible, such that a more lenient structure can be quickly put in place to combat the early stages of an epidemic; and (iii) initially institute a limited liability model that would incentivize labs, like those at Stanford and the University of Washington, to begin using their test if they have good scientific data backing their safety and efficacy, especially if EUA processing delays are expected. An absence of any regulatory oversight brings its own problems—witness antibody testing—but overly tight entry rules can also be disastrous. FDA eventually adopted a more lenient policy incorporating some of these points, but the delay was costly. Perhaps most significantly, therefore, we think it important for FDA to consider the potential danger of single-sourcing when shaping its early pandemic responses to avoid a situation like that faced in early 2020. We recognize that these changes are not a panacea—some labs lacked CLIA approval, creating a parallel barrier to testing—but think that they deserve careful consideration.

24 Rand Paul, *Dr. Rand Paul Introduces VITAL Act to Speed Availability of Testing in Health Emergencies*, https://www.paul.senate.gov/news/dr-rand-paul-introduces-vital-act-speed-availability-testing-health-emergencies (accessed Mar. 18, 2020); Richard Burr, *S.3404—116th Congress (2019–2020): VALID Act of 2020*, https://www.congress.gov/bill/116th-congress/senate-bill/3404 (accessed Mar. 5, 2020).

25 Rand Paul, *supra* note 26; Richard Burr, *supra* note 26.

26 Shear et al., *supra* note 1.

27 *Id.*

28 Julia Ioffe, *The Infuriating Story of How the Government Stalled Coronavirus Testing*, GQ, https://www.gq.com/story/inside-americas-coronavirus-testing-crisis (accessed Mar. 16, 2020).

29 *Id.*

III. LESSONS FOR DIAGNOSTIC TEST DEVELOPMENT INCENTIVES MORE BROADLY

The failure of diagnostic testing during the US response to the Covid-19 pandemic provides a warning and a lesson for policy surrounding diagnostic tests more generally. Good policy for diagnostic testing in non-emergent times requires both protecting clinician access to diagnostic testing and creating appropriate incentives to support diagnostic test development. An incentive model for diagnostic tests should thus focus on three main aims: (i) promote the typical use case for tests, including allowing physicians to obtain second opinions; (ii) minimize the cost of research and development; and (iii) ensure rapid deployment of safe and effective tests. The third and especially the first of these aims are hindered by single-sourcing. And thus any sort of incentive model that relies on granting market exclusivity—such as the traditional patent system, FDA approval exclusivity, or trade secret protection—raises the same sorts of issues, if on a smaller scale, as those grimly demonstrated by the failure of U.S. SARS-CoV-2 testing at the onset of the Covid-19 pandemic, which ultimately resulted in the loss of many lives.[30] By preventing access to second opinions or incentivizing fast, but ultimately ineffective science, we risk putting patients in harm's way.[31] A better incentive system would allow for an increased number of players in the market, all vying to be the best diagnostic for each indication. Such a system would promote diagnostic creation and implementation that mirrors actual diagnostic usage.

We first (i) summarize a recent history of diagnostic test patentability, since patents have both created incentives but hampered access and clinical practice; (ii) describe current efforts to increase diagnostic test patents; and then (iii) propose improved reimbursement mechanisms as a solution to the balancing act of managing appropriate economic incentives and allowing for optimal clinical practice during non-emergent conditions.

A. A Brief History of Diagnostic Test Patentability

Clinical diagnostic tests were relatively straightforward to patent until recently. Three United States Supreme Court cases (Association for Molecular Pathology v. Myriad Genetics, Inc., Mayo Collaborative Services v. Prometheus Laboratories, Inc., and Alice Corp. v. CLS Bank International) between 2012 and 2014 made certain tests unpatentable.[32] The Court's rulings helped to assuage concerns regarding diagnostic test monopolies and to protect scientific and clinical freedom. Previously, Myriad Genetics had enforced its patents on the breast and ovarian cancer-related BRCA1/BRCA2 genes, hindering physicians seeking to independently verify genetic test results.[33] In the Myriad case, the Supreme Court weighed the availability of patent incentives for innovation against the concerning ability to monopolize natural

30 Weaver et al., *supra* note 8.

31 Aaron S. Kesselheim, *An Empirical Review of Major Legislation Affecting Drug Development: Past Experiences, Effects, and Unintended Consequences*, 89 Milbank Q 450 (2011).

32 Robert Cook-Deegan & Annie Niehaus, *After Myriad: Genetic Testing in the Wake of Recent Supreme Court Decisions about Gene Patents*, 2 Current Genetic Med Rep 223 (2014).

33 Myriad also used broadly worded method claims, later invalidated by the United States Court of Appeals for the Federal Circuit (CAFC), covering the use of the genes to block any competitors or verification testing. *See supra* note 20.

biological materials, such as DNA, concluding that only man-made complementary DNA could be patented, not the isolated genomic DNA used in genetic diagnostic tests. The Court's 2012 Mayo decision made diagnostics based on biomedical correlations, such as genetic risk scores or the use of biomarkers to identify disease states, difficult to patent as well.[34]

B. A Looming Threat to Diagnostic Tests in Clinical Practice—the Tillis-Coons Draft Legislation

Diagnostic testing patentability has once again entered public debate, this time in Congress rather than the courts. In the summer of 2019, Senators Thom Tillis (R-N.C.) and Chris Coons (D-Del.) proposed draft legislation to modify existing patent law, rendering many diagnostic tests patentable.[35] The proposal no longer considers 'abstract ideas,' 'laws of nature,' or 'natural phenomena' to be exceptions to patent eligibility, explicitly overturning the three Supreme Court decisions.[36] Under the proposal, courts would no longer be able to invalidate patents because they cover underlying biological relationships—precisely the stuff of diagnostic tests.[37]

The desire to incentivize diagnostic test development through exclusivity rights granted by patents drives the biotech industry's support of the bill.[38] While single gene patents are unlikely to reemerge due to the critical patent requirement of novelty—the human genome has been sequenced many times over, so genes are unlikely to be patentably 'new'—patenting in other areas of molecular diagnostics (e.g., polygenic risk scoring or autoantibody detection) remains a concern.[39]

Although the pandemic has sidelined unrelated legislative efforts, there remains interest in revising patent law. If the Tillis-Coons bill passes, we may see a return to the pre-Mayo era in which certain diagnostic tests existed as patent-protected monopolies, making it hard to verify quality or to obtain confirmatory tests.[40] Outside the pandemic's recent horrifying exemplar, confirmatory tests have been stymied by patent-

34 *Id.*; Stuart P. Meyer, *supra* note 19; Rebecca S. Eisenberg, *Diagnostics Need Not Apply*, 21 B.U. J. Sci. & Tech. L. 256 (2015).

35 Michael Borella, *Senators Tillis and Coons Release Statement on Recent Patent Reform Hearings*, Patent Docs, https://www.patentdocs.org/2019/06/senators-tillis-and-coons-release-statement-on-recent-patent-reform-hearings.html/ (accessed June 26, 2019).

36 *Id.*

37 Stuart P. Meyer, *supra* note 19.

38 'The State of Patent Eligibility in America: Part III': Hearings before the Subcomm. On Intellectual Prop. of the S. Comm. on the Judiciary, 116th Cong. 1–16 (2019) (written statement of Laurie Hill, Ph.D., J.D., Vice President, Intellectual Property, Genentech, Inc.).

39 Mateo Aboy et al., *How does emerging patent case law in the US and Europe affect precision medicine?*, 37 Nature Biotechnology 1118 (2019).

40 Overturning the Supreme Court's unanimous rulings via the Tillis-Coons bill could introduce further uncertainty for diagnostic protection; many of which were previously protected by broadly worded method patents that are now invalidated. *See* Huys et al., *Legal uncertainty in the area of genetic diagnostic testing*, 27 Nature Biotechnology 903 (2009) (surveying the legal landscape for 22 common genetic diagnostic tests, finding that most are protected by methods claims rather than strict gene patents). Passage of the Tillis-Coons bill may also necessitate the complementary policy action in the form of research, second opinion, and verification testing infringement liability exemptions, as suggested by a pre-*Mayo* 2010 SACGHS report on patents impacting access to genetic tests. *See* Secretary's Advisory Committee on Genetics, Health, and Society (SACGHS), *Gene Patents and Licensing Practices and Their Impact on Patient Access to Genetic Tests*, https://osp.od.nih.gov/wp-content/uploads/2013/11/SACGHS_patents_report_2010.pdf (accessed Apr. 2010). The monopoly concerns that precipitated this report could once again be an issue if the Tillis-Coons bill passes.

based single-sourcing in the past. For instance, until 2009, PGxHealth was the sole provider of genetic testing services for Long QT Syndrome.[41] Independent assessment by clinicians suggested discrepancies in test accuracy and quality.[42] A competing diagnostic test could have allowed clinicians to discover these shortcomings and further validate false negatives.[43] Good clinical practice also requires the availability of multiple diagnostic test options, including ideally by alternate test providers, as physicians frequently rely on second opinions to choose the best care for their patients. Previous studies exploring the practice of second opinions in diagnostics have suggested that the ability to verify the results of an initial diagnosis may lead to a change in diagnosis or treatment.[44] Before the Supreme Court intervened, Myriad's exclusivity for BRCA1/2 genetic variant testing prevented precisely this ability.[45]

The Tillis-Coons bill relies on patents to provide an incentive in the form of market exclusivity, but exclusivity is especially problematic for diagnostic tests. (There are other problems with relying on patents to drive biomedical innovation, especially in relation to equity, but we do not focus on those challenges here).[46] Though patent holders may not always exercise their monopoly rights, the danger lies in their potential to do so.

C. A More Effective Incentive System—Novel Diagnostics Reimbursement Model

Instead, we should create incentives for diagnostic test development by leveraging non-patent policy levers. A more effective incentive system would allow an increased number of players in the market, all vying to be the most accurate and cost-effective test for each indication. Such a system would promote diagnostic creation and implementation that mirrors actual physician usage.

Increasing reimbursement rates to reflect the expected value of diagnostic tests could help. Public and private insurance providers use the Current Procedural Terminology (CPT) system to determine the level of reimbursement warranted by new diagnostics.[47] The CPT system, in which diagnostics are often treated as commodities, is based on cost and procedure instead of the diagnostic's value.[48] To incentivize diagnostic development without creating monopolies, health insurance reimbursement strategies should be updated to provide a monetary reward for the potentially substantial cost-savings and health improvements of diagnostics.

For administrative simplicity, the CPT shoehorns new tests into established reimbursement categories ('codes') that have established prices, generally evaluating new

41 Misha Angrist et al., *Impact of gene patents and licensing practices on access to genetic testing for long QT syndrome*, 12 Genetics in Med S111 (2010).

42 Cook-Deegan & Niehaus, *supra* note 34; Angrist et al., *supra* note 43.

43 Angrist et al., *supra* note 43; Cook-Deegan & Niehaus, *supra* note 34.

44 Dana Ruetters et al., *Is there evidence for a better health care for cancer patients after a second opinion? A systematic review*, 142 J. Cancer Res. Clinical Oncology 1521 (2016).

45 John Liddicoat, Kathleen Liddell & Mateo Aboy, *The Effects of Myriad and Mayo on Molecular Test Development in the US and Europe: Interviews from the Frontline*, 22 Vand. J. Entm't & Tech. L. (forthcoming 2020).

46 Amy Kapczynski, *The Cost of Price: Why and How to Get Beyond Intellectual Property Internalism*, 59 UCLA L. Rev. 970 (2012).

47 Genomic and Personalized Medicine 451–452 (Geoffrey S. Ginsburg & Huntington F. Willard eds., 2nd ed. 2013).

48 *Id.*

diagnostics only in comparison to existing diagnostics.[49] New tests that found analogous to old tests may be 'cross-walked' to the old test's price, even if the new test is far more effective—and provides much more value.[50] In December of 2019, 70 per cent of new diagnostics were cross-walked.[51] Completely novel tests with no adequate comparison may require new pricing determinations that can take years to implement.[52] Thus, new diagnostics face relatively cheap prices that may not offset research and development costs, decreasing incentives to create new tests. In an attempt to promote value-based pricing, some diagnostic test manufacturers have opted for a 'miscellaneous' CPT code.[53] Such coding requires an assignment of value from each payer, which effectively bypasses traditional cost-based pricing but represents a logistical nightmare that dissuades most manufacturers.

Effective diagnostic tests, however, can shift healthcare spending from therapeutic to preventative care, promote precision medicines responding specifically to a patient's disease state, lower physician trial and error, and reduce hospital stays[54]—all of which reduce health-care system costs and improve patient care. Shifting to a reimbursement model that recognizes these substantial savings could properly incentivize diagnostic tests' true value.

CMS has recently acquired a new set of tools that may facilitate a leadership role in reimbursement model changes. The Clinical Laboratory Fee Schedule underwent a major overhaul as part of the Protecting Access to Medicare Act of 2014 (PAMA). Though the system had not been updated in three decades, many cumbersome but necessary changes, such as a national fee schedule and private market data collection, were implemented in order to save Medicare nearly $4 billion over 10 years.[55] While there are likely to be bureaucratic challenges to implementing value-based reimbursement for diagnostics via CMS, some of the provisions of the new PAMA Fee Schedule, such as the shift to national pricing, could ease simpler regulatory updates rather than a complete overhaul of the Fee Schedule and thus make change easier.

To be sure, some diagnostics will recommend more expensive care; getting the incentives right across the board will be complicated, but reimbursement is a better and more nuanced tool than bringing back broad patent exclusivity.[56] We recognize that reimbursement will not create a complete incentive regime and may need supplementing with grants or prizes.[57] And in some instances, patents will still be present, especially

49 *Id.*

50 *Id.*

51 *2019 ICD-10 Procedure Coding System*, https://www.cms.gov/Medicare/Coding/ICD10/2019-ICD-10-PCS (follow '2019 ICD-10-PCS Conversion Table (ZIP)' hyperlink; then select 'icd10pcs_conversion_table.xlsx' file) (last visited Apr. 9, 2020) (listing new and cross-walked CPT codes).

52 Genomic and Personalized Medicine, *supra* note 49.

53 *Id.*

54 *Id.* at 337.

55 Suzanne Murrin, Office of the Inspector General Health and Human Services, *HHS OIG Data Brief Medicare Payments for Clincial Diagnostic Laboratory Test in 2015: Year 2 of Baseline Data*, 2, https://oig.hhs.gov/oei/reports/oei-09-16-00040.pdf (accessed Sept. 2016).

56 *See*, e.g., Rachel E. Sachs, *Prizing Insurance: Prescription Drug Insurance as Innovation Incentive*, 30 Harv. J.L. & Tech. 153 (2016).

57 *See*, e.g., Lisa Larrimore Ouellette, *Patentable Subject Matter and Non-Patent Innovation Incentives*, 5 U.C. Irvine L. Rev. 1115 (2015).

for more technically complex diagnostics.[58] But as a general level, reimbursement policy reform shows substantial potential for creating incentives without relying on single-sourcing.

IV. CONCLUSION

SARS-CoV-2 did not create new problems in biomedical innovation; instead, it dramatically exposed underlying issues, including in the development and deployment of diagnostic tests. In particular, single-sourcing, whether through regulatory restrictions or patent quasi-monopolies, may seem like an attractive way to centralize control and to create incentives. But for diagnostic tests which rely on confirmatory testing, innovative improvements, and robust access to supply, single-sourcing creates a host of serious problems. Creating the right incentives demands careful attention to these problems and ideally structuring a regime that avoids them. Reimbursement, especially structured through public involvement, provides a promising option for such a regime. Both to avoid future pandemic-related disasters and to improve the normal practice of medicine, it is worth rethinking how we drive and shape the development of diagnostic tests.

ACKNOWLEDGEMENTS

We thank Rebecca Eisenberg for helpful comments on an earlier draft.

FUNDING

W.N.P. was supported by a grant from the Collaborative Research Program for Biomedical Innovation Law, a scientifically independent collaborative research program supported by a Novo Nordisk Foundation grant (NNF17SA0027784).

58 We acknowledge the existence of the rare cases in which early patent protection may be necessary to secure enough resources for development, most famously theorized by Edmund W. Kitch in *The Nature and Function of the Patent System*, 20 J.L. & Econ 265, (1977) (discussing the 'prospect theory' of patents). The judicious use of grants and prizes may minimize the number of such cases.