

# United States of America Federal Trade Commission

Health Care, Technology, and Health Care Technology: Promoting Competition and Protecting Innovation

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### I. Introduction

Good evening. Thank you to Erika Amarante and Bob Langer for inviting me to participate in this event. I am delighted to speak to you today about the Federal Trade Commission's recent efforts to protect competition and consumer welfare in two overlapping sectors of the U.S. economy: the health care sector and the technology sector. Each of these sectors represents a significant portion of the U.S. economy. Together, they comprise many key areas of innovation and change in private commerce, as well as central areas of concern for policy makers. I want to talk about some of the work that my agency has done in these two areas, as well as some issues where they intersect in health information technology and telemedicine.

As you know, the U.S. health care sector is undergoing a non-trivial amount of change

<sup>&</sup>lt;sup>1</sup> The views expressed in these remarks are my own and do not necessarily reflect the views of the Commission or any other Commissioner. I would like to thank Daniel J. Gilman for his assistance in preparing this speech.

with the passage of the Patient Protection and Affordable Care Act, which reaches far beyond the hotly discussed topics of the health care exchanges and the web site. Partly due to the Affordable Care Act, the health care sector has seen a significant amount of consolidation — among hospital systems and among physician groups, as well as combinations of hospitals and physician groups. On the tech side, under the American Recovery and Reinvestment Act of 2009, the Centers for Medicare and Medicaid Services (CMS) has already spent more than \$19 billion on electronic health records, or "e-HRs," including incentive payments to encourage health care providers and professionals to implement e-HR systems. As they say in Washington, a billion here, a billion there. But, it is not just real money at issue. It is spending and regulation that affects the shape of tech markets and health care practice, affects the integration of health care providers and health care information, and implicates standard-setting, payment, privacy, data security, and many other issues in the health and health-tech sectors.

Because of the importance of health care competition to the economy and consumer welfare, anticompetitive conduct and regulation in health care markets has long been a key focus of FTC law enforcement, research, and advocacy. The FTC has investigated and litigated antitrust cases in markets across the country involving hospitals, physicians, pharmaceuticals, and other health care goods and services. We regularly issue informal advisory opinions on the

<sup>&</sup>lt;sup>2</sup> Pub. L. No. 111-148, 124 Stat. 119 (2010), *amended by* Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152, 124 Stat. 1029 (2010).

<sup>&</sup>lt;sup>3</sup> Pub. L. No. 111-5, 123 Stat. 115 (2009).

<sup>&</sup>lt;sup>4</sup> See Ctrs. for Medicare and Medicaid Servs., HER Incentive Programs: the Latest Monthly Payment and Registration Summary Report (Dec. 2013), available at <a href="http://www.cms.gov/Regulations-and-guidance/Legislation/EHRIncentivePrograms/Downloads/December2013">http://www.cms.gov/Regulations-and-guidance/Legislation/EHRIncentivePrograms/Downloads/December2013</a> SummaryReport.pdf.

<sup>&</sup>lt;sup>5</sup> See, e.g., FED. TRADE COMM'N STAFF, OVERVIEW OF FTC ANTITRUST ACTIONS IN HEALTH CARE SERVICES AND PRODUCTS (2013), available at <a href="http://www.ftc.gov/bc/healthcare/antitrust/hcupdate.pdf">http://www.ftc.gov/bc/healthcare/antitrust/hcupdate.pdf</a>; FED. TRADE COMM'N STAFF, OVERVIEW OF FTC ANTITRUST ACTIONS IN PHARMACEUTICAL SERVICES AND PRODUCTS (2013), available at <a href="http://www.ftc.gov/bc/healthcare/antitrust/rxupdate.pdf">http://www.ftc.gov/bc/healthcare/antitrust/rxupdate.pdf</a>.

application of the antitrust laws to health care markets.<sup>6</sup> In addition, we have conducted hearings, undertaken research, and issued reports and policy statements on various issues in health care competition, often in conjunction with the U.S. Department of Justice (DOJ).<sup>7</sup>

The hearings, research, reports, and other competition policy efforts represent a distinctive part of the FTC's statutory mission under the FTC Act and are a crucial complement to our law enforcement mission. Next month, we are conducting a two-day workshop — scheduled for March 20 and 21 and open to the public — to examine a range of health care competition issues, including ones raised by the regulation of health care professionals, innovations in health care delivery, advances in health care technology, the measurement of health care quality, and price transparency. I would encourage you to attend this workshop, if you can.

These types of research and education projects play an especially important role in dynamic industries, where it is important for the Commission to be apprised of facts on the ground in a changing landscape and to spot competition and consumer protection issues as they arise – and not just in hindsight. In those quickly evolving industries, we should always be mindful of both the fact that the ground may be shifting and the fact that we want it to do exactly that. We want a law enforcement and regulatory environment that protects consumers against

<sup>&</sup>lt;sup>6</sup> Information regarding the Commission's competition advisory opinion program is available at http://www.ftc.gov/bc/advisory.shtm.

<sup>&</sup>lt;sup>7</sup> See, e.g., Fed. Trade Comm'n & U.S. Dep't of Justice, Statements of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program (2011), available at <a href="http://www.ftc.gov/opp/aco/">http://www.ftc.gov/opp/aco/</a>; Fed. Trade Comm'n & U.S. Dep't of Justice, Improving Health Care: A Dose of Competition (2004), available at <a href="http://www.ftc.gov/reports/healthcare/040723healthcarerpt.pdf">http://www.ftc.gov/reports/healthcare/040723healthcarerpt.pdf</a>; U.S. Dep't of Justice & Fed. Trade Comm'n, Statements of Enforcement Policy In Health Care (1996), available at <a href="http://www.justice.gov/atr/public/guidelines/1791.htm">http://www.justice.gov/atr/public/guidelines/1791.htm</a>.

<sup>&</sup>lt;sup>8</sup> Information regarding the workshop is available at <a href="http://www.ftc.gov/news-events/events-calendar/2014/03/examining-health-care-competition">http://www.ftc.gov/news-events/events-calendar/2014/03/examining-health-care-competition</a>.

substantial market failure and fraud, but we also want an environment that permits and even fosters innovation.

It is not surprising, then, that the FTC has pursued these types of policy development efforts in the tech sector as well as the health care sector. Last November, the FTC held a workshop on "the Internet of Things" – that is, all sorts of sensors and other types of telemetry embedded in physical objects, from watches to cars to medical devices, which are linked through wired and wireless networks using the Internet. We held the workshop to get a better sense of this emerging space and a better understanding of how to achieve its benefits while reducing risks to consumers' privacy. As someone who has focused on technology policy, I am inspired by the transformative potential of the Internet of Things, but I am also sensitive to the fact that the ability to collect large amounts of information and, in some cases, to act on that information also raises important consumer privacy and data security issues.

Our research in the tech sector continues, as we recently announced a proposal to gather information on patent assertion entities, or PAEs, and other types of entities asserting patents in the wireless communications sector. <sup>10</sup> These entities are also affectionately, or not so affectionately, referred to as patent trolls by some people. Using our authority under Section 6(b) of the FTC Act, <sup>11</sup> which allows us to obtain information under compulsory process from market participants and pursue a study of a particular competition (or consumer protection) issue, the FTC will study the impact of patent assertion entity activity on competition and innovation,

<sup>&</sup>lt;sup>9</sup> Information regarding this workshop is available at <a href="http://www.ftc.gov/news-events/events-calendar/2013/11/internet-things-privacy-and-security-connected-world">http://www.ftc.gov/news-events/events-calendar/2013/11/internet-things-privacy-and-security-connected-world</a>.

<sup>&</sup>lt;sup>10</sup> See Press Release, Fed. Trade Comm'n, FTC Seeks to Examine Patent Assertion Entities and Their Impact on Innovation, Competition (Sept. 27, 2013), available at <a href="http://www.ftc.gov/opa/2013/09/paestudy.shtm">http://www.ftc.gov/opa/2013/09/paestudy.shtm</a>.

<sup>&</sup>lt;sup>11</sup> 15 U.S.C. § 46(b).

hopefully providing us with a better understanding of the activity of PAEs and its various costs and benefits.

In the rest of this speech, I would like to focus on recent competition advocacy efforts pursued by the FTC in the health care area, as well as some competition and regulatory policy issues that the FTC and other policy makers will have to confront with the emergence of telemedicine.

### II. Important Role of Competition Advocacy

Advocating for competition is an important part of the FTC's mission. Broadly speaking, competition advocacy at the FTC involves the use of our expertise in competition and economics to persuade other government actors to pursue policies that promote competition and consumer welfare. This advocacy takes a number of forms, including providing testimony or comments on proposed federal and state legislation and regulations, advising other federal agencies on competition issues, filing amicus briefs in federal and state courts, and advocating for competition principles in public fora. Sometimes, this advocacy is conducted in *support* of a particular law or regulation that would benefit competition and consumers. All too often, however, advocacy addresses proposed laws or regulations that would limit choices and make consumers worse off – by, for example, restricting certain business practices or prohibiting some business models altogether, or even seeking to immunize certain anticompetitive conduct from the federal antitrust laws. Even if well-intentioned, these government-imposed restraints can inflict as much, if not more, harm on consumers than private anticompetitive conduct. And, as statutes or regulations enacted by the government, these restraints are, of course, more durable than any private conduct could be.

Not surprisingly, a significant portion of the FTC's competition advocacy work is focused on the health care sector. Over the past decade, we have targeted, among other things, (1) proposed antitrust immunity for certain health care providers to bargain collectively with health insurers, (2) scope of practice regulations, and (3) restrictions on retail clinics. I will discuss these in turn.

### A. Proposals for Antitrust Immunity

First, and particularly troublesome as far as I am concerned, are federal and state legislative proposals to create antitrust exemptions for collective negotiations by otherwise competing health care providers. The FTC has long advocated against such exemptions for the simple reason that they tend to raise prices and harm consumers. A recent letter issued by FTC staff addressed just such a proposed exemption in the state of Connecticut. Is should point out that the FTC staff did this analysis – as is our practice – at the request of state policy makers. This particular letter also enjoyed the support of the Connecticut Attorney General's office, with AG George Jepson having voiced concerns similar to ours in independent testimony before the state legislature.

The Connecticut bill provided for the formation of so-called health care collaboratives comprising otherwise independent health care practitioners, such as physicians. It would have authorized these collaboratives to jointly negotiate prices and other terms with health plans, requiring the health plans to deal with the collaboratives only under particular terms and under the threat of substantial financial penalties, but not vice versa. It also attempted to immunize these joint negotiations from scrutiny under the antitrust laws.

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<sup>&</sup>lt;sup>12</sup> See Letter from Fed. Trade Comm'n Staff to Conn. Gen. Assemb. Labor & Pub. Emps. Comm. regarding Conn. H.B. 6431 (June 4, 2013), available at <a href="http://www.ftc.gov/os/2013/06/130605conncoopcomment.pdf">http://www.ftc.gov/os/2013/06/130605conncoopcomment.pdf</a>.

As the FTC staff recognized in their advocacy letter, collaborations among physicians and other health care professionals can benefit consumers. At the same time, the letter made three primary arguments against the bill. First, the antitrust laws are *not* a barrier to the formation of efficient health care collaborations that benefit consumers. As explained in guidance issued by the FTC and the Justice Department, competitor collaborations – including health care provider collaborations – often are entirely consistent with the antitrust laws. <sup>13</sup> That is, the antitrust laws do not stand in the way of health care providers who form collaborative arrangements that are likely to reduce costs and benefit consumers through increased efficiency and improved coordination of care. We have also produced detailed advisory opinion letters on specific integration proposals by various types of providers.<sup>14</sup> In addition, the FTC and DOJ have provided joint guidance concerning both Medicare and commercial accountable care organizations (ACOs) to ensure that the prospect of antitrust liability would not impede the formation of beneficial ACOs. 15 In fact, the FTC/DOJ policy statement on ACOs established a process for newly formed ACOs to seek an expedited agency review if they are concerned about potential antitrust exposure. 16

Second, the Connecticut advocacy letter observed that a central purpose of the proposed legislation appeared to be to permit physicians to extract higher reimbursement rates from health plans through joint negotiations, not to integrate their practices to reduce costs or better coordinate care for their patients.

<sup>&</sup>lt;sup>13</sup> See generally Fed. Trade Comm'n & U.S. Dep't of Justice, Antitrust Guidelines for Collaborations among Competitors (2000), available at <a href="http://www.ftc.gov/os/2000/04/ftcdojguidelines.pdf">http://www.ftc.gov/os/2000/04/ftcdojguidelines.pdf</a>.

<sup>&</sup>lt;sup>14</sup> See supra note 6.

<sup>&</sup>lt;sup>15</sup> See Fed. Trade Comm'n & U.S. Dep't of Justice, Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program, 76 Fed. Reg. 67,026 (Oct. 28, 2011); see also generally Susan S. DeSanti, ACO Antitrust Guidelines: Coordination Among Federal Agencies, Antitrust Source 1, Dec. 2011.

<sup>&</sup>lt;sup>16</sup> See FTC/DOJ ACO Policy Statement, supra note 15, at 67,030-31.

Third, because procompetitive health care collaborations already are permissible under the antitrust laws, the bill's main effect would be to foster precisely those types of collective negotiations that would *not* generate efficiencies and therefore would *not* pass muster under the antitrust laws. The joint negotiations contemplated by the bill were likely to lead to increased health care costs and decreased access to services for consumers. Given the substantial risk that the bill would encourage the formation of inefficient and anticompetitive collaborations among providers, FTC staff urged Connecticut legislators not to attempt to shield them from the antitrust laws. Thus far, at least, they have not done so.

Looking beyond the proposed Connecticut bill, health care providers repeatedly have sought antitrust immunity for various forms of joint conduct, including agreements on the prices they will accept from health insurers and other payers, asserting that immunity for joint bargaining is necessary to "level the playing field" so that providers can create and exercise countervailing market power. Our response has come down to the following point: reducing competition on one side of a market (that is, physicians or other providers) is not the answer to a perceived lack of competition on the other side of that market (that is, insurers and other third-party payers). If we start to prop up certain parts of the playing field, we will likely find that our landscaping abilities have their limits. More than that, we need to worry that consumers might find themselves in an ever-deepening pit in the middle, as other stakeholder positions get one boost after another. The U.S. antitrust agencies have consistently opposed these exemptions because they are likely to harm consumers by increasing costs without improving quality of care, and I expect that we will continue to oppose these attempts to authorize departures from competition.

# **B.** Scope of Practice Regulations

A second area of focus for our competition advocacy has been scope of practice regulations, which often seek to limit competition from newer providers that are able to supply comparable (or even superior) services – often at lower cost. In many states, there has been an interest in allowing basic medical services to be provided, not just by physicians, but by advanced practice registered nurses, or APRNs, who are nurses with graduate nursing degrees in addition to undergraduate nursing education and practice experience. APRNs include both general nurse practitioners and specialists, such as nurse-midwives or certified registered nurse anesthetists. This expanded licensing of APRNs could have increase affordable access to quality care in rural and poorer areas of the country – that is, where there are fewer physicians. The FTC's Office of Policy Planning – which I had the honor of heading from 2004 to 2008 – has been actively advocating to state legislatures to loosen the restrictions on APRNs to allow them to provide certain treatments and to prescribe certain medications, subject, of course, to responsible measures to control for quality and safety. <sup>17</sup> In short, our advocacies have suggested that any limits on APRNs' ability to provide medical services should be no stricter than necessary to protect patient safety. Interestingly, our competition analyses on these restrictions is closely aligned with the health policy analysis of the Institute of Medicine, which concluded

<sup>&</sup>lt;sup>17</sup> See, e.g., Letter from Fed. Trade Comm'n Staff to the Hon. Kay Khan, Mass. H.R., Concerning the Likely Competitive Impact of H.B. 2009 (Jan. 17, 2014), available at <a href="http://www.ftc.gov/policy/policy-actions/advocacy-filings/2014/01/ftc-staff-comment-massachusetts-house-representatives">http://www.ftc.gov/policy/policy-actions/advocacy-filings/2014/01/ftc-staff-comment-massachusetts-house-representatives</a>; Letter from Fed. Trade Comm'n Staff to the Hon. Theresa W. Conroy, Conn. H.R., Concerning the Likely Competitive Impact of Conn. H.B. 6391 on Advanced Practice Registered Nurses (Mar. 19, 2013), available at <a href="http://www.ftc.gov/os/2013/03/130319aprnconroy.pdf">http://www.ftc.gov/os/2013/03/130319aprnconroy.pdf</a>; Testimony of Fed. Trade Comm'n Staff before Subcommittee A of the Joint Comm. on Health of the State of W. Va. Legis. on the Review of W. Va. Laws Governing the Scope of Practice for Advanced Practice Registered Nurses and Consideration of Possible Revisions to Remove Practice Restrictions (Sept. 10, 2012), available at <a href="http://www.ftc.gov/os/2012/09/120907wvatestimony.pdf">http://www.ftc.gov/os/2012/09/120907wvatestimony.pdf</a>.

that "[r]estrictions on scope of practice . . . have undermined the nursing profession's ability to provide and improve both general and advanced care." <sup>18</sup>

#### C. Limited Service Clinics

A third, related, set of advocacies have addressed so-called retail clinics or limited service clinics – the types of small, limited, primary care service clinics you have probably seen at some chain drug stores, supermarkets, or malls. Retail clinics tend to be staffed by APRNs, and they offer consumers a convenient way to obtain basic medical care at transparent and competitive prices. <sup>19</sup> Evidence indicates that retail clinic care, although limited in scope, tends to be of high quality. <sup>20</sup> That may be partly due to the fact that APRNs generally get high marks for quality of care and, in retail clinics, only provide a very basic and limited set of the health care services that they are trained to provide. It may be partly due, as well, to their use of electronic health records, electronic prescribing, and up-to-date practice guidelines, as well as remote oversight and consultation – basic forms of telehealth that can deliver expertise where and when it is needed, but may run afoul of particular state supervision requirements for APRNs. I will return to the subject of telehealth shortly.

One of the major competition issues with retail clinics has been separating bona fide attempts to provide basic health and safety quality assurances from attempts to suppress innovative models of health care delivery. For example, in 2007, we reviewed proposed clinic rules next door, in Massachusetts. In that case, the Department of Public Health seemed to

<sup>18</sup> Inst. of Med., The Future of Nursing: Leading Change, Advancing Health 4 (2011), available at <a href="http://www.thefutureofnursing.org/sites/default/files/Future%20of%20Nursing%20Report\_0.pdf">http://www.thefutureofnursing.org/sites/default/files/Future%20of%20Nursing%20Report\_0.pdf</a>.

<sup>&</sup>lt;sup>19</sup> See, e.g., William M. Sage, Might the Fact that 90% of Americans Live Within 15 Miles of a Wal-Mart Help Achieve Universal Health Care?, 55 U. KAN. L. REV. 1233, 1238 (2008) (describing the size and scope of retail clinics).

<sup>&</sup>lt;sup>20</sup> See, e.g., Ateev Mehrotra et al., Comparing Costs and Quality of Care at Retail Clinics with That of Other Medical Settings for 3 Common Illnesses, 151 ANNALS OF INTERNAL MED. 321, 325-6 (2009) (explaining that evidence shows that the quality of care in limited service clinics is "similar to that provided in physician offices and urgent care centers and slightly superior to that of emergency departments").

recognize the pro-competitive and pro-consumer potential of the clinics. Most of the proposed rule seemed to try to make room for the clinics within the larger body of the state's health care clinic regulations. FTC staff generally did not find concerns with much of what was proposed in Massachusetts. Certain stakeholders had, however, lobbied for very restrictive pre-screening requirements for all clinic advertising – including things like changes to web site listings of hours of operation and the availability of flu shots – that were not imposed on other types of health care facilities and seemed potentially very burdensome for operators of small, low-cost, flexible clinics. I am glad to report that the Department of Public Health took our economic and legal concerns seriously and eliminated the troubling provisions from its final rule. You can find retail clinics operating across Massachusetts today or, closer to home, here in Connecticut. Whether these clinics offer what you or your family need or want is for you to say, not for competitor-crafted regulations.

To be clear, trying to formulate some sort of competitively ideal clinic regulations has never been our concern, and we are in no position to value a state's own health and safety priorities. We have been concerned, however, where heightened restrictions seem to be aimed at particular businesses or business models, rather than particular and well-founded consumer risks, both because the restrictions might discriminate against an innovative model of delivery and because they can work as *de facto* scope of practice restrictions on those professionals employed under the model. For example, proposed Kentucky rules would have allowed an APRN practicing at a retail clinic to provide physical exams for sports or camp, but not for school. The

<sup>&</sup>lt;sup>21</sup> See Letter from Fed. Trade Comm'n Staff to Mass. Dept. of Public Health Concerning Proposed Regulation of Limited Service Clinics (Sept. 27, 2007), available at <a href="http://www.ftc.gov/policy/policy-actions/advocacy-filings/2007/10/ftc-staff-comment-massachusetts-department-public">http://www.ftc.gov/policy/policy-actions/advocacy-filings/2007/10/ftc-staff-comment-massachusetts-department-public</a>.

same practitioner could provide a school physical at comparable clinics, however.<sup>22</sup> Maybe there is a decent health and safety rationale for that distinction, but it is hard to imagine what it could be, and no such thing was ever entered into the record. A working parent who has a hard time scheduling that school physical and a harder time still doing it when he or she can get off work might really appreciate a low-cost, after-hours option with an APRN just down the road. If the clinic wants to offer that service from a qualified, licensed health care professional, there ought to be a good reason why that is not allowed, and in my view protecting incumbent providers from new forms of competition does not count.

# III. Telemedicine: Policy Measures for the Future of Health Care

The last area that I would like to address is telemedicine, which is a developing and, for me, intriguing area at the intersection of health care and technology. The prefix "tele" comes from the Greek word meaning far, and the modern era has been shaped by technologies that put us in touch with others who are far away, such as the telegraph (far writing), the telephone (far hearing), the television (far seeing), and telemetry (far measuring). As revolutionary as these technologies have been on their own, they have the potential to offer great benefits in another "tele" field, telemedicine, which combines many of these capabilities to monitor, diagnose, and in some cases even treat patients who are in different locations than their doctors or other medical professionals, whether they are separated by a hospital floor, a state line, or even an ocean.

As a policy maker, I believe we also need to be far seeing and far reaching in our policies to allow the potential of telemedicine to become a reality for patients in the U.S. Although this will necessarily involve a wide array of government and private actors, as an FTC

<sup>&</sup>lt;sup>22</sup> See Letter from Fed. Trade Comm'n Staff to Ky. Cabinet for Health and Family Services Concerning Proposed Regulation of Limited Service Clinics, at 6 (Jan. 28, 2010), available at <a href="http://www.ftc.gov/policy/policy-actions/advocacy-filings/2010/01/ftc-staff-comment-kentucky-cabinet-health-and-family">http://www.ftc.gov/policy/policy-actions/advocacy-filings/2010/01/ftc-staff-comment-kentucky-cabinet-health-and-family</a>.

Commissioner, there are policies that I can encourage my agency to pursue to help facilitate the successful proliferation of telemedicine.

Telemedicine – sometimes called telehealth – might sound like science fiction, but it is important to keep in mind that many of its most interesting applications involve tried and true technologies, applied in novel ways. For example, Dr. Sanjiv Arora at the University of New Mexico struggled for years with Hepatitis C referrals from rural parts of the state, where patients faced real shortages of primary care doctors, not to mention specialists. As you might imagine, patients who are uninsured or underinsured or simply live in rural areas often have limited access to state-of-the-art specialty care. People with chronic diseases like Hepatitis C can sometimes travel to larger cities and seek access to tertiary care centers, but it is often difficult for them to do so – even once they have a correct diagnosis.

To deal with this problem, Dr. Arora did not establish a network of clinics staffed with multidisciplinary specialists across the far-flung regions of New Mexico. Instead, he established what is called the ECHO Program – the Extension for Community Health Outcomes. The ECHO program uses telehealth technology and best practices protocols to connect rural primary care practices with multi-disciplinary specialist resources at the University's academic medical center in Albuquerque. That connection enabled him to do two things: deliver expertise to primary care providers and patients far from his academic medical center and – maybe more radically – use that consultation and delivery of care to help train a far-flung network of primary care doctors with significant expertise in the diagnosis and treatment of Hepatitis C. No extra residency or board certification; no extra professional licensure; just heightened practice abilities that allow the doctors to better diagnose and treat this disease and to refer patients earlier, when

<sup>&</sup>lt;sup>23</sup> See Sanjeev Arora, et al., Expanding Access to Hepatitis C Virus Treatment—Extension for Community Healthcare Outcomes (ECHO) Project: Disruptive Innovation in Specialty Care, 52 HEPATOLOGY 1124 (2010).

referral is needed. The program has provided more than 57,000 hours of continuing medical education to more than 300 clinical care teams in 74 New Mexico communities.<sup>24</sup>

Due to its documented success – made easier with electronic records and remote monitoring – Project ECHO has expanded to deal with a number of other disease indications, including hypertension, diabetes care, chronic pain, and HIV care. ECHO centers have been established at the University of Chicago, the University of Washington, in Mumbai, India, and – closer to home – at the Community Health Center in Middletown, Connecticut.

I want to remark on a couple of additional features of the ECHO program. First, recalling our nursing competition advocacies, ECHO now employs and is expanding the use of APRNs to improve its network of primary care professionals in rural and underserved areas. In some states, this is simply harder to do than in others because of state-by-state regulatory differences, not differences in APRN training or quality of care.

Second, although Dr. Arora's ECHO program generally serves New Mexico patients, many newer implementations of the ECHO model work across state lines. Some states permit that and some do not. Telemedicine can reduce the costs and extend the reach of many health care services, but the advantages of remote and networked expertise do not always fit professional licensing schemes that were developed to regulate local medical practices — practices historically dominated by face-to-face encounters between a physician and her patient. What counts as telemedicine, telehealth, or "the practice of medicine," and when telemedicine requires a local state license, is generally a matter of state law and sometimes left to determinations of independent state boards. Link experts across three or four jurisdictions and things start to get pretty complicated and, for providers, unpredictable. Generally, the practice of

<sup>&</sup>lt;sup>24</sup> See Sanjeev Arora, et al., Demonopolizing Medical Knowledge, 89 ACADEMIC MED. 30, 32 (2014).

medicine without such licensure is prohibited and subject to criminal sanction by statute. The variation in requirements persists despite the fact that the core entry requirements for physicians are essentially uniform across the U.S.<sup>25</sup>

Some provider services have responded to the state regulatory patchwork by buying dozens of licenses for their practitioners – doable for some, but probably a barrier for many would-be entrants, and efficient for nobody. My point is not anti-licensure and it is not that we need some particular model of state or federal regulation. It is that we need to take seriously that our legacy statutes and regulations have, in addition to strengths, some serious competitive weaknesses. In particular, they can erect barriers to the efficient flow of health care information and expertise and, indeed, specialized labor – barriers that can be costly to public and private payers and, in the end, individual patients and barriers that do not always offer countervailing consumer protection benefits. As lawyers and policy makers, we need to think creatively about ways to lower these barriers without sacrificing what works in our regulations.

In what I view as a positive development, a bipartisan group of sixteen U.S. Senators recently commended state medical boards and the Federation of State Medical Boards (FSMB) for their efforts to streamline the licensing process for physicians who wish to practice in multiple states.<sup>26</sup> More specifically, the Senators applauded the boards' development of the Interstate Medical Licensure Compact (Compact), which would provide a new licensing option under which qualified physicians seeking to practice in multiple states would be eligible for

<sup>&</sup>lt;sup>25</sup> All state medical boards recognize and require passage of the same sequence of tests: the United States Medical Licensing Examination (USMLE), which is jointly administered by the Federation of State Medical Boards and the National Board of Medical Examiners. *See, e.g.*, Fed'n of State Med. Bds., State of the States: Physician Regulation 2009, at 3, 10-11 (2009).

<sup>&</sup>lt;sup>26</sup> See Fed'n of State Med. Bds., Press Release, State Medical Board Effort to Streamline Medical Licensing Gains Support in U.S. Senate (Jan. 14, 2014), available at <a href="http://www.fsmb.org/pdf/interstate\_compact\_senators\_january13C.pdf">http://www.fsmb.org/pdf/interstate\_compact\_senators\_january13C.pdf</a>. The letter from the U.S. Senators is available at <a href="http://www.thune.senate.gov/public/index.cfm?a=Files.Serve&File\_id=9fa6c905-ec33-4191-bd79-ad6991942dac">http://www.thune.senate.gov/public/index.cfm?a=Files.Serve&File\_id=9fa6c905-ec33-4191-bd79-ad6991942dac</a>.

expedited licensure in all states participating in the Compact, which would be voluntary, for both states and physicians. This Compact, while still in development, would appear to greatly facilitate the use of telemedicine while still allowing states to regulate medicine within their borders.<sup>27</sup>

Now, there are of course other applications of established technology beyond telemedicine. For example, how about electronic prescribing so that your pharmacy can read the prescription that your physician did not have to write out in script? And that you did not have to hand-deliver, or possibly lose before you get to the pharmacy? And perhaps automatically check for contraindications or other issues? This is well-established technology in most pharmacies, if in a smaller percentage of physician offices.

The application of established technology can be truly innovative and can pay great dividends, but we also want to pay attention to nascent technology. Remember the Internet of Things? For some reason, the most cited example of the potential benefit of the Internet of Things is that your refrigerator will note that you have run out of milk and it will email or text you to remind you to buy milk. Maybe milk is a more important part of some people's lives than it is of mine, but I am much more excited about the prospect that a wearable health device will detect an impending medical crisis and alert me or my doctor. Maybe that's just me, but consider this: recently, a story about Google – no, this is new and it does not concern an antitrust investigation – really caught my eye, so to speak. Google has been testing a means of monitoring blood glucose levels for diabetics, not through a pinprick, but through a contact

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<sup>&</sup>lt;sup>27</sup> There have been policy discussions of various options to lower barriers to interstate practice of telemedicine for some time. *See, e.g.*, Daniel J. Gilman, *Physician Licensure and Telemedicine: Some Competitive Issues Raised by the Prospect of Practicing Globally While Regulating Locally*, 14 J. HEALTH CARE L. & POL'Y 87, 117 (2011).

lens.<sup>28</sup> Monitor, record, and, ultimately, transmit. I don't know if that's the greatest thing since sliced bread or free search, but for me, if it works, it is much more exciting than a glass of milk.

We might have all sorts of questions about new devices like this: How well do they work? What will they cost? From a competition perspective, what, if any, barriers to entry are there in these types of industries? And, from a consumer protection standpoint, what are the provisions for the security of our personal health information? This is a particularly interesting area for me as an FTC Commissioner because it draws together several hot issues my agency has been addressing and will continue to address for the foreseeable future, including data security and mobile privacy in the consumer protection space, as well as competition issues such as net neutrality and broadband data prioritization.

On a more philosophical level, these developments also raise the question of what is the best approach for a government agency like the FTC to take with regard to technological and business innovation. The success of the Internet and the tech sector have in large part been driven by the freedom to experiment with different business models, the best of which have survived and thrived, even in the face of initial unfamiliarity and unease about the impact on consumers and competitors. If health care needs anything, it needs this type of innovation too. It is thus vital that policy makers, like myself, approach new technologies with a dose of regulatory humility, by working hard to educate ourselves and others about the innovation, understand its effects on consumers and the marketplace, identify benefits and likely harms, and, if harms do arise, consider whether existing laws and regulations are sufficient to address them before assuming that new rules are required.

<sup>&</sup>lt;sup>28</sup> See Google's Vision of Diabetes through a Contact Lens, PR Web (Feb. 21, 2014), available at <a href="http://uk.prweb.com/releases/contact-lenses/diabetes/prweb11604772.htm#ixzz2tzjaMdbt">http://uk.prweb.com/releases/contact-lenses/diabetes/prweb11604772.htm#ixzz2tzjaMdbt</a>.

For the FTC, I believe we can help ensure that the promise of innovations in health care technology, like telemedicine and the Internet of Things, is realized by using our unique set of policy and law enforcement tools. First and foremost, in a new technology or industry that is rapidly innovating, we should use our policy research and development function to get a better understanding of: the technology itself; the new business models it may enable; any existing regulatory structures, including any self-regulation; relevant market dynamics; and the nature and extent of likely consumer and competitive benefits and risks. We should also use our policy tools to educate other policy makers, as well as ourselves, about undue impediments to innovation and competition. Of course, the FTC is also an enforcement agency and it can and should use its traditional deception and unfairness authority to stop consumer harms that may arise from particular health information technology devices.

Finally, the FTC should use its flexible and fact-intensive approach to antitrust enforcement to investigate and, where appropriate, challenge competitive harms occurring in health care, technology, and even health care technology. There is much that we can do here, and we have a variety of tools with which to do it. To take a cue from the doctors, however: first, we should do no harm.

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Thank you very much for your attention. I would be happy to entertain any questions you may have.