



Federal Trade Commission

CLINICAL INTEGRATION: THE CHANGING POLICY CLIMATE AND WHAT IT MEANS FOR CARE COORDINATION

Remarks of
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* The views expressed herein are Commissioner Harbour's, and do not necessarily reflect the views of the Commission or any other individual Commissioner.

I. INTRODUCTION

Good morning, and thank you so much for inviting me to participate on this panel.

As noted during the introductions, I have become particularly interested in clinical integration issues over the last couple of years. In July 2007, my advisor and I actually took a field trip to Advocate Health Partners in suburban Chicago, an entity that is trying to implement clinical integration. We spent a whole day observing its operations – from the individual physician’s office, to the hospital, to the eICU, to the back-room analytical functions. I wanted to see what such an arrangement looks like in the real world, as opposed to just reading about it or being told about it.

I came back from that trip convinced that clinical integration, when done right, has tremendous potential to create efficiencies and improve health care quality. This is exactly the message the Federal Trade Commission has been sending for years, ever since we and the Department of Justice jointly issued the revised Health Care Statements in 1996.¹ It remains our message today.

But when I returned from Chicago, I was still an FTC Commissioner, and still a champion of the antitrust laws. In my role as an antitrust enforcer, I continue to believe that competition is just as beneficial in the health care industry as it is in other industries. And I have U.S. Supreme Court case law and other legal precedent on my side,² which fully supports my position that consumers benefit when competition and health care co-exist.

Provider networks attempting clinical integration are, in one important way, like networks that do no more than attempt to aggregate market power. They often involve competitors getting

¹U.S. Dep’t of Justice & Fed. Trade Comm’n, *Statements of Antitrust Enforcement Policy In Health Care* (1996) [hereinafter *Health Care Statements*], available at <http://www.ftc.gov/bc/healthcare/industryguide/policy/index.htm>.

²See *infra* Part II for a discussion of the relevant legal framework.

together to jointly set prices and negotiate with payors. This is precisely the kind of behavior that invites antitrust scrutiny in every other industry. Therefore, when faced with arrangements claiming to involve clinical integration, it makes sense for antitrust enforcers to view these arrangements with a healthy dose of skepticism, and to be vigilant in blocking those that are likely to lead to anticompetitive effects.

The Commission applies a careful legal analysis to purported clinical integration arrangements, on a case-by-case basis. In short, our job is to ensure that cognizable efficiencies are indeed likely to result; that any price-fixing agreements are reasonably related to achieving those efficiencies; and that the arrangement is not likely to create market power.

I intend to cover three main areas during my remarks.

- First, I will sketch out the legal framework that the Commission applies when analyzing current or proposed entities that rely on clinical integration to justify joint pricing.
- Second, I will do my best to put clinical integration into the larger context of health care reform, and to explain why antitrust will not be a barrier to reform efforts.
- And finally, I will talk a little bit about the need for more empirical research on the outcomes of clinical integration, to ensure that promises of efficiencies and quality improvements are being fulfilled.

II. LEGAL FRAMEWORK FOR ANTITRUST ANALYSIS OF PHYSICIAN JOINT PRICING ARRANGEMENTS

To begin, let me briefly review the legal framework for antitrust analysis of physician joint pricing arrangements – especially clinically integrated entities.

A. Maricopa: The Antitrust Laws Apply To The Health Care Industry

The analysis begins from the premise I mentioned a moment ago: the antitrust laws apply to the health care industry, including physicians. In its 1982 *Maricopa* decision,³ the U.S. Supreme Court condemned agreements among competing physicians regarding the fees they would charge health insurers for their services, holding that this constituted *per se* unlawful horizontal price fixing.⁴

The Court has never overruled *Maricopa*.⁵ Nor has the Court ever wavered from its position that physicians are capable of unlawful price-fixing under the antitrust laws, and that it is appropriate to use the antitrust laws to stop such conduct.

B. Polygram and NTSP: Consideration of Potential Efficiencies

In its 2005 *North Texas Specialty Physicians* (“NTSP”) administrative opinion,⁶ which challenged joint pricing by a group of independent competing physicians in Fort Worth, the Commission said it is important to “avoid interference” with innovative approaches to health care delivery that may increase quality and contain costs.⁷ Therefore, rather than attack NTSP’s price-fixing behavior as an outright *per se* violation under *Maricopa*, the Commission instead adopted the

³Arizona v. Maricopa County Medical Soc’y, 457 U.S. 332 (1982).

⁴*Id.* at 356-57.

⁵*See, e.g.*, North Texas Specialty Physicians v. Fed. Trade Comm’n, 528 F.3d 346, 360 (5th Cir. 2008) [hereinafter *NTSP v. F.T.C.*] (citing *Maricopa* favorably).

⁶In the Matter of North Texas Specialty Physicians, FTC Dkt. No. 9312, Opinion of the Commission (Nov. 2005), available at <http://www.ftc.gov/os/adjpro/d9312/051201opinion.pdf> [hereinafter NTSP Commission Opinion], *aff’d sub nom. NTSP v. F.T.C.*, 528 F.3d 346.

⁷NTSP Commission Opinion at 1.

more flexible “inherently suspect” methodology set forth in its *Polygram Holding*⁸ administrative opinion, which had been upheld by the D.C. Circuit earlier that year.⁹

Without going into too many details, the essence of the *Polygram* approach is that it allows for some consideration of defenses, especially efficiency justifications. But when conduct is inherently suspect – when it is the type of restraint that is generally presumed to harm competition, such as horizontal price fixing among competitors – the bar is set fairly high to put forth a plausible procompetitive justification that is worthy of consideration. If this hurdle is not overcome, then the conduct may be summarily condemned, even without a detailed analysis of market facts or competitive effects.

In *NTSP*, both the Administrative Law Judge and the Commission were able to delve deeply into the efficiencies question, based on evidence put forward by a renowned expert whom complaint counsel had retained to analyze and test NTSP’s efficiency justifications. The Commission ultimately found, and the Fifth Circuit agreed, that joint pricing by this group of independent competing physicians constituted horizontal price fixing that was not reasonably related to any procompetitive efficiencies. Therefore, said the court, the Commission had properly condemned

⁸In the matter of *Polygram Holding, Inc., et al.*, FTC Dkt. No. 9298, Opinion of the Commission (July 2003), available at <http://www.ftc.gov/os/2003/07/polygramopinion.pdf>, *aff’d sub. nom.* *Polygram Holding, Inc., et al. v. Fed. Trade Comm’n*, 416 F.3d 29 (D.C. Cir. 2005).

⁹*Polygram*, 416 F.3d 29.

the conduct under the inherently suspect framework, without the need for a full-blown market analysis.¹⁰

The *NTSP* opinions should be “required reading” for anyone contemplating an arrangement that would involve joint pricing among independent physicians, including a clinically integrated arrangement. If one cannot articulate efficiencies sufficient to overcome the threshold presumption of illegality that is central to the *NTSP* analysis, one will find it very difficult to justify any joint pricing.

C. Over The Inherently Suspect Hurdle: Efficiencies And Ancillarity

Going one step further in the analysis, let us assume we are looking at an entity that purports to be engaging in a high level of integration – either through more traditional financial integration, or through a clinical integration program that “create[s] a high degree of interdependence and cooperation among the physicians to control costs and ensure quality.”¹¹ Assuming the organization appears sufficiently integrated to clear the “inherently suspect” hurdle, the next step in the analysis is to more closely evaluate whether the integration is, indeed, likely to yield significant efficiencies. It is also critical to evaluate “ancillarity” – that is, whether any joint pricing has a close nexus to the procompetitive goals of the venture, and is reasonably necessary to achieve the efficiencies that

¹⁰The framework articulated by the Commission and adopted by the Fifth Circuit in *NTSP* was consistent with various forms of Commission guidance regarding joint physician pricing. See, e.g., *Health Care Statements*, *supra* note 1; Fed. Trade Comm’n & U.S. Dep’t of Justice, *Antitrust Guidelines for Collaborations Among Competitors* (April 2000) [hereinafter *Competitor Collaboration Guidelines*], available at <http://www.ftc.gov/os/2000/04/ftcdojguidelines.pdf>; Letter from David R. Pender, Acting Assistant Director, Bureau of Competition, Federal Trade Commission to Clifton E. Johnson & William H. Thompson, Hall, Render, Killian, Heath & Lyman (March 28, 2006) (staff advisory opinion concerning Suburban Health Organization, Inc.), available at <http://www.ftc.gov/os/2006/03/SuburbanHealthOrganizationStaffAdvisoryOpinion03282006.pdf>

¹¹*Health Care Statements*, *supra* note 1, at Statement 9.

would be made possible by the joint venture. Of course, the arrangement as a whole is still subject to a full rule of reason analysis to determine overall competitive effects.¹²

Most of the advisory opinions the Commission staff has issued in recent years regarding clinical integration have focused heavily on the efficiencies and ancillarity elements of the analysis – including the TriState advisory opinion, issued just a couple of weeks ago, which I will discuss in a few minutes.

D. Prosecutorial Discretion

Before I conclude this legal framework primer, I do want to make one comment about prosecutorial discretion. I would not want any of you to leave here today, thinking that the Commission pursues any and all physician price fixing cases, just because we would be likely to prevail under the inherently suspect framework.

Like most government agencies, our resources are severely constrained. Therefore, in pursuing potential enforcement actions, our approach has always been to focus on cases where there appears to be real harm to competition and consumers. Commission staff follows this same general approach for physician price fixing cases, even though we would not be required to prove such harm under *Polygram* and *NTSP*. In my experience, when we challenge a physician group for price fixing, it tends to be a very clear-cut violation, where we have looked closely at the market facts and determined that there are no redeeming efficiency justifications. *NTSP* itself is an excellent example

¹²The foregoing abbreviated summary of the legal analysis assumes that there is no market power issue – i.e., that combining the group of physicians is unlikely to create market power. Of course, the competitive effects analysis would proceed differently if the arrangement involved a large enough number of physicians (e.g., from a given geographic area, practice specialty, etc.), posing a risk that market power might be created by the arrangement.

of this enforcement philosophy, given that the ALJ, the Commission, and the Fifth Circuit all had an extremely detailed factual record on which to rely.

II. CLINICAL INTEGRATION IN THE CONTEXT OF HEALTH CARE REFORM

With that basic legal framework in place, I will turn to the policy portion of my remarks. Given the legal approach to antitrust analysis of joint pricing arrangements by physicians, what will happen with clinical integration as the new Administration seeks to implement comprehensive health care reform measures?

This audience lives and breathes health care issues every day, and knows far more about health policy than I do, so I certainly will not attempt to analyze all of the details of the Obama Administration's likely reform proposals. But in order to provide some context, I do want to review a few core principles that appear to be driving the Administration's reform efforts, so that we can understand how they relate to clinical integration.

A. Obama Health Care Reform Principles

In preparing for this talk, I looked to a few sources of basic information about health care reform in the new Administration. For example, I reviewed the original Obama/Biden health plan from the campaign,¹³ as well as the eight principles outlined in the budget President Obama submitted to Congress in February of this year.¹⁴

¹³Organizing for America, *Barack Obama and Joe Biden's Plan to Lower Health Care Costs and Ensure Affordable, Accessible Health Coverage For All* [hereinafter *Obama Health Care Plan*], at <http://www.barackobama.com/pdf/issues/HealthCareFullPlan.pdf>.

¹⁴Office of Mgmt. & Budget, *A New Era of Responsibility: Renewing America's Promise* (Feb. 26, 2009), at 27-28, available at http://www.whitehouse.gov/omb/assets/fy2010_new_era/a_new_era_of_responsibility2.pdf.

I was able to discern a few themes that are relevant to any discussion of clinical integration.

1. The Importance of Competition

First and foremost, the Obama Administration has emphasized that competition is, and will continue to be, an important element of the American health care system. The Administration supports a combination of government mandates and market-based approaches, but has made clear that competition is central to the Administration's reform proposals.¹⁵ For those of us in the antitrust community – and especially those of us who think the Fifth Circuit got it right in *NTSP* – this is welcome news. As best as I can tell, the Administration does not intend for health care reform to supplant or conflict with either the antitrust laws or competition policy.

2. Improving Quality and Efficiency

Next, the Administration's plan strongly emphasizes improving the quality of health care delivery. Quality can be defined in different ways. Expanded access to care, broader insurance coverage, and implementation of better patient safety measures all would be expected to improve health care outcomes.

But as I read the plan, a critical component of the Administration's philosophy is that *more* health care does not always mean *better* health care. For example, the plan emphasizes preventive care and disease management, which presumably will reduce the need for aggressive and

¹⁵For example, the Administration proposes the creation of a National Health Insurance Exchange. This has been described as a government-organized marketplace, where consumers will be able to compare health plans, gather information about their options, and exercise informed choices. In the end, however, consumers will pick their own plans and their own doctors. The President also has suggested that any government-sponsored insurance plan should compete with private insurers in that same marketplace. See *Obama Health Care Plan*, *supra* note 13.

interventionist treatments down the road. The plan also relies on better coordination of care at all levels of the health care system – through health information technology (“HIT”) measures, the “medical home” model of care management,¹⁶ and other approaches to reduce fragmentation. Better coordination is likely to reduce duplicative testing, facilitate consultations among various specialists, and help patients get the right treatments faster, among other goals.

And this leads directly to the all-important financial aspect of health care reform. Clearly, the Administration intends to devote significant resources to this endeavor. I will not get into a political discussion of where this money will, or should, come from. But I think most of us would agree that all the money in the world will not fix this nation’s health care system unless there are some changes to the underlying incentive structure that governs how health care services are sold and purchased in this country. Health care dollars cannot just be spent – they must be spent efficiently.

In keeping with the coordination-of-care model, the Administration’s plan strongly suggests that physicians should be paid based on the *value* of the care they deliver over time, not the number of tests and examinations they perform. Implementing a quality-based, pay-for-performance model will require a fundamental shift in mindset, not to mention changes in reimbursement methodology, for most doctors and their patients.

¹⁶See American Academy of Family Physicians, American Academy of Pediatrics, American College of Physicians, & American Osteopathic Association, *Joint Principles of the Patient-Centered Medical Home* (March 2007), available at <http://www.medicalhomeinfo.org/Joint%20Statement.pdf> (“The Patient-Centered Medical Home (PC-MH) is an approach to providing comprehensive primary care for children, youth and adults. The PC-MH is a health care setting that facilitates partnerships between individual patients, and their personal physicians, and when appropriate, the patient’s family.”).

3. A Note About HIT

I mentioned HIT a moment ago, and I'd like to say just a few more words about that topic, because it is something that will be of particular interest to the FTC in the coming years.

The stimulus package included a number of provisions, and \$19 billion in financial incentives, to encourage investments in HIT.¹⁷ I think it would be fair to say that the Administration views HIT development and deployment as central to its vision of health care reform.

When used to its fullest potential, a robust HIT system can serve as a hub for effective coordination-of-care efforts, which can lead to improvements in quality, access, and cost – all three of the dimensions of the “iron triangle” of health care delivery. For example, the effective use of HIT may reduce medical errors and duplicative testing, increase transparency of information regarding the comparative quality of different providers and systems, make health records more portable, and make it easier for patients to exercise informed market choices by switching to another doctor or health plan.

HIT implementation also will raise important privacy and data security questions, which are squarely within the purview of the FTC's consumer protection expertise. In fact, the stimulus bill requires the FTC to consult with the U.S. Department of Health and Human Services (“HHS”) to conduct a study and generate a report on privacy, security, and breach notification requirements for vendors of personal health records and related third party products and services. In the interim, the stimulus legislation requires the FTC to conduct a rulemaking to enforce breach notification requirements for non-HIPAA-covered entities. The legislation gives the FTC civil penalty authority for violations of the new rule. HHS is developing a similar breach notification rule for HIPAA-covered entities.

¹⁷American Recovery and Reinvestment Act of 2009, H.R. 1, 111th Cong. (2009); *see especially id.* at Title XIII (“Health Information Technology”).

I realize that privacy is not our primary topic today. But it is one of my pet topics, so I am taking advantage of this opportunity to remind you that privacy and data security is another arena where your organizations may cross paths with the FTC. This is a high-priority area for the Commission, and I urge every health care entity to take the utmost care to protect patients' individually identifiable health information.

B. Clinical Integration Reflects Health Care Reform Principles

After that privacy detour, let me return to clinical integration, now that we have some context in mind. It seems clear to me that clinical integration, done right, embodies the principles of health care reform under the Obama Administration.

The essence of clinical integration is the creation of interdependence among health care providers. Put simply, each provider must have a vested interest in the performance of the other providers, such that their financial and other incentives are closely aligned to meet common objectives. In addition, physicians are most likely to conform their behavior to network goals when their performance is judged by objective standards, in comparison to their peers.

An effective organizational structure likely will facilitate coordination of care – for example, across different primary and specialty practice areas, or between different locations where care may be provided to a given patient. An effective organization also is likely to be structured in a way that encourages adherence to common quality and outcome objectives. Ongoing peer review, data-driven utilization management and outcome measurement, and other mechanisms are likely to ensure that high-quality care is being delivered in the most cost-effective manner.

HIT typically is a critical element of this coordination, which is exactly why the Administration is funneling so much money towards it. If HIT is used in the ways I described a few

minutes ago – as a hub for coordination-of-care efforts – its implementation will be completely consistent with procompetitive clinical integration.

It is important to realize, however, that HIT adoption *alone* does not constitute lawful and effective clinical integration. HIT is a tool, not an end in itself. Far more important is the quality of the coordination facilitated by HIT. Is it being used to reduce fragmentation and foster interdependence among providers? Does it contribute toward aligning provider incentives so that they are all working toward common goals? Does its use actually lead to better health care outcomes and improved efficiency? These are key questions, the answers to which will inform a determination of whether HIT has helped providers achieve clinical integration.

C. Antitrust Is Not A Barrier To Health Care Reform

And now, we get to the real reason why I suspect I was invited to speak on this panel.

Start from the premise I just articulated: that clinical integration is, in theory, a strong expression of current health reform principles.

Then, let me acknowledge that the Commission, in recent years, has paid quite a lot of attention to physician groups that engage in joint pricing. In a number of cases, the Commission has concluded that the physicians were *not* sufficiently integrated to generate procompetitive efficiencies to which joint pricing arrangements would be reasonably ancillary. Many of these cases have led

to consent agreements.¹⁸ *NTSP* was litigated, and resulted in favorable appellate case law that endorses the Commission’s analytical framework.¹⁹

Looking at all of these factors, one might wonder whether antitrust enforcement might impede health care reform. Some people have said directly that antitrust enforcement *is* a barrier

¹⁸For a summary of recent FTC actions involving physician networks, *see* Federal Trade Commission, Bureau of Competition, Health Care Services and Products Division, *Overview of FTC Antitrust Actions in Health Care Services and Products* (Sept. 2008), at 10 *et seq.* (“Agreements on Price or Price-Related Terms”), *available at* <http://www.ftc.gov/bc/0809hcupdate.pdf>. *See also* In the Matter of Independent Physicians Associates Medical Group, Inc. d/b/a AllCare IPA, FTC Dkt. No. C-4245 (decision and order entered Feb 2, 2009), *available at* <http://www2.ftc.gov/os/caselist/0610258/index.shtm>; In the Matter of Boulder Valley Individual Practice Association, FTC File No. 051-0252 (proposed consent agreement accepted Dec. 19, 2008), *available at* <http://www2.ftc.gov/os/caselist/0510252/index.shtm>.

¹⁹*See* NTSP Commission Opinion, *supra* note 6, at 11-12, 28-30, 33-34 (discussing clinical integration in evaluating NTSP’s claimed efficiencies, and concluding that NTSP had not achieved clinical integration); *accord* *NTSP v. F.T.C.*, 528 F.3d at 368-69 (rejecting NTSP’s “spillover” defense arguments; agreeing with the Commission’s conclusion that, even if any efficiencies did exist, NTSP had not explained how such efficiencies were furthered by its anticompetitive activities, i.e., how the restraints were ancillary to any procompetitive integration).

to reform.²⁰ And some of those critics may be talking to their Congressional representatives, because the Commission has received a few inquiries from the Hill along these lines.

1. Existing FTC Guidance Is Consistent With Reform Models

I cannot emphasize this strongly enough: I do *not* believe that antitrust will be a barrier to health care reform, and I suspect that my fellow Commissioners and FTC staff would agree. Looking at the myriad forms of guidance the FTC has provided on clinical integration,²¹ all of that

²⁰See, e.g., American Hospital Association, *Statement of the American Hospital Association on the Importance of Clinical Integration to the Nation's Hospitals and Their Patients* (May 29, 2008), at 2, available at <http://www.ftc.gov/bc/healthcare/checkup/pdf/AHAComments.pdf> (“... because of their complexity and potential consequences, the antitrust laws are among the most significant barriers to clinical integration.”); Letter from Michael D. Maves, MD, MBA, Executive Vice President, CEO, American Medical Association, to the Honorable William E. Kovacic, Chairman, U.S. Federal Trade Commission, regarding Physician Network Integration and Joint Contracting (June 20, 2008), available at <http://www.ftc.gov/bc/healthcare/checkup/pdf/AMACComments.pdf> (“We are extremely concerned with what we see as the significant regulatory barriers that restrict physicians’ ability to collaborate in ways crucial to improving quality and containing costs. To that end, we submit our comments discussing changes in the health care market that we believe warrant a shift in the Agencies’ health care antitrust regulatory approach.”). These public comments were submitted as part of Federal Trade Commission, Public Workshop, *Clinical Integration in Health Care: A Check-Up* (May 29, 2008) [hereinafter FTC Clinical Integration Workshop], available at <http://www.ftc.gov/bc/healthcare/checkup/index.shtm>.

²¹See sources of guidance cited in note 10, *supra*. See also Fed. Trade Comm’n & U.S. Dep’t of Justice, *Improving Health Care: A Dose of Competition* (July 2004), available at <http://www.ftc.gov/reports/healthcare/040723healthcarerpt.pdf>; FTC Clinical Integration Workshop, *supra* note 20; Letter from Jeffrey W. Brennan, Assistant Director, Bureau of Competition, Federal Trade Commission to John J. Miles, Ober, Kaler, Grimes & Shriver (Feb. 19, 2002), available at <http://www.ftc.gov/bc/adops/medsouth.shtm> (staff advisory opinion concerning MedSouth, Inc.); Letter from Markus H. Meier, Assistant Director, Bureau of Competition, Federal Trade Commission to John J. Miles, Ober, Kaler, Grimes & Shriver (June 18, 2007), available at <http://www.ftc.gov/bc/adops/070618medsouth.pdf> (follow-up to 2002 MedSouth staff advisory opinion); Letter from Markus H. Meier, Assistant Director, Bureau of Competition, Federal Trade Commission to Christi J. Braun & John J. Miles, Ober, Kaler, Grimes & Shriver (Sept. 17, 2007), available at <http://www.ftc.gov/bc/adops/gripa.pdf> (staff advisory opinion concerning Greater Rochester Independent Practice Association, Inc.); Letter from Markus H. Meier, Assistant Director, Bureau of Competition, Federal Trade Commission

guidance is consistent with current reform models. In fact, one might argue that reform efforts are actually moving closer to where the Commission has been all along, in terms of receptivity toward arrangements involving the kind of coordination that aligns provider incentives and generates real efficiencies.

The most current example of FTC guidance is the very recent advisory opinion that Commission staff issued to TriState Health Partners, a physician-hospital organization (“PHO”) based in Maryland.²² Notably, this is the first time a PHO has requested a staff advisory opinion on clinical integration. In a 37-page, single-spaced letter, staff carefully analyzed TriState’s description of its proposed program, and concluded that the proposed plan has the potential to lower health care costs and improve the quality of care. As in several earlier advisory opinions, coordination of care is central to the logic of the TriState opinion – including coordination between physicians, as well as between physicians and the hospital. Moreover, the hospital will play an important management and decisionmaking role.

2. The FTC Will Not Endorse Specific Models

The federal antitrust agencies have been criticized for not providing sufficient guidance to providers, who are struggling to craft and implement clinical integration programs whose joint pricing components will pass antitrust muster. The risk, we are told, is that procompetitive arrangements are being deterred by the risk of antitrust enforcement. As a result, there have been

to Christi J. Braun, Ober, Kaler, Grimes & Shriver (April 13, 2009), *available at* <http://www.ftc.gov/os/closings/staff/090413tristatealetter.pdf> (staff advisory opinion concerning TriState Health Partners, Inc.) ([hereinafter TriState Advisory Opinion]).

These written forms of guidance are supplemented by frequent speeches delivered by FTC Commissioners and staff, as well as plentiful informal guidance shared by FTC staff.

²²TriState Advisory Opinion, *supra* note 21.

many calls for “more guidance” – although, reading between the lines, some of those requests may really be calls for “safe harbors,” or other bright-line rules, that will offer greater comfort to physicians who choose to engage in joint pricing.

At the moment, at least, we may just have to agree to disagree about whether more guidance is possible or necessary. By its nature, antitrust analysis is highly fact-specific. The FTC’s clinical integration advisory opinions are a prime example. Did I mention that the TriState advisory opinion is 37 single-spaced pages? And the vast majority of those pages are devoted to reviewing the elements of a specific geographic market and a specific proposed arrangement.

History teaches us that when the antitrust agencies issue guidelines, the agencies tend to take a conservative, risk-adverse approach, to leave enough room for case-by-case analysis.²³ Our concern is that any bright-line guidance on clinical integration is likely to stifle the innovation and creativity that are true hallmarks of the ever-evolving American health care system. It is also worth noting that guidelines, once issued, may be difficult to change, even if new information comes to light.²⁴

For these reasons – and based on what we know right now about the relative benefits and risks of clinical integration – a flexible, case-by-case approach may be best for market participants as well as consumers.

²³See, e.g., Fed. Trade Comm’n & U.S. Dep’t of Justice, *Horizontal Merger Guidelines* (rev. April 8, 1997), available at <http://www.ftc.gov/bc/docs/hmg080617.pdf>; U.S. Dep’t of Justice & Fed. Trade Comm’n, *Antitrust Guidelines for the Licensing of Intellectual Property* (April 6, 1995), available at <http://www.ftc.gov/bc/0558.pdf>; *Competitor Collaboration Guidelines*, *supra* note 10.

²⁴Changes to existing guidelines may be even more difficult to draft and implement when the original guidelines have been issued jointly by two agencies, such as the Federal Trade Commission and the Antitrust Division of the U.S. Department of Justice. Even when relationships between these sister agencies are at their most collegial, the agencies’ approaches are rarely identical, and coordinated policy development takes time.

IV. NEED FOR MORE EMPIRICAL RESEARCH ON CLINICAL INTEGRATION OUTCOMES

Speaking of what we know about clinical integration outcomes. . . in closing, I'd like to shift to a more philosophical, and perhaps controversial, question. All of my comments up until now have taken for granted that legitimate clinical integration will improve quality of care and generate efficiencies. Intuitively, this assumption makes sense. But how much do we *know* regarding the actual benefits of clinical integration?

As it turns out, there are many different views, but no clear answers. As we heard during the Commission's clinical integration workshop last May,²⁵ there have been very few empirical studies of clinical integration outcomes.²⁶ And to the extent studies have been conducted, the results

²⁵FTC Clinical Integration Workshop, *supra* note 20.

²⁶For example, during the FTC's May 2008 clinical integration workshop, a speaker from the Agency for Healthcare Research and Quality reviewed the empirical literature on clinical integration; he noted that, while some related work had been done, few directly relevant studies had been conducted. He called for the development of a research agenda on clinical integration. Herbert S. Wong, Ph.D., Center for Delivery, Organization and Markets, Agency for Healthcare Research and Quality, U.S. Dep't of Health & Human Servs., *Clinical Integration: An Economic and Research Perspective* (May 29, 2009) (presentation at FTC Clinical Integration Workshop, *supra* note 20), available at <http://www.ftc.gov/bc/healthcare/checkup/pdf/Wong%20Presentation%20-%20Clinical%20Integration%20Workshop.pdf>. See also Robert Baldwin & Tracy Weir, *Health Care Services Research on Initiatives to Improve Health Care Delivery through Collaboration among Health Care Providers, Panel IV*, in American Bar Association, Section of Antitrust Law, ANTITRUST HEALTH CARE CHRONICLE, Vol. 22, No. 1 (Aug. 2008), at 13 (summary of same workshop panel):

Finally, Dr. Wong turned to the empirical literature on clinical integration, noting the scarcity of relevant studies. . . . Additional research could examine whether clinical integration improves the financial performance of hospitals and, thus, quality of care. Given this dearth of research, Dr. Wong suggested that if stakeholders think there is a need for a more systematic research agenda on the effects of clinical integration, they should convey their thoughts to the FTC.

have been inconsistent, which provides a less-than-stable foundation for further policymaking and legal development.²⁷

Let me draw an analogy to another controversial area of antitrust law – vertical minimum price fixing, or resale price maintenance (“RPM”), whereby manufacturers dictate the minimum prices at which retailers can sell their products. The Supreme Court recently reversed *per se* illegality for RPM, which had been in place since 1911. Without a rule of *per se* illegality, the antitrust community has been struggling to develop an appropriate legal framework to analyze this conduct, and we are finding our efforts hampered by a dearth of empirical evidence.

I have been extremely vocal in advocating for additional empirical research to evaluate the true costs and benefits of RPM.²⁸ I would like to issue a similar call with respect to clinical integration. Health care is too important, and the stakes are too high, to rely on untested assumptions. Rigorous empirical analysis, along with a comprehensive review of existing research,

²⁷See, e.g., TriState Advisory Opinion, *supra* note 20, at note 45 (cataloguing recent literature demonstrating that, “[w]hile the potential benefits of a robust [clinical integration] program appear intuitively obvious,” clinical integration does not always lead to expected quality of care improvements or other anticipated benefits).

²⁸See, e.g., Pamela Jones Harbour, Commissioner, Federal Trade Commission, *Consumer Benefits and Harms from Resale Price Maintenance: Sorting the Beneficial Sheep from the Antitrust Goats?*, Opening Remarks at the Federal Trade Commission Resale Price Maintenance Workshop (Feb. 17, 2009), available at <http://www.ftc.gov/speeches/harbour/090217rpmwksp.pdf>; *Bye Bye Bargains? Retail Price Fixing, the Leegin Decision, and Its Impact on Consumer Prices*, Hearing Before the Subcomm. on Courts and Competition Policy, H. Comm. on the Judiciary, 111th Cong., 1st Sess. (April 28, 2008) (statement of Pamela Jones Harbour, Commissioner, Federal Trade Commission), available at <http://www.ftc.gov/speeches/harbour/090428rpmtesti.pdf>.

will enable all of us to channel health care reform efforts toward the areas where we will get the greatest “bang for our buck” – in terms of quality as well as efficiency.²⁹

Antitrust lawyers and economists are particularly fond of “natural experiments” that enable us to test empirical assumptions in the real world. To those skeptics who may be nervous about the huge amounts of stimulus money being directed into HIT, perhaps it would help if we think of this massive investment as an opportunity to enable a plethora of natural experiments, which will generate the data needed for further empirical research. It is certainly worth thinking about as HIT projects are designed and implemented.

V. CONCLUSION

In closing, I want to return to the guidance point. The Commission takes seriously its obligation to provide as much guidance as possible to the business community. We have offered more guidance in the health care industry, especially on clinical integration, than in any other area within our competition jurisdiction. We will continue to refine our guidance, and our doors are always open if you want to speak with our talented staff about potential clinical integration plans.

²⁹A DOJ Antitrust Division official has expressed similar thoughts.

I agree that additional [guidance] is likely to be beneficial. However, I do not think that the answer right now is to issue more general guidelines or “rules of the road.” The primary problem is not doctrinal. Rather, the gap is empirical. The Agencies and the health care community need more information about the actual effectiveness of provider collaborations in improving patient care and reducing costs.

Featured Item: Interview With Josh Soven, in American Bar Association, Section of Antitrust Law, ANTITRUST HEALTH CARE CHRONICLE, Vol. 23, No. 4 (March 2009), at 3. Mr. Soven is Chief of the Antitrust Division’s Litigation I Section, which is responsible for DOJ’s health care antitrust enforcement.

If what you are looking for, however, are bright-line rules of antitrust legality, the federal antitrust agencies probably cannot give you much more certainty at this time.

But this should not cause too much discomfort to the medical community. After all, there are no absolute certainties in medicine. Often, it is possible to come up with different interpretations for the same collection of symptoms. And even when a diagnosis is reached, there likely are multiple treatment approaches available, depending on factors very specific to the individual patient. Doctors tend to appreciate autonomy in crafting a recommended course of treatment, relying on their hands-on evaluation of each patient, combined with expertise and good judgment.

The legal approach to clinical integration generally, and physician pricing agreements specifically, requires the same degree of flexibility. This flexibility benefits the health care industry, and consumers, in the long run, because it is the best way to foster innovation and creative thinking about the challenges we face.

Thank you, and I would happy to answer questions.