

American Bar Association



# Antitrust Health Care l'hrnnj

#### Health Care Committee Newsletter

October 2005 Vol 19/No.3

that this issue of the Chronicle reflects a number of changes. First generally changing the look of the of all, we are making the magazine available only on the Internet. This not only saves substantial paper and costs, but enables us to get the issue out to readers faster. It will also will facilitate a major advance coming later this year which will enable all Section publications to be searchable on the Section's website.

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### Chair's Report

Robert F. Leibenluft, Washington, D.C.

It should be immediately obvious We've also done the first "makeover" of the Chronicle in its history, But the changes go magazine. much deeper than just appearances, as Seth Silber explains in his Editor's Report. The goal here is to get more information to our readers,

> including commentary and analysis, and to get it out on a more timely, reader-friendly basis.

> You also will notice that this issue of the Chronicle does not include a "Recent Developments" section. We haven't forgotten it - rather, we are converting it to a monthly publication that also will be sent via

e-mail to all of our Committee members. You should be getting the first issue shortly. Again, the goal here is to provide information to our readers as soon as we can. Back issues of Recent Developments will also be available on our website.

Thanks are due to Seth Silber who is the new Editor of the Chronicle and Ashley Fischer who is heading up our Recent Developments publication. Let us know what you think of these changes. And if you would like to help, please contact either Seth at ssilber@ftc.gov or Ashley at afischer@gcd.com.

#### Interview with **Commissioner Tom Leary**

The following interview with Commissioner Tom Leary -- the longest serving current FTC Commissioner -- was conducted on September 26. It covers a broad range of issues reflecting Commissioner Leary's extensive experience at the Commission, having served with three different Chairmen, and five different Commissioners. On health care and antitrust. Commissioner Leary offers his views on the importance of guidelines and hearings, FTC enforcement in pharmaceutical markets and physician practices, the goals of the Hatch-Waxman Act, the FTC's hospital merger retrospective, disgorgement, and health care markets generally.

Chronicle: Having served as a Commissioner for a full term, what observations do you have on how the Commission has changed during that period?

Leary: I don't think the substance of our analysis has changed much. It certainly changed a great deal less than people anticipated in 2001, with the change in the administration and Tim [Muris] onboard.

The priorities have changed a bit over time. I think some of these changes were driven by outside events. For example, when Bob [Pitofsky] was here the merger wave sucked up resources from other areas of the Commission. As you probably know, we had to really strip people away from non-merger enforcement in order to deal with

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### Editor's Report

Seth C. Silber, Washington, D.C

Welcome to the new look *Chronicle*. We hope you find the new format pleasing to the eye. In addition to aesthetic changes, we are changing our approach to articles - moving toward shorter commentary or op-ed style pieces. We will still include the occasional longer "journal" length article (including two feature articles in this issue on economic credentialing), but will primarily focus on shorter, timely pieces analyzing current cases and issues. We are also introducing interviews on health care antitrust with prominent enforcers and practitioners. Finally, we are expanding the scope of our coverage to go beyond traditional health care antitrust concerns \_ hospitals, doctors, etc... - to include more pharmaceutical coverage of antitrust issues.

The current edition includes the following pieces:

• Interview with Commissioner Tom Leary – Covering his thoughts on the Commission and health care enforcement during his seven year tenure at the Commission, plus a

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Mark Botti Department of Justice 202-307-0827 mark.botti@usdoj.gov discussion of a range of specific topics including the Health Care Guidelines, pharmaceutical markets, and disgorgement.

• "Generic Drug Merger Enforcement" – A perspective by Steven Bernstein (former head of the FTC's Mergers I Division) and Weil, Gotshal colleague Jeff White on recent FTC consents in generic drug mergers and advice for practitioners advising clients in this area.

• "An Overview and Roadmap to 'The Evanston Case" – A detailed description by Theresa E. Weir of Hogan & Hartson distilling the FTC's challenge (including a summary of the parties' main arguments and key issues to be determined by the administrative law judge) to this consummated hospital merger challenge brought by the Commission.

• "Rx for Caution: Economic Credentialing and the Antitrust Laws" – Feature article by Connie Robinson (former Director of Operations and Director of Civil Enforce ment at DOJ), Peter Boyle and

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Council Liaison Neil Motenko Nutter, McClennen & Fish 617-439-2216 nmotenko@nutter.com Saadeh Al-Jurf of Kilpatrick Stockton regarding economic credentialing and the antitrust issues raised by it.

• *"Economic Credentialing and Exclusionary Conduct Under the Sherman Act" – Mark Horoschak's further analysis on economic credentialing.* 

We are also seeking articles for our next edition, likely out in December. If you have ideas for commentary type pieces or journal length articles, please contact me at ssilber@ftc.gov or 202-326-3121, or our Articles Editor James Yoon at james.yoon@oag.state.ny.us or 212-416-8822. We are also looking for a Production Editor (preferably with experience with Adobe Illustrator) for our next edition.

Finally, I would like to thank Dusty Peters, the Antitrust Section's Technology and Communications Specialist, for his extensive help in the redesign and launching of the *Chronicle* in electronic format.

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#### Interview with Commissioner Tom Leary Continued.....

that avalanche, and I think that inhibited Bob's ability to do some of petition and consumer protection the more innovative things that he might have wanted to do. On the other hand, he did start to revitalize the Commission's role in "competition R&D." Bob started that in 1995 when he had these big hearings on global competition and, of course, you saw a lot more of it going on in Debbie comes out of the world of Tim's tenure, and continuing.

When Tim came on board, he had a more affirmative agenda on the consumer protection side, particularly, than we've seen around here in guite a while. Of course "do not call" was the big thing, but there were a whole bunch of other things done on the consumer protection side. In part, it was because he wanted to do them, and in part, it was because consumer protection became the focus of attention up on the Hill -- reflecting concerns about privacy and spam. On balance we probably get more inquiries from the Hill on consumer protection issues today than we do on competition issues.

The big competition issue up on the Hill that drives a lot of our activity right now – and the only one that we hear anything about, as you can imagine - is gasoline pricing. We are inundated with letters all the time about gasoline prices, particularly in the last month or so after the So, those are the hurricane. changes. I think an awful lot of people expected big changes in the Commission, and I just don't think increasing at a rather low level. that we saw them.

Chronicle: Can you comment on any changes between Chairman Majoras and her predecessors?

Leary: Well, there's one small Debbie difference. Majoras followed two people who've been

longtime scholars in the field of comlaw - in Bob's case, dating back from before Debbie was born and in Tim's case, dating back about 30 years. They had to deal with these issues over a long period of time. They're both academics.

private practice and the Department of Justice which is more specificcase oriented. I've heard her say that "I am a bottom up person rather than a top down person." So I think that her first initiative, and the one thing that she wants to do affirmatively before she really turns to anything else, is deal with the merger review process. That must be in its final stages right now. So, there's some difference, based on their experience. Their focus is a little bit different but I don't think her substantive response to any particular case or controversy would be any different than either Bob's or Tim's.

Chronicle: Turning to health care markets, have there been significant changes in those markets and the FTC's efforts regarding health care during your tenure here?

Leary: I think the one thing I've noticed here is a greater focus on health care issues in the last several years, and I think there are a couple of reasons for it. There was a period of time when health care costs seemed to be at a plateau or at least They have spiked much more sharply in the more recent years.

There are various causes for the cost increases that we could go into, but I think this has stimulated more focus here at the Commission on health care. If you were to look at our allocation of resources to health

care issues, both on the competition side and on the consumer protection side, I think you see a fairly dramatic increase.

Chronicle: The FTC/DOJ Health Care Guidelines were last updated nearly ten years ago. What are your thoughts on how useful these Guidelines have been to private parties?

The Guidelines are very Leary: helpful to practitioners who are willing to pay attention to them and deal with them. I think they're very fulsome. It may be, quite frankly, that collectively they're too big a mouthful for outside-the-beltway practitioners. And I am not saying that in a patronizing way.

I get the impression there are an awful lot of lawyers giving antitrust advice on the Health Care Guidelines who are not really antitrust lawyers, and I think that it might be desirable to consider amplifying on those Guidelines through speeches and things of that kind to make them more focused for the edification of outsiders. As you know we've got a case under consideration right now [North Texas Specialty Physicians] involving possible application of the When that opinion Guidelines. comes out, it may provide some quidance for people - regardless of the outcome.

Chronicle: What about updating the Guidelines, would that be a good idea?

**Leary:** I think we're learning that the process of revising and updating guidelines is fairly excruciating and should not be undertaken very frequently. The amount of effort involved in dealing not just with the various constituencies of the Federal Trade Commission, but also

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with the Department of Justice, is something for the primary purpose horrendous. I think you could say the same thing about merger guidelines generally, or about collaborative venture guidelines, or about Maybe, it's too early to judge and intellectual property guidelines. just don't see any great enthusiasm for revising guidelines in the near future.

Chronicle: In a 2002 speech you integration. We did have one more discussed in detail a Commission staff advisory opinion in Med South. What did that advisory opinion add to our understanding of how the Health Care Guidelines operate, particularly relating to clinical integration?

Leary: What I was trying to do in that speech is similar to what we're talking about here. I was trying to take an advisory opinion, which is necessarily a somewhat starchy document, and turn it into language that outside practitioners might understand a little bit better. I also wanted to indicate how many unanswered questions there were. think the speech was also intended to provoke people into thinking about clinical integration and trying to encourage clinical integration. I might say, up to now at least, we've been disappointed by the reaction.

The Med South opinion letter was intended to be an invitation to doctors to genuinely try to integrate their practice, and incidental to integrating their practice there might be certain things they can do in the joint contracting area that would be prohibited otherwise. Unfortunately, I think a great many of these medical groups or associations still have the cart before the horse. Their prime focus is on using negotiations and contracts for the purpose of enhancing their bargaining power. And the one thing that seems to distinguish the good from the bad is that if you are putting together

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of enhancing your bargaining power you're going to buy trouble.

maybe that comment isn't accurate about what's going on in the medical community, but my impression is that we're not seeing too many examples of aenuine clinical example, where they tried to negotiate collectively first, and then integrate, rather than the other way around. They had to go back and start over.

Chairman Chronicle: Muris initiated a well-publicized retrospective look at hospital mergers and promised that the Commission would distribute its findings. The Commission has challenged one hospital merger in Evanston that was the subject of this retrospective, may be able to identify tend to get but there has been no report released summarizing the staff's findings relating to the broader retrospective. Anything you can share concerning the results of this retrospective?

Leary: Well I obviously can't talk about the case that's in litigation, but I think I can predict it's highly unlikely that we will issue any kind of a report on the retrospective while we've got a case in litigation. There are also a couple of other things that I know I've said publicly and I think can be safely said here.

We learned in the course of doing this that a retrospective is very hard to do. It seems so logical that we ought to try to go back and see whether past enforcement efforts have been effective, or whether the denial of our efforts to enforce have led to harmful results. You may remember that a few months ago, Hew Pate – in the letter he sent to the Antitrust Modernization Com-

mission just as he was walking out the door at DOJ - suggested that retrospective analysis of the effectiveness of antitrust across the board might be something that would be worth doing.

I think the lesson that we learned is that it is very hard to do a retrospective. There are two reasons. Number one, it's very hard to get the data. It's one thing to be able to get data from companies that are contemplating a merger or that are in the process of just putting one together because its right up front and there tends to be a lot of internal communication about that particular Once it's done, people subject. aren't thinking anymore about the merger as such and what the merger will do.

Number two, any effects that you blurred with all kinds of outside effects. When I was in the auto business. I used to use an analogy. Suppose there is a new government standard, say for a different kind of stop light or a different kind of a bumper. Your first year, within the limits and the vagaries of cost accounting, you can have a ballpark idea of how much that standard costs. But as the years go by and it becomes just integrated in the way you do things, you can't pull it out any more and you have no idea. I think that's the trouble with trying to determine the impact of either a consummated or a failed transaction.

Then, if you are to go beyond that and try, somehow or other, to assess the potential efficiencies that might have been lost from mergers that never even saw the light of day. that were killed in lawyers' offices because of the fear of antitrust consequences, I think it's hopeless. You may not even be able to find out

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what they were because companies **Chronicle:** Do you think there's any don't like to talk about them, and the advantages and disadvantages of the road not taken are hard to figure out. I think the bottom line lesson we can learn from that retrospective is that we've got to be very, very modest about our ability to identify effects on a broad basis. Individual cases might be different, but broad conclusions are pretty hard.

Chronicle: years the Commission has brought may be that we could be a little bit about two dozen enforcement cases harsher on them than we've been. physicians alleging that engaged in price-fixing. Why do you think such conduct continues to occur?

Leary: I think the fundamental reason it occurs is that doctors have this desire to get some countervailing power. I think that doctors feel they've been pushed around by pavors. They believe that the payors have interfered unduly with their ability to practice medicine and deliver the kind of quality care that they want to deliver. Now, whether that's good or bad involves issues that are certainly beyond our competence. I don't think we're in a position to determine whether some of the protocols that are laid down by the payors are or are not detrimental to patient care. But I do think beleaguered mindset. that а prompts doctors to combine their forces to counter this.

And, of course, there are legal ways to do it. We point out to them that there are legal ways to do this. But, the antitrust laws don't have any broad exemption for collective attempts to resist countervailing power. Doctors attempted to get Commission? legislative relief. We don't happen to think that's necessarily good Leary: policy, but they're entitled to try to get it if they want to.

role for enhanced penalties here, such as civil or criminal penalties, in order to deter physician pricefixina?

**Leary:** I think there might be a role for enhanced penalties for these against some of those consultants. There are some people who get these doctors together and promise that they can represent them collec-Within the past few tively in negotiations with payors. It have I'm really hesitant to get in the business of hitting these doctors too terribly hard because my impression is that a lot of them have been led down the garden path and they've gotten a lot of really bad advice.

> Chronicle: Regarding the Hatch-Waxman Act, what are your thoughts on whether the Act has achieved its original objectives in creating incentives for both innovation and the development and introduction of generic products?

> Leary: Up to now, I think that the Hatch-Waxman Act and the FTC's initiatives concerning Hatch-Waxman have done both, and I think that they've been very useful. I can't really talk about the ongoing Schering matter or what the impact of any final decision on that matter will be. The Commission has said things publicly, and I don't think I want to add to it.

> Chronicle: The Commission continues to be active in reviewing pharmaceutical mergers. Has enforcement in these matters changed during your tenure at the

> It doesn't seem to have changed. I still think the focus of our inquiry is on overlaps in various different therapeutic categories.

There is, I think, some overarching concern if these very, very big mergers that we're seeing continue indefinitely. We need to be continually concerned about possible longterm effects on innovation if these big mergers continue because I don't know the extent to which research directed at one particular therapeutic category may or may not have spillover effects into other areas.

I think we're assuming that you can kind of deal with the pharmaceutical business as if it consists of myriad separate markets. When you're looking at R&D, I am less sure. As you know, there have been certain blockbuster discoveries in the pharmaceutical area that were almost accidental B people were looking for something in category A and it turns out it had some unanticipated impact in category B. I think that's something we need to always be aware of, and we do look at it. We have a very knowledgeable staff who have dealt with these things over a period of years and know a great deal about them. It's a guestion I always ask.

Chronicle: There has been some criticism of the Commission using different product market definitions in merger cases, and between merger and conduct cases. Sometimes the Commission defines a generic only market, sometimes it's generic and brand, and sometimes it's a branded market. Do you have any thoughts on this?

**Leary:** People tend to forget that market definition is a tool, not an end in itself. We actually addressed this specific issue in the Schering opinion. For example, the question of whether or not the brands and the generics are or are not really in a separate submarket depends a lot on the product. Are they the only

close substitutes, or are there myriad other substitutes? And that depends on case-by-case analysis.

In some cases – and I guess Schering was one of them - we found there was a very close interaction. predicted by both the branded and the generic. I think we're pragmatic about whether you can generalize from that to other kinds of drugs.

Chronicle: In recent years the Commission has sought disgorgement in three matters, all of which involved pharmaceuticals in some matter. Is this just a coincidence?

I don't think it's a coinci-Leary: dence, but also I don't think it's because we're targeting pharmaceuticals. I think it's because the criteria for disgorgement that we've agreed to, and that are in the Commission policy statement on disgorgement, seem to fit in drug cases. Our policy focuses on the nature of the offense and the likelihood of private remedies. It just so happens in pharmaceuticals that Chronicle: You commented in a we've seen some fairly eqregious restraints – probably driven by the fact that, at least in some areas, the profit opportunities are immense. These pharmaceuticals companies drill a lot of dry holes and they depend for their profitability on a few real blockbuster drugs. They try to protect them. I think the financial temptations are very strong. And, of course, the harm is diffused over hundred of thousands of consumers out there, so the likelihood of meaningful consumer redress is rather slim. Disgorgement is particularly attractive in those situations.

Chronicle: You've offered statements in two of the Commission's disgorgement matters reflecting your view that restraint is needed in the Commission's use of its ation, or we're not sure whether our disgorgement authority. Can you

comment on your views generally regarding disgorgement and where you stand today?

Leary: Well, I signed onto the recent policy statement. I was initially very dubious about the whole program for reasons that I explained in my dissenting opinion in Mylan. But I was outnumbered and I couldn't persuade anyone else here to go along with it, and once the battle is lost, there's no point in flogging a dead horse. So I participated very actively in the crafting of the policy statement and I'm satisfied that if the Commission adheres to those general principles down the road, we won't damage our mission. That's the primary thing. One of the potential problems I mentioned in Mylan, is that collecting money is such a seductive activity that we may tend to focus on it too much. Then we're just another prosecutor and, in some ways, we've lost our reason for being. I don't want to see that happen.

speech given about two years ago that the FTC/DOJ Health Care Hearings enriched the Commission's understanding of health care issues. Can vou describe how the Hearings and the Report following the Hearings accomplished this, and whether additional hearings down the road will be useful as health care markets change?

Leary: I think it's a mistake to assume that we go into a hearing with no knowledge of the subject and that we are learning health care 101. We go into the hearing with a great deal of embedded knowledge on the subject but we are not sure whether there are things that we may not be taking into considerviews on this are in the mainstream

of views that are out there. It provides reassurance that we're taking account of the right things if people from the outside – a broadly representative group of people from the outside - come in and have an opportunity freely to comment.

Let me give you just one example. Health care is too recent so I can't really comment. When Bob Pitofsky had his hearings on international competitiveness in 1995, they didn't just focus on international matters but considered just about any complaint that the business community might have about the direction of the FTC. I was advising The Business Roundtable very actively at that time, and I said to them this is your opportunity if you've got any serious concerns about the direction the FTC is taking. It's an open invitation to come in and give some views. And as you probably know, very little critical comment from members of the business community came in.

That provided the leadership of the FTC in 1995 with some reassurance that they were not going down a road that an awful lot of people would be concerned about. When you have a hearing and people are just reaffirming some of the ideas you have already had, it gives you some assurance that you're going down the right road.

Chronicle: Last question, any additional thoughts or comments you'd like share regarding to the Commission's role in health care?

Leary: One thing that I've noted, and I've talked about a little recently, is that health issues provide a very good example of the interface between competition and consumer protection matters. Some of these health issues are the best examples that I can think of. We're inviting collective private initiatives to

weight-loss products. I was also very pleased to see that the soft drink manufacturers have come up with some kind of compact among themselves to restrict the distribution of the sweet soft drinks in the primary school setting. I was gratified to see that because I have trust Law Journal, that's an introducencouraged them directly to do it.

reduce "red flag" false claims for They were concerned that there would be some antitrust reaction to it, and of course, an antitrust lawyer might well give some cautious advice on that subject. But, I think there is a scope for targeted efforts.

I wrote a little piece in the latest Anti-

tion to the subject. I think health issues are a wonderful example of ways in which self regulatory efforts can go beyond what people may have thought in the past. Another area, by the way, is the whole field of information security, but that's not the subject of this discussion.

The generic drug industry has experienced significant consolidation in recent months. In July of 2005, Novartis acquired Eon Labs, Inc. in a \$1.72 billion transaction<sup>3</sup> that established Novartis as the world's leading generic drug manufacturer. Shortly thereafter, Teva agreed to acquire IVAX Pharmaceuticals for \$7.4 billion.<sup>4</sup> This transaction would result in Teva surpassing Novartis as the world's top generic drug firm. Some industry experts predict that these transactions, while significant, may be only the beginning of a major wave of merger activity in this industry. The Federal Trade Commission (FTC) historically has reviewed mergers involving pharmaceutical companies and has the authority to challenge such transactions if the agency believes that they may harm consumers. Legal practitioners advising pharmaceutical companies must be aware of any below. antitrust implications a deal may present and the likelihood of an FTC A. Novartis / Eon Labs challenge.

This article summarizes the FTC enforcement involvina history generic drug mergers and provides a framework that antitrust practitio-

Generic Drug Merger Enforcement: A Guide for Antitrust Practitioners

By Steven K. Bernstein<sup>1</sup> and Jeff L. White<sup>2</sup>

ners can use to advise clients on the likelihood of enforcement in any acquisition opportunities being explored. If the predicted wave of consolidation continues among generic producers, FTC scrutiny of such deals may have an important impact on the ultimate shape of the industry. Understanding enforcement history is critical in effectively advising clients on the likelihood of regulatory hurdles and developing winning arguments that get deals through with as little disruption as possible.

#### Recent Enforcement in Generic **Drug Mergers**

Over the past ten years, three proposed mergers involving generic drug producers have resulted in FTC enforcement. These enforcement actions are summarized

Novartis, through its Sandoz subsidiary, captured the leading position among generic drug manufacturers following its \$8.3 billion acquisition of Hexal AG. This acquisition

included Hexal's U.S. subsidiary, Eon Labs (which was valued at \$1.72 billion), and resulted in several overlaps between the two companies' generic drug products.<sup>5</sup>

Following its antitrust review, the FTC concluded that the acquisition would eliminate actual, direct, and substantial competition between Novartis and Eon Labs in the U.S. markets for three products: (1)generic desipramine hydrochloride tablets; (2) generic orphenadrine citrate extended release (ER) tablets; and (3) generic rifampin oral capsules. Desipramine hydrochloride tablets are tricyclic antidepressants with annual generic sales in the U.S. of \$6 million. Orphenadrine citrate ER tablets are muscle relaxants having annual generic sales in the U.S. of \$10 million. Rifampin is used to treat tuberculosis and has annual generic sales in the U.S. totaling \$14 million. The FTC found that in each of these markets, the branded drug exerted no pricing pressure on its generic equivalents other than serving as a price ceiling that was several times higher than the price of the generics. Accordingly, the FTC found the relevant

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<sup>2.</sup> Jeff L. White is an associate in the Washington, D.C. office of Weil, Gotshal & Manges LLP.

<sup>3.</sup> In the Matter of Novartis AG, File No. 051-0106 (July 19, 2005) (news release), available at www.ftc.gov/opa/2005/07/novartis.htm.

<sup>4.</sup> Press Release, Teva to Acquire Ivax for \$7.4 Billion (July 25, 2005), available at www.tevapharm.com/pr/2005/pr\_536.asp. 5. See In the Matter of Novartis AG, File No. 051-0106 (July 19, 2000) (case materials), available at www.ftc.gov/os/caselist/0510106/0510106.htm

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generic versions of the drug.

In addition, the Commission found that in each of the three markets, the combined firm would face competition from only one other entity. In other words, the acquisition would result in markets with three competitors being reduced to two. In the market for desipramine hydrochloride, Watson Pharmaceuticals, Inc. was the only other generic provider and sold products in just three of the six dosages offered by Novartis and **B.** Baxter / Wyeth The combined firm's Eon Labs. post-acquisition market share would have approached 95%. In the market for orphenadrine citrate ER tablets, Impax Laboratories, through its Global Pharmaceuticals subsidiary, was the only other generic The combined share of supplier. Novartis and Eon Labs in this market approached 70%. In the market for generic rifampin, VersaPharm Inc. was the only other generic provider and post-merger market shares also approached 70%.

Moreover, the FTC concluded that entry in these three generic markets would not be timely, likely, or sufficient in magnitude, character, and scope to deter or counteract any competitive harm that would result from the acquisition. The Commission stated that developing and obtaining FDA approval for any of these three drugs would take at least two years due to substantial regulatory, technological, and intellectual property barriers. It appears that no other companies had similar generic drugs sufficiently along in their development "pipelines" to warrant a finding of timely entry. Novartis and the FTC reached a consent agreement requiring the divestiture of all assets necessary to manufacture and market

product market to be limited to designamine hydrochloride tablets. orphenadrine citrate ER tablets, and rifampin oral capsules. The consent agreement provided for the divestiture of these assets to Amide Pharmaceutical, Inc. within 10 days of consummation of the Novartis acquisition of Eon Labs. The FTC determined that Amide was a reputable generic manufacturer, wellpositioned to obtain FDA approval to manufacture and market each of the three generic drugs.

On June 10, 2002, Baxter International Inc. announced its proposed \$305 million acquisition of the generic injectable drug business of ESI Lederle Inc., a subsidiary of Wyeth Corporation. Baxter, one of the world's largest generic providers, did not manufacture generic iniectable drugs, but rather contracted with third-party manufacturers so that it could market and supply such products for sale. Following antitrust review of the proposed transaction, the FTC issued a consent order requiring remedies in the markets for five injectable drugs: (a) propofol; (b) pancuronium; (c) vecuronium; (d) metoclopramide; and (e) New Injectable Iron Replacement Therapies.<sup>6</sup>

#### 1. Propofol

In the market for propofol, the Commission alleged that the acquisition would result in significant anticompetitive harm by eliminating potential competition in the manufacture and sale of the drug. Propofol is a general anesthetic used in surgery and as a sedative for patients on mechanical ventilators. Annual U.S. sales of the drug range between \$375 and \$400 million. At the time of the acquisition, there were only two propofol products on the

AstraZeneca market. sold the branded version of the drug and Baxter, through a supply agreement with GensiaSicor, marketed the only generic version of the product. Wyeth was in the process of seeking FDA approval for its own generic propofol product, and was considered to be one of the two bestpositioned potential entrants in the market. The FTC concluded that the acquisition would have the effect of reducing the number of future propofol suppliers from four to three. In order to preserve the future competition that would have resulted from Wyeth's entry, the Commission required the divestiture of Wyeth's propofol business to Faulding Pharmaceutical Company.

#### 2. Pancuronium

Pancuronium is a rapid-onset, longacting neuromuscular blocking agent used to temporarily freeze muscles during surgery or for use with patients who are mechanically ventilated. In this \$2 million market, the FTC found that Baxter, Wyeth, and Abbott Laboratories were the only suppliers of the drug in the U.S. Through an exclusive supply agreement with GensiaSicor. Baxter accounted for nearly 50% of all U.S. pancuronium sales. The combined market share of Baxter and Wyeth approached 74%. In addition, the FTC noted that new entry was unlikely because pancuronium was an older drug with limited usage. The consent order required Baxter to terminate all of its rights and interest in GensiaSicor's pancuronium product and divest all of its pancuronium assets to GensiaSicor.

#### 3. Vecuronium

Vecuronium is an intermediateacting neuromuscular blocking agent used to freeze muscles during

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<sup>6.</sup> See In the Matter of Baxter Int'I Inc. and Wyeth Corp, No. C-4068 (Feb. 7, 2003) (case materials), available at www.ftc.gov/os/caselist/c4068.htm.

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surgery or mechanical ventilation. The U.S. market for this drug was approximately \$21 million. Baxter, through an exclusive supply agreement with GensiaSicor, and Wyeth were the two largest suppliers of the drug until Wyeth discontinued production in 2001. The Commission noted that Wyeth indicated an intention to re-launch its vecuronium product, and that based on 2001 market shares, the combined firm would have a 53% share of the Three other suppliers of market. vecuronium, Abbott, Bedford, and Organon (which offered the branded version of the drug), comprised the rest of the market. The Commission concluded that the acquisition likely would delay or eliminate the re-entry of a significant supplier in the market and the associated price competition from such entry. To address these concerns, the Commission required Baxter to terminate all of its rights and interest in GensiaSicor's vecuronium product and divest all of its vecuronium assets to GensiaSicor.

#### 4. Metoclopramide

Metoclopramide is an antiemetic used to treat nausea in patients undergoing chemotherapy and other post-operative treatments. Annual U.S. sales of the drug were approximately \$13 million. In this market, Wyeth produced Reglan, the branded version of metoclopramide. Through an exclusive supply agreement with GensiaSicor, Baxter sold a generic version of the drug. The combined shares of the companies made up more than half of all U.S. sales of metoclopramide. Only two other companies, Abbott and Faulding, supplied metoclopramide in the U.S. The Commission noted that new entry was unlikely to occur in a timely manner and, in fact, was unlikely to occur

at all due to the limited sales opportunities available to new entrants. The Commission therefore found that, by reducing the number of suppliers from four to three, the proposed acquisition likely would result in higher prices for metoclopramide. Accordingly, the Commission required Baxter to terminate all of its rights and interest in GensiaSicor's metoclopramide product and divest all of its assets relating to the drug to GensiaSicor.

5. New Injectable Iron Replacement Therapies

Lastly, the Commission alleged that the acquisition would result in harm to potential competition in the market for New Injectable Iron Replacement Therapies ("NIIRTs"). including both iron gluconate and iron sucrose, used to treat iron deficiency in patients undergoing hemodialysis. Annual U.S. sales of NIIRTs were approximately \$225 million. Watson, the only injectable iron gluconate producer in the U.S., had been engaged in a copromotional agreement with Baxter for its branded drug, Ferrlecit. The only other competitor in this market was American Regents, which marketed Venofer, an injectable iron sucrose product sold in the U.S. The FTC concluded that entry was difficult due to FDA-imposed New Chemical Entity exclusivity periods and the lack of raw material suppliers. Nonetheless, the Commission concluded that Wyeth, which was developing an alternative iron gluconate product, was the bestpositioned firm to enter the market and that the acquisition would eliminate this potential competition and associated price competition. The FTC required Baxter to terminate its co-marketing agreement with Watson in order to provide incentives for the combined firm to

proceed with development of Wyeth's alternative iron gluconate product.

# C. Hoechst AG / Marion Merrell Dow

In September 1995, Hoechst AG and the FTC entered into a consent agreement resolving competitive concerns raised by the company's \$7.1 billion acquisition of Marion Merrell Dow (MMD). At the time, the acquisition created the world's third largest pharmaceutical company. Although the FTC took enforcement action in four product markets, only one market implicated generic drugs: oral-dosage forms of mesalamine, a drug used to treat the gastrointestinal diseases of ulcerative colitis and Crohn's Disease.<sup>7</sup>

In this potential competition case, Pentasa. MMD marketed the branded version of mesalamine. Only one other oral form of mesalamine was present in the marketplace. Hoechst was one of only a few firms developing a generic version of Pentasa. The Commission concluded that the acquisition likely would delay or prevent altogether Hoechst's development of a generic version of the drug, and therefore required the parties to either divest the rights to Pentasa or the generic formulation in development to a Commission-approved buyer.

#### Lessons Learned

Although the Commission has taken enforcement action in only three mergers involving generic drug producers in the last ten years, these cases provide a useful guide for determining the factors the Commission deems most important when it analyzes generic drug mergers. While it would be unwise to

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<sup>7.</sup> See Hoechst AG / Marion Merrell Dow, Inc., File No. 951-0090 (September 26, 1995) (case materials).

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suggest that hardened rules can be applied in every transaction, antitrust lawyers should be familiar with the key enforcement trends that stand out in this industry.

- Number of Competitors: Enforcement action appears most likely when an acquisition reduces the number of competitors to three (or fewer). With the exception of one relevant market, enforcement in the above three cases occurred in markets where the acquisition reduced the number of competitors from four to three or three to two.<sup>8</sup> The lone exception to this was in Baxter, where the number of potential competitors in the market for vecuronium was reduced from five to four. Although enforcement in this market may be attributed to the fact that the merging parties had historically been the two leading suppliers of the product, generic drug companies should still be cautious when proposing five to four mergers. In a recent FTC report on generic drug entry, the agency cited a study that suggests that generic drug pricing may continue to fall until at least the fifth generic provider enters a market.<sup>9</sup> To the extent the Commission relies on such data, its enforcement activities in this industry may extend to more five to four transactions.
- Drugs in the Pipeline: Understanding the pipeline activities of the merging companies is critical in assessing the antitrust risks of a transaction. Even if there is no ongoing competition between the two merging firms, antitrust concerns may be raised where one of the parties to the merger has a drug on the market or in

development and the other has a potentially competing product in its development pipeline. In such a situation, the Commission may conclude that the merger will delay or eliminate the procompetitive effects resulting from the independent development of the new product. Generally speaking, the closer a company is to completing development or obtaining regulatory approval, the greater the chance that the FTC may conclude that the product in development would have had a pro-competitive effect on the market absent the merger.

- Likelihood of Entry: The development pipelines of competitors are highly important to the persuasiveness of any entry arguments. Although barriers to entry tend to be lower for generic drugs than for innovative pharmaceutical products, the history of FTC enforcement suggests that, at least in some cases, the barriers are still sufficiently high to support an enforcement action. Thus, to make an effective entry argument in generic drug markets, it may be necessary to demonstrate that products being developed by potential competitors are sufficiently along in the development or regulatory approval process to be considered a competitive force that will deter or counteract any anticompetitive harm from the transaction.
- Relationships with Third Parties: In analyzing a transaction, it is necessary to understand the relationships that the merging companies have with other companies. For example, in Baxter/Wyeth, Baxter did not actually produce any of the generic drug products at issue. Instead, it competed

through distribution and comarketing agreements with other producers. In several markets, the FTC required a termination of these agreements as part of its remedy.

A Company's Non-Generic Products: As shown in Baxter and Hoechst, a company's branded products may play an important role in the FTC's evaluation of an acquisition of a generic drug supplier. Where the FTC concludes that a company's nongeneric products compete with the merging party's generic prodthe Commission ucts. will consider the transaction to be removing a competitor. However, as the Novartis case demonstrates, sometimes the branded drug exerts no pricing pressure on its generic equivalent other than setting a price ceiling. Where this is the case, parties have an opportunity to argue that no overlap exists when a branded competitor merges with a company competing with a generic version of the product. In addition, in certain cases it may be possible to successfully argue that the relevant product market should include not only the branded product and its generic equivalents, but also other competing branded and/or generic products that are based on different active ingredients.

*Size of Market:* In several of the generic drug markets where the FTC has taken enforcement actions, the size of commerce affected was very small. Indeed, in Baxter, the pancuronium market was only \$2 million, and in Novartis, all of the relevant markets were under \$15 million. Given this history, one should not

9. See Generic Drug Entry Prior to Patent Expiration: An FTC Study, Federal Trade Commission, July 2002, at 9 (citing David Reiffen and Michael R. Ward, Generic Drug Industry Dynamics, Bureau of Economics Working Paper No. 248 (Feb. 2002)).

<sup>8.</sup> In Hoechst, it is unclear how many companies the Commission considered to be likely potential entrants in the market for mesalamine. The Commission stated that "Hoechst was one of only a few firms developing a generic form of this drug." See Hoechst AG / Marion Merrell Dow, Inc., File No. 951-0090 (September 26, 1995) (Proposed Consent Agreement with Analysis to Aid Public Comment).

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discount the possibility of an FTC enforcement action simply because the size of the overlapping market is small.

Need for a Buyer Up-Front: Although the Commission in recent years has relaxed its preference for a buyer up-front in many industries, the trend in pharmaceutical enforcement appears to be moving in the opposite direction. This likely can be attributed to the fact that most divestitures in pharmaceutical the industry involve divestitures of product lines, rather than stand-alone businesses. In the 1995 Hoechst consent order, the order did not name a buyer of the assets, instead requiring the parties to divest after the close of their transaction to a "Commissionapproved buyer." In contrast, in the 2003 Baxter and 2005 Novartis consent orders, a buyer upfront for all the assets to be divested was required. Given this trend in the industry, parties negotiating with the FTC should expect this requirement in most pharmaceutical cases and need to consider the timing issues raised by having to find a buyer for the assets to be divested before the FTC staff agrees to a consent order.

The foregoing principles represent the key lessons to be learned from the FTC's enforcement activity in the generic drug industry. Antitrust lawyers advising pharmaceutical companies involved in generic drug mergers need to understand these principles in order to advise their clients accurately and effectively. In addition, knowing the enforcement history in this industry is a tremendous benefit when deciding which arguments are likely to be successful in obtaining antitrust clearance for their clients' transactions.

#### An Overview and Roadmap to the Key Issues in the "The Evanston Case"

#### By Theresa E. Weir<sup>1</sup>

#### I. Introduction and Overview

In January 2000, Evanston Northwestern Healthcare Corporation ("ENH") acquired Highland Park Hospital ("Highland Park") through what seemed at the time to be a benign combination of hospitals in the Chicago area. Four years later in February 2004, the Federal Trade Commission ("FTC") sued ENH through the Commission's Part III administrative litigation procedures claiming that the merger violated antitrust laws. The challenge was premised on claims that postmerger prices paid by health insurers for inpatient services at ENH hospitals increased substantially and non-competitively. Both the rationale for price changes and the relative and absolute magnitude of the changes are among the key issues in the litigation. While the FTC alleged that price increases are due to market power gained by merger, ENH claimed that there are alternative and competitively neutral rationales for price changes, and also that prices did not actually increase to non-competitive levels when appropriately measured.

The lawsuit and its focus on postmerger pricing raises a number of interesting antitrust issues related to market definition, competitive effects theories, quality defenses, and burdens of proof under Clayton Act § 7 jurisprudence. In particular. the scope of geographic market, the number of hospitals that are practical alternatives for the merging hospitals, and the measurement and magnitude of quality of care evidence are the subject of sharp disagreement. The case is also compelling because it is the first federal-level hospital merger case following a string of seven federal court losses in hospital merger enforcement.<sup>2</sup> However, with over two months of trial, 1500 trial exhibits, and thousands of pages of argument and factual findings, there is a tremendous record to review in order to understand the nuances of what is being called "The Evanston Case." This article – which was written on the eve of Administrative Law Judge ("ALJ") Stephen J. McGuire's decision<sup>3</sup> – provides an overview of the case, and seeks to distill the parties' main arguments. The overview presented herein is intended to be a roadmap to the core contested issues that will likely be addressed in the ALJ's decision and that foreshadow the potential battlegrounds of any subsequent appeals that may be taken.

The following sections set forth some of the key areas and arguments/analyses presented by the parties. The article is not to be taken as a critical analysis of either side's positions or as a review of

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<sup>2.</sup> See California v. Sutter Health Sys., 84 F. Supp. 2d 1057 (N.D. Cal.), *aff'd mem.*, 217 F.3d 846 (9th Cir. 2000), *revised*, 130 F. Supp. 2d 1109 (N.D. Cal. 2001); FTC v. Tenet Healthcare Corp., 17 F. Supp. 2d 937 (E.D. Mo. 1998), rev., 186 F.3d 1045 (8th Cir. 1999); United States v. Long Island Jewish Med. Ctr., 983 F. Supp. 121 (E.D.N.Y. 1997); FTC v. Butterworth Health Corp., 946 F. Supp. 1285 (W.D. Mich. 1996), *aff'd*, 121 F.3d 708 (6th Cir. 1997); United States v. Mercy Health Services, 902 F. Supp. 968 (N.D. Iowa 1995), vacated as moot, 107 F.3d 632 (8th Cir. 1997); FTC v. Freeman Hosp., 911 F. Supp. 1213 (W.D. Mo.), *aff'd*, 69 F.3d 260 (8th Cir. 1995); In re Adventist Health Sys., 117 F.T.C. 224 (1994)

<sup>3.</sup> As of the writing of this article, the due date for Judge McGuire's decision is October 11, 2005. See Order Extending the One Year Deadline for Filing the Initial Decision, No. 9315 (Aug. 8, 2005). Case documents and pleadings cited herein are available at www.ftc.gov/os/adjpro/d9315/index.htm.

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specific arguments against underlying facts. Rather, as stated above, its purpose is to hone in on and highlight the key areas of difference that may be focal points in the case. Moreover, since much of the trial testimony is in camera, this review relies almost exclusively on the post-trial briefs of Complaint Counsel and Respondents and materials expressly referred to therein.

There are five key areas disputed in the case. They include the following:

• **Product market** – The FTC alleged that it is limited to inpatient services, while ENH claimed that it includes inpatient and outpatient services (either because both types of services are bought by plans or because there are trade-offs made in the pricing of these services such that outpatient services may act as a constraint on inpatient prices).

 Geographic market – The FTC alleged that the geographic market is limited to a triangle encompassing just the merging firms, while ENH alleged that it encompasses at least the hospitals in the immediate area as well as potentially those in a broader area in and around Chicago. As such, there is a substantial difference in the parties' views as to the number of competitors faced by ENH that can serve as alternatives such that payors could use them to discipline the pricing of the margining hospitals.

• Mechanisms by which prices were increased/market power achieved – The FTC alleged that Evanston and Highland Park were close competitors and that certain payors had no effective alternatives with which to discipline

pricing or avoid non-competitive price increases. ENH claimed that Evanston and Highland Park were not necessarily close substitutes, that there were other effective alternatives that served to discipline pricing, and that some non-testifying payors had demonstrated the ability to discipline pricing by means other than excluding ENH from their networks.

· Price effects and measurement of price effects - The FTC alleged that ENH was able to achieve supracompetitive а percentage increase in prices relative to "comparable" hospitals. ENH claimed that the resulting levels achieved were competitive as compared to those of other hospitals and that there were competitive rationales for the including "learning changes, about demand." The FTC also asserted that demonstrating anticompetitive effects is sufficient to show liability without the need to prove precise antitrust markets.

• Efficiencies and offsetting benefits of the transaction – The FTC alleged that the merger yielded no compelling efficiencies and that claims of improved quality did not justify the price increases. ENH claimed that considerable investments were made in quality improvements and that there were efficiencies achieved.

# II. Background: "The Evanston Case"

ENH acquired Highland Park in January 2000. Through that transaction, Highland Park joined an existing network of two other hospitals - Evanston Hospital and Glenbrook Hospital. All three hospitals are located in the "North Shore" of the Chicago's metropolitan area, with Highland Park situated north of Evanston and northeast of Glenbrook.

The transaction consummated outside of the merger notification and pre-clearance review process dictated by the Hart-Scott-Rodino Antitrust Improvements Act of 1976 (the "HSR Act"). At the time of the transaction, Northwestern Healthcare Network ("NHN") was the sole corporate member of both Evanston and Highland Park. Because NHN owned all of the assets held by both hospitals, the FTC staff determined that the merger did not result in an acquisition that would need to be reported under the HSR Act.<sup>4</sup> As a result, neither the FTC nor the United States Department of Justice reviewed the merger prior to its occurrence.

In late August 2002, the FTC announced the creation of the Merger Litigation Task Force, which would be charged with, among other things. "reinvigorating the Commission's hospital merger program" <sup>5</sup> after numerous hospital merger loses in the 1990s. The program, which developed under the leadership of then-Chairman Timothy Muris, resulted in the retrospective study of some number of consummated hospital mergers in markets around the country.

The purpose of these studies was to determine – using "real-world empirical evidence" – whether the transactions were anticompetitive and, if so, challenge them through the Commission's Part III administrative litigation process.<sup>6</sup> Chicago was one of the markets selected; the acquisition of Highland Park by ENH was one of the consummated hospital mergers studied. After a

5. See Press Release, Federal Trade Commission Announces Formation of Merger Litigation Task Force (Aug. 28, 2002), available at http://www.ftc.gov/opa/2002/08/mergerlitigation.htm.

<sup>4.</sup> See FTC Pre-Merger Notification Office Informal Staff Opinion No. 9908002 (Aug. 10, 1999), available at http://www.ftc.gov/bc/hsr/informal/opinions/9908002.htm

<sup>6.</sup>See Timothy J. Muris, Everything Old is New Again: Health Care and Competition in the 21st Century, Prepared Remarks before 7th Annual Competition in Health Care Forum, Chicago, Illinois, 19-20 (Nov. 7, 2002).

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period of investigation into the Highland Park transaction, the FTC formally challenged the merger as being anticompetitive and sued ENH on February 10, 2004. The following sets out the key elements raised and litigated in the case. <sup>7</sup>

# III. Key Elements of The Parties' Arguments

In most litigated merger cases, market definition and competitive effects theories were the core issues in dispute; many also involved efficiencies defenses. The Evanston case is not unique in this regard. However, there are distinctive twists on the way these issues were litigated, in part, because the case deals with a consummated merger. In pre-consummation cases, the task generally is to use predictive factors to determine the likelihood of harm to competition. In the Evanston case, however, the parties spent significant time arguing about what the relevant analyses are, accusing each other of their failure to satisfy burdens of proof, and assessing the significance and meaning of pricing and quality evidence. For example, one significant issue in the case is whether the FTC even needs to prove a relevant market in the claimed presence of direct evidence of market power and anticompetitive effects.

#### A. Market Definition

On market definition the parties agreed that health plans (not patients) are the relevant consumers and that the "Elzinga-Hogarty" test no longer applies to hospital mergers. 8 Beyond that, they agreed on very little, including issues related to evaluating the competitive mechanisms by which health plans choose among hospitals and discipline pricing, and identifying the alternatives that are available for patients. For instance, the FTC's primary position on market definition was that it need not engage in an elaborate structural analysis when there is direct evidence of anticompetitive effects.<sup>9</sup> According to the FTC, structural analyses in merger cases are intended to be predictive in nature. Their purpose is to see if the market is concentrated enough to raise a presumption that a merger is likely to harm competition. However, in consummated mergers, evidence of anticompetitive effects eliminates the need to predict harm because there is evidence that harm has already occurred.

To ENH, the FTC's argument is inconsistent with established precedent under section 7 of the Clayton Act. No court as a matter of law has ever permitted the government to avoid proof of a relevant market.<sup>10</sup> According to ENH, the case law on this point is that the government must establish every element of its prima facie case which includes establishing a presumption that the merger will substantially lessen competition by producing evidence of undue concentration *in a relevant geographic and product market.*<sup>11</sup> Thus, failure to meet that burden means that, as a matter of law, the claim should be dismissed.

Notwithstanding its primary position that a structural analysis is not necessary, the FTC argued that such an analysis in this matter nevertheless leads to the conclusion that the market was (and continues to be) highly concentrated and, thus, presumptively indicative that market power rests in the hands of ENH.<sup>12</sup> In this regard, the FTC defined the relevant (product and geographic) market as inpatient acute care services sold to health plans by the three ENH hospitals. ENH's market was more expansive, including outpatient services, but more importantly adding at least seven hospitals other than the ENH hospitals.

Product Market: The FTC defined the relevant product market as general acute-care inpatient services sold to health plans.<sup>13</sup> Inpatient encompass services primary, secondary and tertiary inpatient services, but not inpatient guarternary or outpatient services. ENH contended that outpatient services, in addition to primary, secondary and tertiary services, should be part of the market. Thus, the dispute is whether outpatient services should be part of the product market, or

<sup>7.</sup> See In re Evanston Northwestern Healthcare Corp., No. 9315 (Feb. 10, 2004) (complaint). The FTC also sued ENH Medical Group on price-fixing charges. ENH Medical Group later entered into a consent agreement with the Commission on April 5, 2005. See Agreement Containing Consent Order to Cease and Desist, No. 9315 (Apr. 5, 2005).

<sup>8.</sup> The Elzinga-Hogarty test, initially developed to analyze the movement of commodities, has been used in hospital merger analysis, albeit primarily by Plaintiffs. References to the Elzinga-Hogarty test appear to be used synonymously with patient flow analyses, which has been more generally accepted by courts. See Complaint Coursel's Post-Trial Reply Brief, 58-59 (July 1, 2005) (hereinafter FTC Reply Brief): see also Report of the Federal Trade Commission and the Department of Justice, Improving Health Care: A Dose of Competition, ch. 4, at 5-7 (July 2004), available at http://www.fte.gov/reports/index.htm. In this case, the FTC appears to have argued that patient flow data is not relevant or useful for the analysis of geographic market definition. See Complaint Coursel's Post-Trial Brief, No. 9315, 58-59 (May 27, 2005) (hereinafter FTC Brief); FTC Reply Brief at 15. For example, FTC witness Dr. Kenneth Elzinga indicated during the Evanston trial that the problem with applying the test to hospital mergers is that it does not account for the "payor problem." See id. He also indicated that one aspect of the "problem" is that there is a disconnect between who pays for health care services and who consumes them. See id. The FTC's references to Dr. Elzinga's testimony seem to dismiss both application of the Elzinga-Hogarty test as well as use of patient flow data in geographic market analysis. See FTC Reply Brief at 15.

<sup>9.</sup> See FTC Brief, 49-51; FTC Reply Brief at 17.

<sup>10.</sup> See Post-Trial Brief of Respondent Evanston Northwestern Healthcare Corporation, No. 9315, 3 (May 27, 2005) (hereinafter ENH Brief).

<sup>11.</sup> See id. at 13-14; Post-Trial Reply Brief of Respondent Evanston Northwestern Healthcare Corporation, No. 9315, 45-49 (July 1, 2005) (hereinafter ENH Reply Brief).

<sup>12.</sup> See FTC Brief at 49-56; FTC Reply Brief at 7-17

<sup>13.</sup>See FTC Brief at 52-53; FTC Reply Brief at 7-8.

alternatively, whether services are used in some way to deciding factor in the Evanston constrain pricing of services.

patients nor health plans view inpatient and outpatient services as substitutes for each other. As a result, prices for outpatient services do not serve as a constraint on the prices for inpatient services. In support of its position, the FTC cited previous hospital merger cases finding that the relevant hospital product market in those cases was inpatient general acute care services.

Rather than focus on whether inpatient and outpatient services are literal substitutes for each other, ENH urged the judge to consider the claimed market realities of how the two services are used in contract negotiations as price constraints14 a small, but significant non-Specifically, they argued that health plans and hospitals negotiate for a bundle of services, which includes both inpatient and outpatient There very often are services. trade-offs or concessions in prices between inpatient and outpatient services in order to "get the deal done."15 Thus, ENH's position was that even where the products are not substitutable in and of themselves, there are certain circumstances in which the products should be considered together in evaluating pricing.

Geographic Market: market definition has a history in case is won or lost. Though it is

outpatient unclear whether it will be "the" inpatient case, geographic market definition was heavily contested nonetheless. This is largely because the parties According to the FTC, neither used different methodologies for defining a market. Specifically, the FTC seemed to assume that the market should include only those hospitals that effectively constrain the merged firm's prices, regardless of whether the hospitals are close substitutes.<sup>16</sup> It also seemed to assume that the method by which a hospital's pricing is constrained is the ability of payors to include or exclude them from a network.<sup>17</sup> ENH – on the other hand – posited that the geographic market must contain those hospitals that are close substitutes to the merged firm.<sup>18</sup> ENH further argued that a market containing close substitutes reflects the analysis of where consumers are practicably able to turn to avoid transitory increase in price.<sup>19</sup>

The FTC argued that the geographic market is the "area of effective competition." 20 Critical to determining that area is the assessment of whether the merged firm's prices are affected by so-called competitors. Largely relying on payor testimony with respect to theories of network formation and ENH documents discussing "leverage" in light of the hospitals' "geographic placement," the FTC defined a narrow and highly concentrated geographic market containing only the ENH Geographic hospitals.<sup>21</sup> That market – the socalled the "geographic triangle" hospital merger cases of being a includes the area "adjacent or primary battleground where the contiguous to the three hospitals." 22

According to the FTC's economic expert - Dr. Deborah Haas-Wilson the geographic triangle provides ENH with a monopoly.23 The FTC also references other cuts at the market - using analyses performed by Dr. Monica Noether (ENH's economic expert) and ENH documents concerning its core service area - that purportedly evidence a highly concentrated market postmerger for ENH.24

According to ENH, the FTC's geomarket proposition graphic unprecedented. "No court has ever defined the relevant market to include only the merging hospitals" 25 especially when the hospitals are located in a large suburban metropolitan area. As with its product market argument. ENH contended that commercial realities ought to be considered in the assessment of geographic market. To that end, ENH appears to claim that the analysis specified in the Merger Guidelines requires identifvina which firms are practical alterna-Dr. Noether found seven tives. Chicago-area hospitals that more closely competed with Evanston and Highland Park than Evanston and Highland Park competed with each other and that these seven hospitals were practical alternatives for payors.<sup>26</sup> As a result, she concluded that the seven other hospitals are closer substitutes for payors to Highland Park and Evanston than the two hospitals are to each other.<sup>27</sup> Dr. Noether's analysis was based on the hospitals' geographic proximity (i.e., driving times), patient travel patterns (i.e., zip codes), physician admitting

18. See ENH Brief at 18-31; ENH Reply Brief at 52-54

- 20. See FTC Reply Brief at 8.
- 21. See FTC Brief at 53-56; FTC Reply Brief at 8-17 22 See FTC Brief at 54

23. See id. at 55. 24. See id. at 55-56.

25. See ENH Brief at 19; see also ENH Reply Brief at 53.

27. See id. at 23-28.

<sup>14.</sup> See ENH Brief at 16-18; ENH Reply Brief at 50-51

<sup>15</sup> ENH Brief at 5

<sup>16.</sup> See FTC Reply Brief at 8-17; see also FTC Brief at 20-43. 17 See id

<sup>19.</sup> See id. at 18. Interestingly, the parties' traded positions on their product market arguments As discussed above, the FTC contended it is the substitutability of inpatient and outpatient services that is the defining element of product market whereas ENH asserted it is the ability to use one product (i.e., outpatient services) to constrain the prices of the other product (i.e., inpatient services) that is the key.

<sup>26.</sup> See ENH Brief at 23. ENH referenced the identification of seven hospitals by Dr. Noether as a conservative estimate of practical alternatives that exist to ENH.

patterns (e.g., staff privileges over- they were unable to sell a network to lap among hospitals) and market participants' views on competition among these hospitals (including hospitals, payors, and ENH and Highland Park executives). 28

#### **B.** Competitive effects

Central to the FTC's claims of anticompetitive effect from the consummated merger are allegations that ENH achieved supracompetitive increases in prices from certain payors subsequent to the transaction. This portion of the trial focused both on the mechanism by which price increases were arguably achieved and the magnitude and measurement of changes.

The FTC's case rests on a bargaining theory of competition, which essentially includes two propositions. First, according to the theory, prior to the merger in 2000, health engaged "selective plans in contracting" whereby they could selectively choose whether to include ments were not probative of market Highland Park or Evanston in their networks based on which had the best mix of services, quality, accessibility and prices.<sup>29</sup> That health plans could selectively contract meant that the hospitals had to compete to be included in payor networks. Second, after the merger, health plans no longer were able to choose among Evanston and Highland Park because ENH sold their services as a bundle, and at allegedly much higher prices. The FTC maintained that health plans, because they testified that they

employers without one or the other of the two hospitals, acquiesced to ENH's demand for higher rates. The FTC further argued that because health plans had no viable network alternatives to networks that included ENH, the only plausible reason for the higher prices was market power achieved through the merger. <sup>30</sup>

The FTC cited other evidence as well. Apparently, numerous ENH documents and some trial testimony suggest, according to the government, that ENH viewed the merger as a way to gain market power and to "thwart competition." 31 In particular, the FTC relied on statements made by Evanston and Highland Park executives regarding "increasing 'leverage,' building 'negotiating strength,' securing 'premium' prices and making itself 'indispensable' to health plans." 32 ENH argued that not only had the FTC taken the statements out of context, the statepower because there is no intent element in a Section 7 claim.<sup>33</sup>

The testimony on price increases, while mostly in camera, highlights the following differences between the FTC and ENH:

The baseline for pricing: Contested points in the case are whether ENH's pre-merger prices are relevant to the analysis and in what ways. ENH claimed that many of the alleged price increases were attempts by ENH to bring prices up

to appropriate levels, and that for some payors, prices had been at well below market levels.34 As a result, it claimed that prices were adjusted after ENH "learned" more about pricing.<sup>35</sup> According to ENH, any price increases it achieved post-merger were not indicative of market power because there were other market realities that explained the increase or the resulting price levels were not out-of-line with price levels at comparable hospitals.<sup>36</sup> In particular, according to ENH, Evanston had gone for many years (e.g., 5-6 years) without an increase in its health plan contracts, and even payors admitted that increases were in order. After the merger, however, ENH learned that Highland Park, an allegedly financially-weak community hospital with quality problems, had better contracts with health plans than Evanston, an academic teaching hospital affiliated with Northwestern Medical School. According to ENH, after the rather surprising realization that it had been underestimating the demand for its services, ENH sought and obtained increases from health plans that would bring Evanston's rates up to a level that would be competitive with comparable academic teaching institutions.<sup>37</sup> In addition to learning about pricing its services commensurate with its academic status, ENH claimed to have made substantial quality improvements at Highland Park with investments of \$120 million. It argued further that the improvement in quality served to adjust downward any price increases achieved

<sup>28.</sup> See id. The seven hospitals included in the market defined by Dr. Noether were Rush North Shore, St. Francis, Advocate Lutheran General, Resurrection, Lake Forest Hospital and Condell. 29. See FTC Brief, at 21-27. Notably, neither party expressly suggested that "selective contracting" is equivalent to "steering."

<sup>30.</sup> There is some ambiguity as to the meaning of "alternatives" in this matter. The FTC references examples of circumstances in which courts have found that payors had the ability discipline. These examples, however, appear to include cases in which payors disciplined by making use of alternatives that were in the network and not just cases in which payors threatened to drop hospitals. See FTC Reply Brief at 16.

<sup>31.</sup> See FTC Brief, at 28-33.

<sup>32.</sup> FTC Brief at 28; see also id. at 28-33; FTC Reply Brief at 19.

<sup>33.</sup> See ENH Reply Brief at 19-24; see also id. at 12-24.

<sup>34.</sup> See ENH Brief at 40-54; ENH Reply Brief at 27-30, 57-69.

<sup>35.</sup> See ENH Reply Brief at 60-69.

<sup>36.</sup> See ENH Reply Brief at 62-69. 37. See ENH Brief at 40-54

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(i.e., quality-adjusted prices). 38

The scope of affected payors: The FTC focused its analysis of affected "customers" on a specific set of testifying payors, while ENH noted that certain payors were not called to testify and did not suffer anticompetitive price increases.39

The magnitude of price increases: A point of contention in the litigation is the magnitude and measure of price increases, and how one assesses whether price increases are supracompetitive. Both parties recognized that price increases were the norm, and not the exception in 2000-2004. In particular, the FTC focused on measures of percentage change in prices over an apparently broader group of hospitals than did the ENH witnesses, with the FTC critiquing the cohort group proposed by ENH witnesses as too narrow.40 surement of quality should be based ENH's experts focused on the resulting levels, while the FTC focused on percentage increases. The FTC cited – as "evidence" of harm – the fact that the ENH hospitals remained in payor networks after the merger (and, as such, failure to exclude meant that noncompetitive price changes had been the uncertainty regarding these achieved). 41

#### C. "Defenses"

Among the many disputed issues in the Evanston case is whether ENH presented certain categories of ENH presented evidence that High-

the competitive effects analysis. The issue raises some challenging issues including how to assess specific types of evidence and how the burdens of proof are supposed to be allocated in merger analysis. The two primary sets of "defensive" evidence in the case relate to ENH's learning about demand theory and post-merger quality improvements at Highland Park.<sup>42</sup> The learning about demand theory evidence is addressed above in the discussion of price changes.

Quality of care evidence: The experts in the Evanston case take divergent positions on what constitutes quality of care, what types of things are appropriate to measure, and what data sources provide the most suitable information to use in the measurement of quality. For instance, ENH argued that the meaon improvements to structure, process and outcomes,43 while the FTC focused primarily on clinical outcomes and claimed that measuring outcomes resulting from improvements to structure and process is far to speculative a test to be useful in merger analysis.44 With most fundamental of issues, a key question raised by the Evanston "how should quality case is. improvement evidence be evaluated in a consummated merger?"

evidence as a "defense" or as part of land Park was in a weakened finan-

cial state and suffered from poor quality before the merger. <sup>45</sup> After the merger, ENH invested \$120 million and improved quality across 16 different service lines at Highland Park, including, for example, obstetrics, nursing, emergency department. adolescent psychiatry services, and cardiac surgery.<sup>46</sup> The improvement evidence quality included both clinical and nonclinical aspects.<sup>47</sup> For instance, ENH cited some improvements related to processes of care that increased the likelihood of desired health outcomes (i.e., clinical improvements, such as installing processes to ensure the administration of beta blockers to heart attack patients upon arrival at the hospital).<sup>48</sup> Other improvements were structural in nature and intended to enhance the patient's overall experience (e.g., improvement and expansions to physical plant). 49 Using clinical data and applying qualitative and quantitative standards of assessment, ENH's expert – Dr. Mark Chassin – measured changes in structure, process and outcomes arising through the merger and found that substantial, quantifiable improvements occurred across all 16 service lines.<sup>50</sup>

The FTC argued that ENH failed to provide any meaningful measurement or quantification of how much quality had improved at Highland Park as compared to other area hospitals, any means to value the claimed improvements, or any valid

<sup>38.</sup> See ENH Brief at 47

<sup>39.</sup> See FTC Brief at 3-6, 33-43; FTC Reply Brief at 28 n.30, 30 n.32; ENH Brief at 8; ENH Reply Brief at 67-69.

<sup>40.</sup> See FTC Reply Brief at 26-28, 30-33; ENH Reply Brief at 60-68.

<sup>41.</sup> See FTC Reply Brief at 30.

<sup>41.</sup> See FIC Reply Brief at 30. 42. Other defenses raised in the case include arguments based on "Copperweld," non-profit status, and the applicability of Section 7 to a consummated merger. See ENH Brief at 65-67, 107-113; ENH Reply Brief at 98-99. Briefly, ENH claimed that Evanston and Highland Park were "sister corporations" prior to the merger – and, thus, were "copperwelded" because they were both wholly-owned by the same entity, NHN. As a result, the hospitals were not distinct entities and would not have been able to conspire as a matter of law. See ENH Brief at 11, 110-113; ENH Heply Brief at 98-99. But see FTC Brief at 52-54; FTC Reply Brief at 44 (arguing that prior to the merger Evanston and Highland Park were separate economic actors pursuing separate economic anterests). ENH also argued that its not-for-profit status significantly reduced the potential for the merger to produce competitive harms. See ENH Brief at 65-67. But see FTC Reply Brief at 36-37 (maintaining that not-for-profit hospitals exercise market power and that not-for-profit status is economically irrelevant). Another argument posited by ENH was that Section 7 of the Clayton Act requires a showing of future competitive harm in order to impose liability. Because the FTC's focus was on harms allegedly occurring in the past, ENH argued that the FTC failed to prove that the merger will cause harm in the future. See ENH Brief at 107-110. But see FTC Reply Brief at 50-52 (contending that Clayton Act incipiency standard does not constitute a limited prohibition on only those mergers that will have a future effect). 43. See ENH Brief at 99-101

<sup>44.</sup> See FTC Brief at 68.

<sup>45.</sup> See ENH Brief at 61-65; ENH Reply Brief at 92-96.

<sup>46.</sup> See ENH Brief at 74-99.

<sup>47.</sup> See id. at 71.

<sup>48.</sup> See ENH Brief at 73

<sup>49.</sup> See id.

<sup>50.</sup> See id. at 99-101.

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reason why Highland Park could not have achieved the improvements absent the merger, especially given the nationwide trend that had been underway since before the merger to improve hospital quality. <sup>51</sup> It also disputed the proposition that Highland Park was in a weakened state with quality of care problems prior to the merger. <sup>52</sup>

In addition, the FTC offered evidence of its own that quality at ENH had not improved as claimed by Dr. Chassin. Dr. Patrick Romano (the FTC's quality expert) prepared a quantitative analysis comparing ENH outcomes to a control group of hospitals. 53 The analysis used administrative data (i.e., billing and claims data) and measures used by the Agency for Healthcare Research and Quality ("AHRQ") and Joint Commission on Accreditation of Healthcare Organizations ("JCAHO").<sup>54</sup> Through his analysis, Dr. Romano found no evidence of improvements at ENH in heart care, obstetrics, nursing, cancer care, psychiatric care or in other service lines.55

The parties each claimed that the other's expert's approach and findings were flawed. For instance, ENH argued that Dr. Romano's use of administrative data was not suitable for measuring quality because such data is not intended to evaluate quality.<sup>56</sup> As a result, it suffers from, among other things, variations and inaccuracies in coding and fails to appropriately account for severity. 57

Moreover, Dr. Romano's findings that quality at Highland Park had failed to improve post-merger were not statistically significant and his reliance on AHRQ measures and patient satisfaction data to determine whether improvements occurred represents an invalid approach.<sup>58</sup> The FTC contested Dr. Chassin's findings arguing, among other things, that 11 of the 16 improvements measured were implemented prior to the merger and that Dr. Chassin's data collection methodology was invalid because he failed to use an empirical qualitative survey tool in his approach.<sup>59</sup>

Burdens of proof: The emphases taken by the parties in their arguments concerning quality of care evidence were very much tied to a dispute regarding which side had the burden of proof as to quality of care propositions. Still, both parties sought to prove as much as possible to support their respective positions on guality of care. Thus, irrespective of which party has the ultimate burden of proving or discrediting quality of care improvements, for practical purposes, the underlying issue of how to assess evidence of quality in a consummated merger case remains a key issue.

ENH introduced evidence of quality of care improvements as part of the competitive effects analysis to rebut any presumption established by the FTC that the merger substantially lessened competition. <sup>60</sup> To that end, ENH claimed that its quality of care evidence was sufficient to rebut the presumption and that it was, therefore, the FTC's burden to present additional evidence of anticompetitive effects so that the court could weigh the pro- and anticompetitive outcomes of the merger<sup>61</sup> Because, according to ENH, the FTC did not present additional effects evidence, ENH contended that the FTC failed in its case in chief to show that anticompetitive effects outweigh the improvements in quality that ENH achieved through the merger.<sup>62</sup>

The FTC viewed ENH's quality evidence as supporting an efficiencies defense to the FTC's case in chief.63 With an efficiencies defense, the entire burden of proof rests on ENH, and the FTC insisted that it had no burden to disprove the claimed efficiencies with additional evidence.<sup>64</sup> Moreover, according to the FTC, ENH's burden of proving efficiencies is a substantial one because such claims must be verifiable and quantifiable so that the finder of fact can assess the likelihood and magnitude of the claim.<sup>65</sup> Furthermore, procompetitive benefits of improved quality of care not only must be merger-specific, they also must outweigh anticompetitive harms arising from the merger.<sup>66</sup> The FTC maintained that ENH failed to meet its burden of proof on all of these points.<sup>67</sup>

#### **D. Remedies**

Throughout the trial, the FTC held to the proposition that divestiture is the only remedy suitable to ensuring the return of competition to the market

57. See id.

- 59. See FTC Brief at 74-75.60. See ENH Reply Brief at 1, 96-98.
- 61. See id.
- 62. See id.
- 63. See FTC Brief at 66; FTC Reply Brief at 38.
- 64. See FTC Reply Brief at 38-39
- 65. See id.
- 66. See id. 67. See id. at 39.

<sup>52.</sup> See FTC Brief at 79-83; FTC Reply Brief at 33-36

<sup>53.</sup> See FTC Brief at 67-74; FTC Reply Brief at 39-41.

<sup>54.</sup> See FTC Brief at 68.

<sup>55.</sup> See id. at 67-74; FTC Reply Brief at 40-41. 56. See ENH Brief at 102.

<sup>58.</sup> See id. at 101-103; ENH Reply Brief at 80-91.

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for hospital services in the North Shore area of Chicago. To support its position, the FTC contended that the law requires the court to order divestiture upon a finding of liability.<sup>69</sup> That, however, may be stretching the bounds of the law because, as ENH pointed out, divestiture is an equitable remedy that need not be employed where there are alternative, less restrictive solutions that can redress the harm. 70 And, in fact, ENH provided two alternatives to divestiture.<sup>71</sup> Interestingly, a central focus of the FTC's proposed order and ENH's arguments against divestiture is the preservation of quality at Highland Park. For instance, the FTC requiring that proposed ENH provide all necessary assistance to ensure continuation of cardiac surgerv and other improvements at Highland Park.<sup>72</sup> ENH argued that divestiture is not in the public interest because it would undo many of the quality improvements achieved through merger.73 Thus, while the parties clearly have opposing views on whether divestiture is appropriate in this case, a key point to watch is how quality of care evidence is assessed in the context of remedies.

*FTC's proposed order:* The FTC has requested the complete divestiture of the Highland Park merger and imposition of other ancillary relief. <sup>74</sup> To accomplish the divestiture, the FTC proposed selling all of the assets of Highland Park to an approved acquirer. The assets to

be sold would include any additions and improvements made since the merger. And ENH would have to restore any assets and clinical services that no longer exist at Highland Park and take all necessary steps to ensure that cardiac surgery continues at the hospital. ENH would also need to comply with other ancillary relief, including ensuring the continuity of clinical practices employed through intellectual property (i.e., an electronic system medical record called "EPIC"), providing transitional clinical and administrative services to Highland Park, helping to recruit key personnel and physicians, maintaining confidential information, and terminating contracts with health plans. The FTC also proposed that a monitor be appointed to oversee the divestiture.

*ENH's alternative remedies:* To the extent that ENH is found to be liable for violating the Clayton Act, ENH offered two alternative remedies to a complete unwinding of the merger. The first remedy would impose an advanced notice requirement on ENH. <sup>75</sup>

If this remedy were to be imposed, ENH, for the next five years, would have to notify the FTC before engaging in any future acquisitions of providers of general acute care inpatient hospital services in whatever area he concludes is the relevant geographic market. Such a remedy recognizes prior wrongdoing, but acknowledges quality improvements achieved since the merger and accounts for the current and future competitive environment (e.g., quality-adjusted pricing; elimination of certificate of need laws in Illinois).

The second remedy proposed is a limitation on ENH's contracting The remedy would practices.<sup>76</sup> require ENH to negotiate and maintain separate managed care contracts for Evanston and Highland Park and acquiesce to the health plans' choice of pricing methodology (e.g., discount off charges, per diems, case rates). This remedy would acknowledge the quality improvements achieved since the merger and address payors' concerns that ENH required a single signature contract for all three hospitals.

#### **IV. Conclusion**

As shown in this relatively quick review of the briefs in the Evanston case, there are a number of key issues to watch for as the ALJ decision is rendered and, depending on the outcome, the case proceeds. These issues include - geographic market definition; analysis of postmerger price changes and available market constraints on such changes; and the measure and magnitude of post-merger quality of care evidence. In turn, these issues will bear on the "end game" guestion of what remedies, if any, are appropriate and, specifically, whether a merger that is now over five years old will ultimately be unscrambled.

<sup>69.</sup> See id.

<sup>70.</sup> See ENH Brief at 114; ENH Reply Brief at 99-100

<sup>71.</sup> See ENH Brief at 123-126.

<sup>72.</sup> See FTC Reply Brief at 57-60.

<sup>73.</sup> See ENH Brief at 116-120; ENH Reply Brief at 103-105.

<sup>74.</sup> See FTC Brief at 85-90; FTC Reply Brief at 55 75. See ENH Brief at 124-125

<sup>76.</sup> See id. at 125-126.

#### <u>Chronicle</u>

# **Rx for Caution: Economic Credentialing** and the Antitrust Laws

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#### I. OVERVIEW – "ECONOMIC CRE- General and health care law DENTIALING" UNDER **TRUST LAW**

"Economic credentialing," the prac- violates the Anti-Kickback Statute, tice by which health care provider raises other fraud and abuse issues, credentialing decisions are based on economic criteria unrelated to quality of care issues, has not received focused antitrust analysis from either academics, courts, or the federal antitrust enforcement there has been relatively little agencies. The need for such analysis is growing as economic credentialing is becoming a more pervasive practice by hospitals in making credentialing decisions. This article seeks to remedy the deficiency by examining the antitrust issues As a whole "the case law dealing raised by the various practices that with economic credentialing is constitute economic credentialing.

become an increasing concern for antitrust claims.<sup>5</sup> A recent economic health care providers, the American Medical Association, the Department of Health and Human Services' Office of the Inspector

**ANTI-** academics.<sup>1</sup> These concerns. however, have largely focused on whether economic credentialing threatens the quality of health care, or restricts patient and physician choice.<sup>2</sup> Aside from noting that the antitrust laws may apply to economic credentialing decisions, antitrust analysis of economic credentialing, as distinguished from peer review credentialing, by academic commentators and the courts.<sup>3</sup>

sparse." <sup>4</sup> Of the few decisions dealing directly with economic creden-Economic credentialing has recently tialing, none have addressed credentialing case, Mahan v. Avera St. Luke's <sup>6</sup> for example, only addressed the issue of whether a hospital board's decision to close its

staff violated the board's bylaws,<sup>7</sup> and not whether the board's action violated the antitrust laws.

The lack of judicial guidance on the possible antitrust risks associated with economic credentialing, in particular, is glaring given that the "most common type of private [health-care related antitrust] claims involve[] staff privileges (...35%), with a physician denied membership on a hospital medical staff suing the hospital and the staff physicians involved in the denial allegation that the action was taken to prevent competition from the newcomer."<sup>8</sup> The paucity of cases analyzing economic credentialing decisions from an antitrust perspective may, in at least part, be due to the general decline in federal enforcement and private antitrust claims based on hospital credentialing decisions as a result of "a shifting jurisprudence that is increasingly deferential to professionalism in the health market interactions."9

6. 621 N.W.2d 150 (S.D. 2001).

<sup>1.</sup> See John H. Sutton, Economic Credentialing: A Growing Concern, 87 Bull. Am. C. Surgeons 15, 15 (Dec. 2002) (examining recent trend of hospitals "using the tool of 'economic credentialing' to pressure surgeons into steering more care toward the hospital"); Richard A. Feidstein, Economic Credentialing and Exclusive Contracts, 9 Health L. 1, 1 (Fall 1996) ("[E]conomic credentialing is becoming an increasing source of tension between medical staffs and governing boards as the practice becomes increasingly attractive as a means of controlling costs"); American Medical Association ("AMA"), Economic Credentialing – Issues and Answers, http://www.ama-assn.org/ama/pub/category/print/10919.html (Mar. 7, 2005); Letter from Michael D. Maves, AMA, to Janet Rehnquist, OIG-71 Solicitation of New Safe Harbors and Special Fraud Alerts (Feb. 6, 2003) ("The AMA has received an increasing number of reports of hospitals making credentialing decisions based upon the level of physician's referrals to that hospital."); Department of Health and Human Services, Office of Inspector General, Solicitation of New Safe Harbors and Special Fraud Alerts (Feb. 6, 2003) ("The AMA has received an increasing number of reports of hospitals making credentialing decisions based upon the level of physician's referrals to that hospital."); Department of Health and Human Services, Office of Inspector General, Solicitation of New Safe Harbors and Special Fraud Alerts, 67 Fed. Reg. 72, 894, at 72, 895 (Dec. 9, 2020) (noting that "an increasing number of hospitals are refusing to grant staff privileges to physicians who (1) own or have other financial interests in, or leadership positions with, competing entities, or (3) fail to admit some specified percentage of their patients to the hospital.") (be codified at 42 C.F.R. pt. 1001); Department of Health and Human Services, Office of Inspector General ('OIG''), OIG Supplemental Compliance Program Guidance for Hospitals, 70 Fed. Reg. 4858, at 4869 (Jan. 31, 2006) (be codified at 42 C.F.R. pt. 1001).</p

<sup>(\*</sup>OIG\*), OIG Supplemental Compliance Program Guidance for Hospitals, 70 Fed. Reg. 4858, at 4869 (Jan. 31, 2006) (to be codified at 42 C.F.R. pt. 1001). 2. See, e.g., Michael A. Kurs, et al., Economic Credentialing: Are Hospital Privileges Contingent Upon Skills—Or Economics?, 67 Conn. Med. 225, 225 (April 2003) (\*The practice poses a serious threat to the economic and professional interests of physicians and also raises significant fraud and abus issues for credentialing hospitals.") (footnote omitted); Department of Health and Human Services, Office of Inspector General (\*OIG\*), Financial Arrangements Between Hospitals and Hospital-Based Physicians, OEI-09-89-00330, (finding some arrangements where physicians are required to pay more than fair market value for hospital services may violate the Anti-Kickback statute); Maves, supra note 1, at 1 (arguing that "[t]hese policies effectively prohibit a physician from referring patients to other facilities for fear of losing their medical staff membership or privileges [and] also stifles patient choice and interferes with the physician-patient relationship"); Memorandum from Barnes & Thornburg to American Medical Association, Exclusive Credentialing 2 (Sept. 25, 2002) (finding exclusive credentialing violates Anti-Kickback law, and "results in higher program costs and, potentially, lower quality patient care"). 3. See, e.g., 2. John Miles, Health Care & Antitrust Law: Principles and Practice § 10:15, at 10-128 (2005) (finding that the "analytical framework [for assessing credentialing decisions based on peer review"); Sandra DiFranco, Denying Medical Staff Privileges Based on Economic Credentials, 242, 362 (1994) (if an adverse peer review decision were based solely upon economic criteria, a stronger antitrust case may be brought by a disgruntied physician [because] economic credentialing would not fail under the protection of the HCQIA immunity provisions."); Thomas L. Greaney, Managed Competition, Integrated Delivery Systems and Antitrust, 79 Cornell L. Rev

<sup>4.</sup> John D. Blum, The Evolution of Physician Credentialing into Managed Care Selective Contracting, 22 Am. J. L. & Medicine 173, 183 (1996); see also Daniel D. King & Joel T. Allison, Medical Staff Credentialing: Taking Steps to Avoid Liability, 61 Def. Couns. J. 107, 113 (1994) (noting that "economic credentialing lawsuits are a recent addition to the colorful panorama of medical litigation"). 5. C.f. Leonard A. Hagen, Physician Credentialing: Economic Criteria Compete with the Hippocratic Oath, 31 Gonz. L. Rev. 427, 446 (1996) (noting that "no court has directly addressed th[e] question" of whether using economic criteria to "adversely impact a provider's ability to practice medicine...will...withstand legal challenges").

<sup>7.</sup> Id. at 153.; see also Jennifer Wagner, Mahan v. Avera St Luke's: Has the South Dakota Supreme Court Set a Precedent Allowing Non-Profit Hospitals the Right to Eliminate Competitors?, 49 S.D. L. Rev. 573 (2004) (analyzing the breach of contract claim based on the hospital's economic credentialing).

<sup>Rev. 573 (2004) (analyzing the breach of contract claim based on the hospital's economic credentialing).
Peter J. Hammer & William H. Sage, Antitrust, Health Care Quality, and the Courts, 102 Colum. L. Rev. 545, 568 (2002); see also John A. Rizzo & John H. Goddeeris, The Economic Returns to Hospital Admitting Privileges, 23 J. Health Pol. Pol'y & L. 483, 484 (June 1998) ("The most numerous antitrust cases in health care markets involve denial or termination of staff privileges.") (citations omitted); 2
Miles, supra note 3, § 10:1, at 10-3 ("By far, the most frequent type of antirust case in the health care sector has been the 'staff-privilege antirust case.""). The second type of private antitrust litigation brought by physicians against hospital's involve "a hospital's decision to grant an exclusive contract to one physician or physician group to provide professional services in a department of the hospital, such as an emergency room or radiology suite (106 disputes; 28%)." Hammer & Sage, supra, at 568.
Thomas L. Greaney, Whither Antitrust? The Uncertain Future of Competition Law in Health Care, 21 Health Affairs 185 (2002); see also 2 Miles, supra note 3, § 10:15, at 10-114 ("So few staff-privilege antitrust decisions have reached this point in litigation that little precise guidance exists."); Sage & Hammer, supra note 8, at 575 (finding that "plaintiffs were least successful in staff privileges cases, largely have been 'inhospitable' to these cases, except when there has been 'clear evidence of bad faith by rival physicians on the hospital's medical staff[, which has] resulted in large demand awards.") (quoting William H. Sage, et al., Why Competition Law Matters to Health Care Quality, 22 Health Affairs 31, 37 (Mar./Apr. 2003) (alteration in original)).</sup> 

Despite this trend. credentialing is unlikely to continue to escape antitrust scrutiny because the rationale for deferring to hospitals and peer review boards on credentialing decisions based on quality of care issues does not extend to decisions based on economic criteria<sup>10</sup> Therefore, there is a growing need to understand the antitrust issues economic credentialing.

#### II. WHAT IS ECONOMIC CREDEN-TIALING?

Another factor possibly contributing to the lack of judicial and academic antitrust analysis of economic credentialing is that there is no uniformly accepted definition of economic credentialing.<sup>11</sup> "Significantly, the lack of a consensus on just what economic credentialing is or how it should be conducted has created difficulty in studying this evolving area of analysis." 12 The American Medical Association's ("AMA's") definition. which is frequently cited and is similar to most other definitions, defines economic credentialing as "the use of economic criteria unrelated to quality of care or professional com-

economic petence in determining a physician's qualifications for initial or continuing hospital medical staff membership or privileges." <sup>13</sup> The AMA's definition of economic credentialing, however, "does little to actually define the term." 14

Specific examples of economic credentialing practices and the idenunderlying tification of economic criteria used in economic credentialing decisions are more helpful. The American Society of Anesthesiologists, for example, uses economic measures to define economic credentialing as:

> economic profiling, including the conditioning of medical staff privileges on the making of direct or indirect payments to the hospital or its agents in amounts that exceed the fair market value of facilities or services provided to the medical staff member, or the conditioning of privileges on the requirement that members of a particular department of the medical staff accept less than fair market value for the provision of care to patients in the hospital.<sup>15</sup>

Physician profiling, which is the collection of economic data on a

physician's practice, is "the major mechanism for implementing economic credentialing." 16 An example of the way a hospital may use profiling data to implement economic credentialing is to "keep track of the number of patients admitted by physicians and include that among the criteria used in determining whether to renew that physician's medical staff privileges."17 Hospitals also track data by diagnosis-related group to evaluate a physician's economic efficiency for credentialing purposes. This data includes: length of stay and charges, length of stay and charges adjusted by severity of illness, "[u]tilization review denials, [b]ad debt expenses, [t]imeliness of record completion, and [i]ncident reports." 18

Some other examples of economic credentialing practices used by hospitals, outside of physician profiling, include:

 Conditioning privileges on a staff member not having a "financial conflict of interest" with the hospital;19

Requiring "loyalty oaths" or

16. Feidstein, supra note 1, at 5.

17. Francis J. Serbaroli, Hospitals, Physicians and 'Economic Credentialing', 231 New York L. J. (May 26, 2004) (reprinted from National Law Journal (May 26, 2004)); see also Hagen, supra note 11, at 442 (identifying one category of "pure" economic credentialing to be evaluating "a physician's performance data to select only those demonstrating the desired level of [economic] resource utilization"). 18. Orie, supra note 11, at 442 (footnotes omitted); see also Feidstein, supra note 1, at 5 (identifying criteria that apply no quality considerations, including: "Personal Referral Patterns[;] Concurrent DRG Review[:] Operating Room Under Utilization[:] Low Census or Admission Rates[:] Revenue Per Physician.").

See Blum, Hospital-Medical Staff Relations in the Face of Shifting Institutional Business Strategies: A Legal Analysis, supra note 3, at 592 ("[1]f a court adopts the position that a physician's privileges should only be evaluated by use of traditional quality standards, the newly adopted economic criteria may be subjected to a higher degree of scruiny."); Rizzo & Goddeeris, supra note 8, at 483 ("With the growing emphasis on managed care, physicians are being scrutinized both in terms of the quality of care they deliver and their impact on economic performance of hospitals and managed care organizations. This suggests that the frequency of lawsuits involving the denial or rescission of medical staff privileges may assume an even greater importance.").
 See, e.g., Paul Danello, Economic Credentialing: Where is it Going?, available at http://library.lp.findlaw.com/articles/file/00989/009358/title/Subject/topic/Professional%20Malpractice\_Medical%20Malpractice/filename/professionalmalpractice\_2\_5109 (2003) ("There is no generally accepted definition of 'economic credentialing."); Feidstein, supra note 1, at 1 ("There is little agreement in the industry on the definition of 'economic credentialing."); Evenard A. 1 agen, Physician Credentialing: Economic credentialing is no uniform definition of 'economic credentialing."); Kurs, et al., supra note 2, at 225 ("[T]here is no uniform definition of 'economic credentialing wists.").
 Bum Hospital-Medical Staff Relations in the Eace of Shifting Institutional Business Strategies: A Legal Analysis, supra note 3, at 592 ("[] a court adopts the position that a physician's privileges in the industry on the definition of 'economic credentialing."); Kurs, et al., supra note 2, at 225 ("[T]here is no uniform definition of 'economic credentialing."); Judith E. Orie, Economic Credentialing: Bottom-Line Medical Care, 36 Duq. L. Rev. 437, 442 (1998) ("No universal definition of 'economic credentialing exists.").
 Bum Hospital-Medicinal

<sup>12.</sup> Blum, Hospital-Medical Staff Relations in the Face of Shifting Institutional Business Strategies: A Legal Analysis, supra note 3, at 583.

<sup>12.</sup> Blum, Hospital-Medical Staff Relations in the Face of Shifting Institutional Business Strategies: A Legal Analysis, supra note 3, at 583. 13. AMA, supra note 1; accord American College of Medical Quality, Policy 19: Economic Credentialing, available at http://www.acmq.org/profess/policy19.htm (11/13/97) ("Economic credentialing defines a health care professional's qualifications based solely on economic factors which are unrelated to the individual's ability to make standard of care medical review or direct clinical care decisions. It involves the use of economic criteria by a health care organization as the only factor which determines a physician's or other health care professional's qualifications for initiation, or revocation of medical care or peer review privileges."); American College of Emergency Physicians, Economic Credentialing, available at http://www.acep.org/1,451,0.html (October 2001) ("[T]he use of economic factors unrelated to quality of care or professional competency either in determining a physician's for initial or continuing hospital medical staff membership or privileges, or in evaluating physician performance within other health care organizations."); David J. Behinfar, Exclusive Contracting Between Hospitals and Physicians and the Use of Economic Credentialing, 1DePaul J. Health Care L. 71, 83 (1996) ("Economic credentialing refers to the use of economic criteria, unrelated to quality of care or professional's qualifications for initial or continuing medical staff privileges."); c.f. Orie, supra note 11, at 442 ("[]]t is commonly defined as the practice of applying economic data and efficiency criteria to hospital medical staff appointment and reappointment decisions.").

<sup>14.</sup> Hagen, supra note 11, at 442

<sup>15.</sup> American Society of Anesthesiologists House of Delegates, Statement on Economic Credentialing, (affirmed 10/15/03).

<sup>19.</sup> Kurs, et al., supra note 2, at 225; see also Danello, supra note 11, at \*1 ("In recent years hospitals have increasingly adopted 'conflict-of-interest and credentialing policies that, more or less explicitly, condition the grant or renewal of medical staff privileges on patient referrals.").

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competing facilities as a condition hospital; 20

- Requiring a physician seeking privileges to admit a certain percentage of patients to the hospital or to practice exclusively at the hospital; 21
- Conditioning a pathologist's opportunity to perform Part B services on not receiving reimbursement for Part A services; 22
- · Requiring radiologists to pay 50% of their gross receipts to a facility endowment fund; 23
- Requiring 33% of all profits above a set amount be paid by a radiology group to the hospital for capital improvements;<sup>24</sup>
- purchase equipment and donate it to the hospital at the termination of the program, while the hospital had the right to terminate the program; <sup>25</sup> and
- Requiring 50% of any net collection over \$230,000 to go to the hospital.<sup>26</sup>

The common element of all these examples of credentialing practices

promises not to refer patients to is the hospitals' conditioning the grant or renewal of physician priviof continued privileges with the leges on economic criteria, or on economic commitments, that are unrelated to quality of care. These practices diverge from the traditional approach of granting hospital privileges based solely on the evaluation of the physician's ability to provide quality health care.<sup>27</sup> The reasons for this divergence are discussed in the next section.

#### III. THE REASONS FOR ECO-NOMIC CREDENTIALING

The rise in economic credentialing is largely due to the advent of managed care. 28 Although managed care's history in the United States can be traced to "as early as the 19th century," it "remained a minor phenomenon until the 1970s."<sup>29</sup> In the late 1960s, rapid developments in medical technology began to · Requiring a radiology group to strain the cost-inefficient fee-forservice health delivery system.<sup>30</sup> By the 1980s and mid-90s, dramatic increases in health care costs and decreases in profits pushed managed care into prominence over fee-for-service. 31 The roots of market imperfections in the fee-forservice system are primarily found in both the nature of demand for medical services and the decisionmaking authority given to health care providers over patient care

decisions due to the asymmetry in information between health care providers and patients.

demand for medical Patient services, in general, and new medical technology, in particular, is inherently different than the nature of demand for most other goods. "The most obvious distinguishing characteristics of an individual's demand for medical services is that it is not steady in origin as, for example, food or clothing, but irregular and unpredictable." 32 Although patient demand for medical care is subject to medical need, when such a need arises patients and medical care providers, especially under the feefor-service system of the 1960s and early 1970s, are essentially indifferent to the price of different treatment modalities.33 ("Moral hazard" is sometimes used to describe consumers who fail to fully internalize the price or cost of an economic decision.)

Because patients are typically uninformed about the available medical treatments for their illnesses, the diffusion of this medical technology was driven by physicians possessing a great deal of decision-making autonomy in the fee-for-service health care delivery system of the day.<sup>34</sup> Supplying newly developed medical technology to physicians,

20. Kurs, et al., supra note 2, at 225; see also see also Danello, supra note 11, at \*1; Maves, supra note 1, at 1 ("The alleged rationale for these policies is to avoid 'conflicts of interest' by physicians having privileges at other hospitals, or other competing entities, to ensure the 'long-term viability of a hospital' or to assure 'commitment' or 'loyalty' to the hospital.").

- 21. See Kurs, et al., supra note 2, at 225; Barnes & Thornburg, supra note 2, at 2 (defining "exclusive credentialing," which the authors treat as a subset of economic credentialing, as "any policy adopted by a hospital that effectively requires physicians on staff to refer only to that hospital by prohibiting its staff physicians from referring to other facilities"). 22. See OIG, supra note 2, at 3.
- 23. See id.

26. See id.

28. See, e.g., Hagen, supra note 11, at 430 ("The recent emergence of economic credentialing is due largely to its use in managed care organizations ('MCO') that use discounted provider contracts and efficient utilization of resources to reduce hospital beds by up to 75%."); Orie, supra note 11, at 442 ("The evolution of managed care led directly to the proliferation of economic credentialing."). 29. Gail B. Argawal & Howard R. Veit, Back to the Future: The Managed Care Revolution, 65 Law & Contemp. Probs. 11, 15 (2002); see also David Dranove, The Economic Evolution of American Health Care 36 (2000) (noting that one researcher "traces the origins of managed care back to the 1890s").

30. See Argawal & Veit, supra note 29, at 15; see also Annetine C. Gelijns, et al., Uncertainty and Technological Change in Medicine, 26 J. Health Pol. Pol'y & L. 913, 914 (2001) ("Since the 1960s, the technological contours of clinical practice have undergone considerable change.").

31. See, e.g., Hagen, supra note 11, at 428 ("Health care costs in the United States have tripled from 1980 to 1992, and were expected to reach \$1 trillion by the end of 1995."); Orie, supra note 11, at 440 (noting that as a result of rising medical costs 'in the 1990s, managed care has become the dominant force in American health care"); FTC & DOJ, supra note 9, at ch. 1, 2 ("Managed care existed for most of the 20th century, but did not spread widely until the 1980s and early 1990s."). C.f. Blum, supra note 3, at 561 ("Between 1980 and 1989, low profit margins and competition for patients, physicians, and managed care contracts largely contributed tot he closure of 698 hospitals.").

32. Kenneth J. Arrow, Uncertainty and the Welfare Economics of Medical Care, 26 J. Health Pol. Pol'y & L. 851, 858 (2001).

33. See, e.g., Dranove, supra note 29, at 29 ("In 1960s and 1970s, not everyone believed that the price of medical care mattered. Many people, including most health care providers, argued that demand was entirely based on need."); Hagen, supra note 11, at 432 ("During the last decade, there has been a noticeable shift from the paradigm of the primary physician practicing quality health care with little concern for costs.")

34. See Argawal & Veit, supra note 30, at 15; Arrow, supra note 32, at 875 ("As a second consequence of informational inequality between physician and patient and the lack of insurance of a suitable type, the patient must delegate to the physician much of his freedom of choice."); Dranove, supra note 29, at 28 (noting that "[f]or most of the twentieth century, the traditional U.S. health economy had three defining features: 1. Patients relied on autonomous physicians to act as their agents. 2. Patients received complex care from independent, non profit hospitals. 3. Insurers did not intervene in medical decision making and reimbursed physicians, hospitals, and other providers on a fee-for-service basis"); Greaney, supra note 3, at 1510 ("Uninformed patients delegate authority to physicians to make appropriate decisions on their behalf.")

<sup>24.</sup> See id.

<sup>25.</sup> See id.

<sup>27.</sup> See, e.g., Hagen, supra note 11, at 431 ("Traditionally, the quality of care has been the sole focus of credentialing standards for physicians."); Blum, supra note 4, at 177 (noting that "[b]etween 1965 and the late 1980s, the dynamics of credentialing did not change significantly").

who did not internalize the various among several potentially appropricosts associated with using these new treatment modalities, lead to "wide variations in medical practice associated with improved not outcomes or differential medical need. The delivery system was increasingly characterized by large numbers of seemingly inappropriate medical interventions and unnecessary, or inappropriately long, hospital stays." <sup>35</sup> It is only rational that in a health delivery system where taking precautions with respect to patient care are costless to the treating physician, and the medical malpractice exposure for providing inadequate or incomplete medical care is high, more medical interventions would be taken, even if those interventions contribute little to The economic credentialing pracimproved clinical outcomes.

In addition to health care providers' failures in internalizing the costs of various medical treatments, physicians' personal financial incentives may have contributed to the wide variations in medical interventions. Although patients and medical ethics expect that the "[a]dvice given by physicians as to further treatment by himself or others is supposed to be completely divorced from selfinterest," <sup>36</sup> there is a wide-spread perception that physicians induce, at least to some degree, patient demand for health services. 37

Physicians may end up inducing demand for medical services under various circumstances. Under relatively innocuous circumstances. physicians may induce patient demand for medical services where vague symptoms or clinical indications make it difficult to decide

ate medical interventions, so the physician ends up selecting the most expensive treatment modality. 38 Under more extreme self-interested circumstances, а physician may simply "ignore unambiguous clinical indications to pursue financial goals." 39

Economic credentialing practices emerged as part of the set of tools managed organizations care employed to combat both the failure of health care providers to internalize the costs of various treatments and physicians' incentives to recommend more expensive medical interventions.

tices of exclusive contracting and economic profiling, for example, may reduce the overall cost of health care by "spur[ring] price competition because providers vie for participating provider status by lowering prices and practicing costeffective, high quality medicine in return for the promise of more patients." <sup>40</sup> As hospitals increase their revenues by increasing patient admissions, they seek medical staff who can admit more patients by offering the same quality of health care at lower prices. One way for a hospital to identify the most efficient physicians or physician groups is by letting them compete on price and guality for limited, lucrative medical staff privileges.

Another way is to review an applicant's utilization records or economic profile, such as data on length of stay, number of ICU days, excessive and redundant testing,

unnecessary treatments, government sanctions, incidence of reimbursement denials, etc., in deciding whether to grant staff privileges. 41 A particular health care provider inefficient utilization may have records for a variety of reasons. Health care providers who are primarily concerned with providing patients with the highest quality care available, or who are concerned with insulating themselves against malpractice claims, may order more diagnostic work or treatment than is clinically required by a patient's indications, especially when the health care provider does not bear the cost of the added diagnostic work or medical treatments. Utilization review may serve as a "means to fight moral hazard and providerinduced demand: [because] providers risk losing access to patients if they fail to adhere to utilization protocols." 42

The economic credentialing practice of conditioning privileges on medical staff members not having a financial conflict of interest with the hospital, for example, may also help guard against physician inducement of demand. Physicians typically do not have financial interests in the hospitals granting them privileges. Therefore, physicians typically have no financial incentive in recommending other hospital services to patients. But, physicians increasingly have financial incentives in ambulatory and tertiary care centers competing with hospitals. "The exploding growth of ambulatory surgery centers and single-specialty outpatient facilitiessurgical coupled with advances in technology that have made these venues

40. Greaney, supra note 3, at 1540.

<sup>35.</sup> See Argawal & Veit, supra note 30, at 15-16; see also Dranove, supra note 29, at 45 ("Of all the factors that contribute to rising health care costs, economists have singled out technological change as the biggest culprit.").

<sup>36.</sup> Arrow, supra note 32, at 859-60.

<sup>37.</sup> See Dranove, supra note 29, at 32 (noting that some of the most fundamental changes brought about by managed care, especially the widespread use of capitation, are direct responses to a perception of wide-spread inducement"); Hagen, supra note 11, at 430 ("Most analyst agree that economic incentives impact a physician's clinical practice.").

<sup>38.</sup> See Dranove, supra note 29, at 33. 39 Id

<sup>41.</sup> See Feidstein, supra note 1, at 5. 42. Greaney, supra note 3, at 1540.

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safe alternatives to resulted settings-have in an increasing number of procedures being shifted out of the confines of the hospital." <sup>43</sup> Physicians invest in these facilities, at least in part, as a means of securina additional revenues in times when their specialty fees are declining.<sup>44</sup> Under circumstances where a patient's medical needs can be equally served by both a hospital and an ambulatory care center, in which a physician has an equity interest, the physician may have financial incentive to direct the patient to the ambulatory care center, even if the center is not as economically efficient as the hospital.

#### IV. DOES ECONOMIC CREDEN-TIALING CHANGE THE EXISTING ANTITRUST FRAMEWORK FOR PEER REVIEW CREDENTIAL-ING?

Will plaintiffs bringing antitrust lawsuits based on economic credentialing decisions be more successful than those challenging peer-review credentialing decisions? This antitrust analysis first discusses whether challenges to credentialing decisions that are based on economic criteria, rather than quality of care issues, are covered by the immunity provided by the Health Care Quality Immunity Act ("HCQIA") of 1986.<sup>45</sup> Second, it **Economic Credentialing** examines whether hospitals employing economic credentialing

inpatient practices are less likely to be protected by the state action doctrine than hospitals denying staff privileges on the basis of quality of care decisions. Third, the available per se theories under Section 1 against hospitals and medical staffs in the credentialing context are addressed. The two principal per se theories in the physiciancredentialing context are: 1) that the denial was part of an illegal group boycott between the hospital and the hospital's medical staff, or 2) that the denial resulted from an illegal tying arrangement of hospital with specialty services health services. Finally, the rule-of-reason analysis is considered to examine how its application to economic credentialing decisions may yield different results than as applied to peer-review credentialing decisions. Rule-of-reason theories in peerreview cases typically allege either: 1) that the denial was based on an anticompetitive agreement between the hospital and the hospital's medical staff to restrain trade; or 2) that the denial of hospital privileges is effectively denving the plaintiff access to an essential facility. None of these theories have been historically successful for plaintiffs in peer review cases.<sup>46</sup>

> A. Immunities Potentially Applicable to Antitrust Challenges to

1. Immunity under HCQIA

HCQIA insulates from antitrust immunity only those credentialing decisions based on the reasonable belief that the decision would further quality of health care.<sup>47</sup> A denial of staff privileges resulting from economic considerations unrelated to the quality of health care would not fall within HCQIA's immunity. "because basing a credentialing decision solely upon economic considerations does not relate to the competence or professional conduct of a physician." 48

#### 2. State Action Doctrine

In addition, hospitals engaging in economic credentialing may not receive the same protection under the state action doctrine as those engaging in traditional peer review credentialing. The state action doctrine immunizes from antitrust liability anticompetitive conduct that is both contemplated by the state pursuant to a clearly articulated and affirmatively expressed state policy and is subject to active supervision by the state. The Ninth Circuit found, in Patrick v. Burget, 49 that Oregon's health care statute contemplated peer review as part of the state's licensing procedures, and, in doing so, both affirmatively expressed a clearly articulated policy of replacing pure competition with licensing regulation and actively supervised decisions regarding the termination and licensing of physicians.<sup>50</sup>

<sup>43.</sup> Sutton, supra note 1, at 16.

<sup>44.</sup> See id.

<sup>45. 42</sup> U.S.C.A. § 11101-52.

<sup>46.</sup> See supra note 9. 47. 42 U.S.C.A. § 11112(a).

<sup>48.</sup> Dallet, supra note 3, at 361.

<sup>49. 800</sup> F.2d 1498 (9th Cir. 1986), rev'd, 486 U.S. 94 (1988).

<sup>50.</sup> See id. 1505-07.

Therefore, the clinic's denial of that unreasonably restrains compephysician privileges was "exempt tition. from liability under the state action impact, if any, certain conduct may doctrine." 51

Ninth Circuit, because it found that old issue of whether the conduct in the challenged conduct was not question is indeed concerted as actively supervised by the state opposed to unilateral. itself. 52 For conduct to be actively supervised by the state, the state The Third Circuit in Weiss v. York must "exercise ultimate control over Hospital<sup>58</sup> court, for example, held challenged the conduct." <sup>53</sup> The state official must medical not only have the power to review conspire with each other, but that a credentialing decisions, but must hospital and its medical staff could actually use the power to supervise not conspire with each other.<sup>59</sup> peer-review decisions.<sup>54</sup> In reality, Medical staff members could legally Oregon's law specified no way in conspire with each other because which state officials could review the each member has "an economic peer-review process, or actual interest separate from and in many credentialing decisions. 55 since Parker. however. granted hospitals state action immu- bers." 60 nity for their credentialing decisions. It would appear less likely that a The Ninth Circuit in Oltz v. St. state would review credentialing Peter's Community Hospital,<sup>61</sup> decisions based on economic crite- the other hand, found that a hospital ria. 56

# 1 of The Sherman Act.

staff credentialing decisions in the reason peer-review area have alleged viola- conspire with its officers and directions of Section 1 of the Sherman tors, Oltz was persuaded by the Act.<sup>57</sup> Section 1 broadly prohibits Eleventh Circuit's rejection of this any contract. combination, conspiracy-i.e., action-between or among two or reasoned that the hospital and its more independent economic actors medical staff differed from a corpo-

Before determining what have had on competition, Section 1 challenges to credentialing deci-The Supreme Court reversed the sions very often confront the thresh-

> anticompetitive as a matter of law, that individual staff members could

> > Courts cases in competition with the interhave ests of other medical staff mem-

on could conspire with its staff. Although it acknowledged that some B. Per Se Theories Under Section cases, like Weiss and Potters Medical Center v. City Hospital Associa*tion*,<sup>62</sup> held that a hospital cannot Most antitrust challenges to medical conspire with its staff for the same а corporation cannot or analogy in Bolt v. Halifax Hosp. concerted Medical Center.63 The Bolt court

ration and its officers and directors because each member of the "hospital and each member of the medical staff were legally separate entities." 64 This apparent split may turn on the extent to which the hospital or hospital board of trustees delegates peer review and credentialing authority to its medical staff.65 For Section 1 purposes, a court is more likely to find that a hospital and its medical staff are capable of conspiring with each other where medical staff possesses autonomy in credentialing decisions.

Once the requisite multiplicity of actors has been established, the next and usually the central issue in any case becomes whether the concerted action in question had an overall anticompetitive effect on competition. Courts have developed two primary standards for assessing economic effect and thus antitrust liability: the rule-of-reason and per se rule. The rule-of-reason entails a relatively rigorous balancing test, which seeks to weigh any anticompetitive effects flowing from concerted conduct. Conduct that on balance has a net anticompetitive effect on competition will be deemed to restrain trade unreasonably and thereby violate Section 1.

Unlike the rule-of-reason, the per se rule does not require any detailed economic analysis of the competitive consequences of concerted conduct. Rather, the courts have identified a very limited number of

61. 861 F.2d 1440 (9th Cir. 1998).

<sup>51.</sup> ld. at 1501.

<sup>52.</sup> Patrick v. Burget, 486 U.S. 94, 106 (1988).

<sup>53.</sup> Id. at 101.

<sup>54</sup> Id at 101-02

<sup>55.</sup> ld. at 104. 56. See, e.g., Todorov v. DCH Healthcare Authority, 921, F.2d 1438, 1460 (11th Cir. 1991).

<sup>57. &</sup>quot;Every contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among several States, or with foreign nations, is declared to be illegal." 15 U.S.C. § 1 (2000).

<sup>58. 745</sup> F.2d 786 (3d Cir. 1984).

<sup>59.</sup> Id. at 814-15. Without any analysis, the Weiss court affirmed the lower court's holding that a hospital, as a matter of law, could not conspire with its medical staff. The Third Circuit did mention the lower court's instruction to the jury "that the medical staff was an 'unincorporated division' of the hospital, and as such the two were legally a 'single entity' incapable of conspiring." Id. at 813. The lower court added "that the hospital, as a corporation, could act only through its 'officers and agents," and that the medical staff were, in fact, the hospital's agents. Id. 60. ld. at 815.

<sup>62. 800</sup> F.2d 568 (6th Cir. 1986).

<sup>63. 851</sup> F.2d 568 573 (11th Cir. 1998)

<sup>64.</sup> Oltz, 861 F.2d at 1450 (citing Bolt, 851 F.2d at 1280).

<sup>65.</sup> See Oksanen v. Page Mem'l Hosp., 945 F.2d 696, 704 (4th Cir. 1991) (finding that the "critical element of delegated authority was absent" in Oltz).

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have such a pernicious effect on competition that courts will conclusively presume the acts, once proven, have adversely affected competition and thus violated the antitrust laws. The courts have limited application of the per se rule over the years and in the last two or three decades have exhibited a willingness to subject traditionally per se unlawful conduct to at least an abbreviated competitive effects analysis.

In any event, with respect to the credentialing cases, antitrust claimants have tried to invoke the per se rule most often under two different the credentialing theories-that process amounts to either (1) a group boycott or (2) a tying arrangement. Group boycotts (or concerted refusals to deal) are the most common theory leveled against credentialing decisions. A group boycott refers to an agreement among competitors, or among a supplier and customers, that the parties to the arrangement will not deal with a third-party, which typically competes against one or more parties to the agreement. The paradigmatic group boycott involves an agreement among competing retailers, at one level of the distribution chain, to threaten to boycott a manufacturer or group of manufacturers, from which the retailers purchase products for resale, if the manufacturers sell to other competing retailers, thereby enabling the other retailers to distribute the manufacturers' products. Typically, when analyzing an arrangement between a hospital and its medical

acts that experience has shown staff, the hospital is "the equivalent of the manufacturer in the example of a classical boycott."66 "Similarly, the M.D.s are the equivalent of the retailers..., in the sense that the physicians require access to a hospital in order to effectively treat patients." 67 Under this theory, the hospital's existing medical staff conspire with each other to threaten the hospital with a boycott if the hospital grants privileges to health care providers in competition with the conspiring medical staff.

> Group boycotts were traditionally considered per se unlawful. The however, have ceased courts. applying the per se rule to all group boycotts.<sup>68</sup> Thus, not every boycott of health care providers by hospitals and medical staff is treated as a per se violations of Section 1.69 Some courts have treated boycotts as per se violations if they fit the "classical" group boycott theory where "competitors agree with each other not to deal with a supplier or distributor if it continues to serve a competitor whom they seek to injure."70 Others ask if the boycott "would almost always tend to be predominantly anticompetitive." 71 Still, other courts treat boycotts as "illegal per se only if used to enforce agreements that are themselves illegal per se-for example pricing fixing agreements."72 elements: 1) the "tying" product and Other circuits treat a group boycott as per se illegal only if there "is an agreement among conspirators whose market positions are horizontal to each other."<sup>73</sup>

It would appear that the most plausible scenario in which the denial of hospital privileges due to economic

factors unrelated to quality of care might be treated as part of a per se group boycott is if the hospital's medical staff conspired to fix the fees for their specialty services, and then threatened to boycott the hospital if it granted privileges to competing health care providers. The other economic credentialing practices, such as economic profiling and utilization review, are less likely to be the result of a conspiracy among physicians, and subsequently less likely to be part of a per se group boycott, because it is the hospitals, not the physicians, who benefit from these practices.

Outside of group boycotts, the other per se theory applied to credentialing decisions is tying. Tying refers to the practice whereby a seller conditions the sale of a highly desirable product, "tying product," on the buyer's purchase of a second product, the "tied product," that the buyer would prefer to buy from someone else or not at all. The per se rule, as applied to tying, requires some degree of market analysis and, accordingly, does not allow for the same abbreviated analysis as do most per se rules. To prove a tying arrangement in violation of Section 1 of the Sherman Act, a plaintiff must establish the following the "tied" product are actually two distinct products; 2) an agreement to sell the tying product only on the condition that the tied product is also purchased; 3) market power in the market for the tying product; and 4) the tied product affects a "not insubstantial" amount of interstate commerce. Generally, a tying arrange-

<sup>66.</sup> Weiss, 745 F.2d at 819.

<sup>67.</sup> ld.

<sup>68.</sup> See, e.g., Northwest Wholesale Stationers, Inc. v. Pacific Stationery & Printing Co., 472 U.S. 284, 294 (1985)

<sup>69.</sup> See, e.g., U.S. Health Care, Inc. v. Healthsource, Inc., 986 F.2d 589, 593 (1st Cir. 1993) (noting that "per se condemnation is not visited on every arrangement that might, as a matter of language, be called a group boycott or concerted refusal to deal").

<sup>70.</sup> U.S. Health Care, Inc., 986 F.2d at 593; see also, Weiss, 745 F.2d at 821.

<sup>71.</sup> Bhan v. NME Hosps., Inc., 929 F.2d 1404, 1412 (9th Cir. 1991) (finding a boycott where a "hospital eliminates a class of providers...to [not] be one that is always anticompetitive").

<sup>72.</sup> Collins v. Associated Pathologists, Ltd., 844 F.2d 473, 479 (7th Cir. 1988) (quoting Marese v. American Academy of Orthopaedic Surgeons, 726 F.2d 1150, 1155 (7th Cir. 1984) (en banc)). 73. Coffey v. Healthtrust, Inc., 955 F.2d 1388, 1392 (10th Cir, 1992).

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ment, in the physician-credentialing eight per cent to provide a reserve context, is found where patients for uncollectible accounts, the fees must purchase both services and specialty services from divided equally between [the anesthe hospital,<sup>74</sup> and where there is thesia group] and the hospital." <sup>80</sup> "sufficient demand for the purchase Under this requirement, unless it of [specialty] services separate from can be shown that the hospital hospital services to identify a distinct directly benefits from the provision product market in which it is efficient of the specialty service (i.e., the tied to offer [specialty] services sepa- product), there is no tying agreerately from hospital services."75 For ment.81 a tying arrangement to be per se illegal, the hospital must have power The only economic credentialing to force patients to make purchases practice susceptible to a per se tying of specialty services "that would not claim is where a physician-specialist otherwise be made." 76

reached different conclusions as to of the hospital's choosing that the whether demand exists for the patients would not have otherwise specialty physician services sepa- chosen for themselves. rate from the demand for the hospi- claims would follow essentially the tal services. In Collins, for example, same pattern as those brought in the court found that pathology the "peer-review" context, and may services were not a separate market be difficult to sustain where the from hospital services, because hospital does not have a direct benpatients almost never request, and efit in the tied specialty service. physicians almost never designate, specific pathologists.<sup>77</sup> The court in C. Rule-of-Reason Theories Oltz v. St. Peter's Community Hospital,<sup>78</sup> on the other hand, found that In addition to group boycott and there was separate demand for tying claims that are not afforded per anesthesia services because there se treatment, rule-of-reason theowas evidence that specific anesthe- ries siologists were requested, albeit not arrangements under both Section 1 in the context of a tying claim.79

Some courts have fashioned a zation theories under Section 2. In "direct economic benefit" require- the typical case, a specialist or class ment to tying claims based on the of health care providers, who were statement in a footnote of Jefferson denied privileges at a local hospital, Parish that "[a]fter a deduction of

hospital [for anesthesiological services] are

is denied staff privileges because a hospital, with market power, forces Courts since Jefferson Parish have its patients to use specialty services These

include exclusive dealing and Section 2, as well as essential facilities claims and other monopoliallege "an unlawful conspiracy

among [specialty health care] providers and the local hospital to enter into an exclusive dealing contract and eliminate competition" in violation of Section 1.82 Similarly, a smaller hospital may claim that a dominant hospital's refusal to grant staff privileges to the smaller hospital's physicians violates Section 2.83 To state a claim under Section 2 of the Sherman Act, a plaintiff must show "two elements: (1) the possession of monopoly power in the relevant market and (2) the willful acquisition or maintenance of that power as distinguished from growth or development as a consequence of superior product, business acumen, or historic accident." 84 To ascertain whether a dominant hospital's efforts in restricting staff privileges constitutes an act of monopolization-the willful acquisition or maintenance of monopoly power-it is necessary to determine if the conduct was exclusionary.<sup>85</sup>

The assessment of whether the credentialing practice of denving the plaintiff health care provider hospital privileges actually injures competition is highly dependent on the definition of the relevant product.<sup>86</sup> That question turns on whether there is a market for specialists or for the specialty medical services.<sup>87</sup> The market for physicians is often being nationwide. treated as because there is evidence that hospitals recruit nationally, and that physicians are mobile. The market for health care services, however, is

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87. Id. at 1446. See also infra note 90 and accompanying text for discussion of whether services or physicians are the relevant market.

<sup>74.</sup> Id. at 150174. Jefferson Parish Hospital District No.2 v. Hyde Jefferson Parish, 466 U.S. 2, 7 (1984). It is unclear what conditions placed on patients between the consumption of different hospital services would qualify as a tying arrangement. In White v. Rockingham Radiologists, Ltd., 820 F.2d 98 (4th Cir. 1987), for example, the court found no tying arrangement existed between surgical services and CT scanning services where "[[]he hospital does not own or operate the CT scanner. The hospital does not require each of its patients to undergo a scan. The patient's physician determines whether a scan is needed." I d. 104. It would appear that the same could be said for the arrangement in Jefferson Parish. The hospital in Jefferson Parish. The hospital is presumably did not require all of its patients to purchase anesthesia services from the hospital's designated anesthesiologists, regardless of whether they actually needed anesthesia, but only those patients who required anesthesia were obligated to the the service of the arrangement in Jefferson Parish. The hospital is designed anesthesia were obligated to be a service from the hospital's designated anesthesiologists, regardless of whether they actually needed anesthesia, but only those patients who required anesthesia were obligated to be a service. use the hospital's designated anesthesiological services.

<sup>75.</sup> Jefferson Parish, 466 U.S. at 21-22. In finding that the specialty service was separately demanded from hospital services, the Jefferson Parish Court noted that "[a]s a matter of actual practice, anesthesological services are billed separately from the hospital services petitioners provide." Id. at 22. Furthermore, the evidence showed "that patients or surgeons often request specific anesthesologaists," Id.

<sup>76.</sup> ld. at 27.

<sup>77.</sup> Collins. 844 F.2d at 477-78.

<sup>78. 861</sup> F.2d 1440 (9th Cir. 1988).

<sup>79.</sup> Id. at 1447; see also supra note 90 (discussing Oltz distinguishing Collins).

<sup>80.</sup> Jefferson Parish, 466 U.S. at 6 n. 4.

<sup>81.</sup> See, e.g., White, 820 F.2d at 104 (distinguishing case from Jefferson Parish because the White hospital "receives no part of the fee for interpreting the scans") (citing Jefferson Parish, 466 U.S. at 6 n.4); Beard v. Parkview Hosp., 912 F.2d 138, 142 (6th Cir. 1990) (finding that "Jefferson Parish was not required to address the 'direct economic benefit' issue because there was no dispute that the hospital in that case received a direct economic benefit from each sale of anesthesiological services.") (citing Jefferson Parish, 466 U.S. at 6 n.4). 82. Oltz, 861 F.2d at 1442.

<sup>83.</sup> Potters Medical Center v. City Hospital Association, 800 F.2d 568, 575 (6th Cir. 1986). 84. United States v. Grinnell Corp., 384 U.S. 563, 570-71 (1966).

<sup>85.</sup> Id. at 575.

<sup>86.</sup> Oltz. 861 F.2d at 1447.

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attack in some instances under Sec-

dependent on the geographic ing decisions may be vulnerable to market in which patients actually receive medical care. because patients are less mobile than physicians.

In Collins v. Associated Pathologists, Ltd,<sup>88</sup> for example, a pathologist, who was denied privileges to practice at the hospital, alleged, inter alia, that exclusive contracts between the hospital and the group providing pathology services "constitute[d] unreasonable restraints of trade in violation of Section 1 of the Sherman Act." 89 In denying the plaintiff pathologist's claim, the court defined the relevant product as "pathologists, not pathology services, and the corresponding relevant market is the market in which pathologists compete for jobs, not the market in which hospitals compete in offering pathology services." 90 Because of the evidence in the record regarding the scope of the market for pathologists, and the plaintiff's own record of working coast-to-coast, the court agreed with the lower court's conclusion that the market for pathologists is nationwide. Even if the plaintiff was excluded from the local market, there were a substantial number of opportunities available to him.91 Plaintiffs, who are denied privileges on the basis of economic credentialing decisions, do not have a stronger antitrust argument than plaintiffs who are denied privileges on the basis of quality of care concerns, because the market for physicians remains the same for both sets of plaintiffs.

tion 2 of the Sherman Act, 15 U.S.C. § 2, which prohibits deliberate to obtain maintain efforts or Generally to monopoly power. establish a violation of Section 2 for monopolization or attempted monopolization, an antitrust claimant must show that the defendant possess monopoly power or something dangerously close, which typically means presenting evidence of a high market share combined with market conditions making the market susceptible to an exercise market power. Thus, similar to cases under Section 1, the definition and scope of the relevant market plays a crucial role in cases under Section 2. Market power alone, however, will not suffice because legitimately obtained power will not trigger antitrust liability. Rather, the monopolist or would-be monopolist must have engaged in a deliberate, anticompetitive act to secure, or to monopolv maintain power. as opposed to obtain monopoly power through a superior product, business acumen or historical accident (i.e., legitimate competition).<sup>92</sup> Credentialing, including economic credentialing, could serve as the predicate, anticompetitive conduct

Indeed, courts have found that plaintiffs alleging "conduct in restraining privileges could state a monopolization claim." 93 "It is not unreasonable to that assume doctors, if they felt compelled to choose between [a smaller rival hospital] and the much larger, dominant...[h]ospital, would likely

for a Sherman Act Section 2 claim.

opt for the latter. It is conceivable that [the larger, dominant h]ospital sought to restrict physicians' staff privileges in order to foreclose competition from [the smaller rival hospital] in the hospital inpatient services market." 94 Exclusive dealing arrangements that require suppliers or customers to deal with a dominant player in a market raise antitrust concerns because they may foreclose competitors from access to either necessary inputs or outlets for their products essential to effective competition.

Several economic credentialing practices, such as "loyalty oaths" or promises not to refer patients to competing facilities as a condition of continued privileges with the hospital, or requiring a physician seeking privileges to admit a certain percentage of patients to the hospital or to practice exclusively at the hospital, may have the effect of compelling physicians to choose against practicing at a smaller, rival hospital. While there may be valid procompetitive justifications for each of these practices, such as allowing the hospital to monitor and control the quality and efficiency of its medical staff, these practices might also have the effect of foreclosing competition from other hospitals in the market for inpatient hospital services. In those cases in which a hospital or a competing medical facility might challenge another hospital's demand that physicians not practice at competing hospitals or facilities, plaintiffs may have slightly better chances of success in asserting antitrust challenges to economic credentialing because the

In addition to Section 1, credential-

93. Potters Medical Center, 800 F.2d at 575 (emphasis added). 94.ld. at 575

<sup>88. 844</sup> F.2d 473 (7th Cir. 1988).

<sup>89.</sup> Id. at 478.

<sup>90.</sup> Id. The court supported this definition by its "earlier holding that no market exists for pathology services separate from hospital services and by analysis of the exclusive dealing claim under the 9U. 10. The court supported this definition by its "earlier holding that no market exists for pathology services separate from hospital services and by analysis of the exclusive dealing claim was, in fact, pathology services if it had first found that a separate market for the pathologists exclusive dealing claim was, in fact, pathology services form hospital services. In Oltz v. St. Peter's Community Hospital, 861 F.2d 1440 (9th Cir. 1988), for example, the court, in finding anesthesia services and not anesthesiologists to be the relevant market, distinguished Collins because there was evidence in Oltz that surgeons and obstetricians actually demanded the specific services of the plaintiff. 861 F.2d at 1440. (9th Cir. 1988), for example, the court, in finding anesthesia services and not anesthesiologists to be the relevant market, distinguished Collins because there was evidence in Oltz that surgeons and obstetricians actually demanded the specific services of the plaintiff. 861 F.2d at 1447. However, this issue may not matter for a rival hospital asserting that a dominant hospital used exclusive dealing contracts to foreclose competition, the market for physicians would still be relevant an unreasonable restraint of trade that foreclosed competition is supported by the Collins court's discussion of Tampa Electric, where it noted that "[]]n it determination of whether the contract was an unreasonable restraint of trade that foreclosed competition, the [Tampa Electric] Court did not consider any impact on the consumers who purchased the resultant electricity. Instead, the Court focused on potential competitors of the party to the contract with Tampa Electric, [i.e.] other coal companies." Collins, 844 F.2d at 478.

<sup>91.</sup> Collins, 844 F.2d at 479.

<sup>92.</sup> In addition, for an attempted monopolization claim, the claimant must establish a specific intent to monopolize and a dangerous probability that the defendant will obtain monopoly power.

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relevant market analysis will more in the same geographic market has likely focus on the provision of medi- market power and has tied up all the cal services to patients and, there- other physicians in the region. But, fore, will more likely be deemed on the other hand, exclusive credenlocal or regional in scope, not tialing practices may also lead to national.

pick up enough physicians from the to enter the market. The effect that national market to compete in the a nationwide market for physicians local market for inpatient hospital would have on the anticompetitive services. But, the fact that physi- impact of exclusive cians may have a nationwide credentialing practices by dominant employment market does necessarily mean that a hospital ated on a case-by-case basis. challenging a dominant hospital in a particular geographic market can V. CONCLUSION attract physicians from across the nation. For instance an out-of-town The antitrust analysis of economic prospective physician candidate credentialing decisions would not may be deterred from joining the likely vary significantly from the staff of a hospital if another hospital

fewer physician services and higher prices for those services, which The rival hospital may be able to could induce out-of-town physicians economic not hospitals would need to be evalu-

existing framework as applied to peer-review credentialing decisions. It does appear, however, that the subset of economic credentialing that conditions staff privileges on "loyalty oaths" or other commitments from physicians not to seek privileges at other hospitals may raise unique concerns under both Section 1 and Section 2 of the Sherman Act. In particular, the concern raised by these practices is that they may be part of an anticompetitive strategy by a dominant hospital with market power, or a conspiring group of physicians, attempting to foreclose competition in the market for inpatient hospital services, or specialized physician services, by limiting rival hospitals' access to admitting physicians.

### Economic Credentialing an Exclusionary Conduct Under the Sherman Act

By Mark J. Horoschak\* Womble Carlyle Sandridge & Rice, PLLC

#### I. Introduction

cians have privileges. This trend to the facility in which they have a market for hospital services.

Physicians often claim that they are ing motivated to invest in specialty might otherwise be achievable at to the extent that such physicianthe community hospitals at which

they practice. Community hospitals, however, have expressed the In recent years, physicians have concern that physicians' investment become investors in specialty hospi- in a competing facility creates an tals or outpatient facilities that com- economic incentive for those physipete directly with full-service, com- cians to "skim the cream" by admitmunity hospitals where the physi- ting profitable, well-insured patients has raised a variety of health care financial interest while admitting policy and antitrust issues relating to lower margin or indigent patients to the merits of physician-owned facili- the community hospital. Because ties and their impact on the broader community hospitals rely upon cross-subsidization from more profitable services as a means of funduncompensated care and providing necessary but unprofitable hospitals not primarily for economic services, the financial viability of gain, but by a professional interest community hospitals may be threatin achieving better outcomes than ened by physician-owned facilities owners siphon off many of the com-

munity hospital's profitable patients.

The economic threat posed by physician-owned facilities has led some community hospitals to implement "economic credentialing," a term that encompasses a variety of physician credentialing policies that are based solely on business considerations, as opposed to professional qualifications, competence or moral character. In some cases, community hospitals have flatly refused to grant medical staff privileges to physicians who have a financial relationship with a competing entity. In other instances, community hospitals have allowed physician-investors to maintain their privileges only for so long as they do not appreciably change their admit-

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ting or referral patterns. Still other hospitals have restricted the privileges granted to physicians who invest in competing facilities as, for example, by limiting their ability to serve in medical staff leadership positions or on emergency room on-call schedules.

# II. Evolving Federal Policy on Specialty Hospitals

The controversy surrounding economic credentialing is a byproduct of the broader policy debate over the role and effect of specialty hospitals in the marketplace. This debate first gained national attention in 2003, when the U.S. General Office issued Accounting two reports concerning specialty hospitals. The first of these reports examined the nature of the physician ownership of, and the patients served by, specialty hospitals.<sup>1</sup> The latter report, which was issued six months later, examined the geographic location, financial performance, and services provided by such hospitals.<sup>2</sup>

Of particular importance, the first report contained data comparing the patients served by specialty hospitals with those served by general hospitals in terms of illness severity, using the All Payer Refined - Diagnostic Related Groups ("DRG") system. The data revealed that at specialty hospitals patients tended to be less sick (and, therefore, were more likely to be profitable) than patients with similar diagnoses at community hospitals. Proponents of economic credentialing seized upon this data to support their contention that physicians that owned specialty hospitals were allowing financial considerations to

influence their referral patterns - - in effect, "gaming" prospective payment systems based upon DRGs by admitting the more complicated cases to full-service community hospitals at which they have privileges and the less severe cases to the specialty hospitals which they own.

In the aftermath of the GAO reports, United States Congress the imposed an 18-month moratorium on the establishment of specialty hospitals as part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003,<sup>3</sup> which took effect on December 8, 2003. In particular, the Act provided that to qualify for Medicare reimbursement, physicians were not permitted to make self-referrals to a hospital "that is primarily or exclusively engaged in the care and treatment of one of the following catego-(i) [p]atients with a cardiac ries: condition (ii) [p]atients with an orthopedic condition (iii) [p]atients receiving a surgical procedure [or] (iv) [a]ny other specialized category of services that the Secretary [of the U.S. Department of Health and Human Services ("HHS")] designates as inconsistent with the purpose of permitting physician ownership and investment interests in a hospital under this section." <sup>4</sup> The Act further required both the Medicare Payment Advisory Commission ("MedPAC"), in consultation with the GAO and HHS, to prepare a report and provide "any recommendations for legislation or administrative changes" by March, 2005. In the ensuing months, MedPAC held a series of hearings on the merits of physician-owned specialty hospitals. In the course of these hearings, several commentators

expressed the concern that physicians with a financial interest in a specialty hospital have an economic incentive to engage in "adverse selection" - - that is, admitting profitable cases (such as well-insured patients requiring uncomplicated care) to the specialty hospital which they own, while admitting to the community hospital at which they also practice those patients who are uninsured or underinsured, as well as Medicare or other "fixed payment" patients whose care is likely to be complicated or whose recovery is likely to be protracted. Such adverse selection, the commentators observed, has the capacity to undermine the ability of the community hospital to offer a full range of clinical services and thus can jeopardize the availability of marginally profitable or unprofitable services - - such as 24-hour emergency care - - as well as the provision of charity care.

Physician-owned specialty facilities countered that they are able to offer better patient care - - because they concentrate on particular types of procedures and the physicians themselves have more control and decision-making authority on clinical matters in such facilities - - sometimes at a lower cost. Physicianinvestors also denied that economic considerations can or do influence their admitting or referral patterns, and maintained that any change in admitting or referral patterns after the opening of a specialty hospital are largely a function of patient choice.

On March 8, 2005, MedPAC submitted to Congress its Report on Physician-Owned Specialty Hospitals. The Report found that

<sup>1.</sup> U.S. General Accounting Office, "Specialty Hospitals: Information on National Market Share, Physician Ownership, and Patients Served," Report No. GAO-03-683R (April 2003) (available at http://www.gao.gov).

<sup>2.</sup> U.S. General Accounting Office, "Specialty Hospitals: Geographic Location, Services Provided, and Financial Performance," Report No. GAO-04-167 (October 2003) (available at http://gao.gov). 3. Public Law No. 108-173.

<sup>4.</sup> The Act did not define what it means for a hospital to be "primarily or exclusively engaged" in the care and treatment of cardiac, orthopedic or surgical patients. In its reports, the GAO considered a hospital to be a specialty hospital if: (1) the DRG classification for two-thirds of its Medicare patients (or two-thirds of all of its patients where such data was available) fell into no more than two major diagnostic categories; or (2) at least two-thirds of its patients were classified in surgical DRGs.

physician-owned specialty hospi- support them have filed lawsuits tals: (i) did not have lower costs for challenging such policies under a Medicare patients than did commu- variety of legal theories, including nity hospitals, although specialty antitrust. hospital patients had shorter length credentialing determinations have of stays; (ii) treated patients who been challenged under Sections 1 were generally less severely ill and and 2 of the Sherman Act, 15 U.S.C. presumably more profitable; (iii) §§ 1 & 2, as well as their state law concentrated on some of the more counterparts. profitable DRG groups; and (iv) served a lower percentage of Medic- A. Section 1 of the Sherman Act aid patients than did community hospitals. found that the financial impact of Sherman Act has been invoked to physician-owned specialty hospitals challenge adverse medical staff on community hospitals thus far had been limited, it noted that this finding these was based on a relatively small data because the privilege determination set covering a limited period of time. at issue was not the product of The MedPAC Report recommended concerted action. To prevail under that Congress, among other things, gainsharing arrangements allow between physicians and hospitals to conspiracy" minimize the financial incentives of restrains competition. physician referrals; refine the Medicare payment system to minimize conduct, regardless of its purpose or the inequities between payments to effect on competition. physician-owned specialty hospitals and community facilities; and extend A hospital's governing board comthe current moratorium on the establishment of specialty hospitals for another 19 months, until January 2007. The moratorium expired as of physician's application for staff privi-June 8, 2005, but bipartisan legisla- leges only after it has reviewed the tion is pending in Congress that recommendations of the hospital's would permanently bar physicians medical from referring Medicare patients to new specialty hospitals in which the physicians have an ownership inter- concerted action by alleging the est.

#### III. Antitrust Implications of Eco- staff, or between the hospital and nomic Credentialing

The controversy over specialty issue of whether a hospital has the hospitals has carried over to court legal capacity to conspire with its proceedings. As community hospitals have adopted economic credentialing policies, specialty hospitals and the physicians who own and

In particular, economic

While the Report also Over the years, Section 1 of the privilege determinations. Many of challenges have failed Section 1, a plaintiff must establish a combination "contract, that unreasonably Section 1 does not proscribe unilateral

> prises a single entity for Section 1 purposes. However, because a board hospital mav denv а staff committees. the aggrieved physician typically attempts to satisfy the element of existence of an unlawful agreement between the hospital and its medical individual members of its medical staff. The courts are divided on the medical staff.<sup>5</sup> Nonetheless, even in jurisdictions where courts have held that a hospital and its medical staff cannot legally conspire, a

hospital may be found to have conspired with individual members of its medical staff who have an independent economic stake in the privilege determination, such as, for example, where they are competitors of the plaintiff.<sup>6</sup> Thus, to minimize the risk of satisfying the element of concerted action, many community hospitals have narrowly circumscribed the involvement of their medical staffs - - or any particular staff physician - - in the development and implementation of economic credentialing policies. This seems to be an appropriate approach from an operational perspective as well, for economic credentialing essentially calls upon the business expertise of the governing board and management of the hospital rather than the professional judgment of medical staff personnel.

Assuming that concerted action is demonstrable, the plaintiff must further establish that the hospital's economic credentialing determinations have unreasonably restrained competition within the meaning of Section 1. The prevailing standard for making the determination is the "rule of reason." Under this standard, the plaintiff must show that the challenged restraint has actual or potential anticompetitive effects and that such effects outweigh any efficiencies or other procompetitive benefits that may be attributable to the restraint.

In practice, the rule of reason tends to be a defense-friendly standard: it is often difficult for a plaintiff to show privilege determination that a caused harm to competition, as opposed to harm to the plaintiff as a competitor. Consequently, plaintiffs often try to characterize privilege

<sup>5.</sup> The Ninth Circuit has indicated and Eleventh Circuit has held that a hospital has the legal capacity to conspire with its medical staff, whereas the Third, Fourth, Sixth and Seventh Circuits have held that the hospital and its medical staff lack such capacity. Compare Oltz v. St. Peter's Cntty Hosp., 861 F. 2d 1440 (9th Cir. 1988); Crosby v. Hospital Auth., 93 F. 3d 1515 (11th Cir. 1996) with Nanavati v. Burdette Tomlin Memil Hosp., 857 F. 2d 96 (3d Cir. 1988); Circusby v. Hospital Auth., 93 F. 3d 1515 (11th Cir. 1996) with Nanavati v. Inc., 70 F. 3d 422 (6th Cir. 1995); Pudlo v. Adamski, 2 F. 3d 1153 (7th Cir. 1993) (unpublished order) (No. 92-1954, August 9, 1993).

<sup>6.</sup> For example, in Biddulph, et al. v. HCA Inc., Case No. CV-2004-1219 (Seventh Judicial District Court, Bonneville County, Idaho, complaint filed March 3, 2004), one of the plaintiff physicians claimed that her privileges were terminated as the result of a conspiracy between the hospital's governing board and a physician member of that board who was her competitor. The court, however, dismissed this claim on the grounds that a member of a hospital's governing board, while acting in his official capacity, was legally incapable of conspiring with that board under the Idaho Competition Act. Id. (Memorandum Decision and Order, August 6, 2004).

# Antitrust Health Care

Consequently, plaintiffs often try to characterize privilege determinations as a form of group boycott or tie-in, categories of conduct that in some instances can be condemned as illegal per se. Courts, however, have generally rejected such characterizations and applied the rule of reason.<sup>7</sup>

To meet its threshold burden under the rule of reason, a plaintiff must show that the hospital's privilege determination has caused competitive injury. Injury to competition is not necessarily synonymous with injury to an individual competitor. The plaintiff must demonstrate that the privilege determination has impaired the competitive process itself, such that the marketwide output of the relevant services has been depressed and/or the prices for those services have been maintained above a competitive level. For example, many antitrust challenges to (conventional) privilege determinations fail because the plaintiff physician cannot prove that hospital's determination the adversely affected the professional services market in which he competes; that is, the plaintiff often is shown to be one of many providers of comparable professional services within the relevant market, and his removal from the hospital's medical staff has no appreciable impact on the provision of such services.

In most instances, a plaintiff has no hope of proving harm to competition unless it can establish that the defendant has "market power." Market power is defined as the capacity to restrict output and raise prices from a competitive level. The possession of a substantial share of privileges, a physician gains access

harm to the plaintiff as a competitor. the relevant market is a necessary but not sufficient requirement for market power. As a general proposition, a defendant will be found to lack market power if its market share is less than 35%.<sup>8</sup> A market share between 35% and 50% allows for the possibility of market power, while a market share in excess of 50% presumptively confers market power.<sup>9</sup>

> In order to circumvent proof of market power, plaintiffs often pursue one of two alternative strategies. In some instances, they will seek to define the relevant market in artificially narrow terms (e.g., "all facilities in the northwest quadrant of a city") so as to inflate the defendant's "market" share. Alternatively, they will contend that there is evidence of actual anticompetitive effects so as to obviate the need for proof of market power altogether. Although the Supreme Court has recognized that market power is merely a proxy anticompetitive effects and for therefore need not be shown where there is direct evidence of such effects.<sup>10</sup> courts have rarely found actual evidence of a reduction in marketwide output or supracompetitive pricing so as to forgo the need for establishing the defendant's market power.

> If the plaintiff physician makes a credible showing of actual or potential anticompetitive effects, the defendant hospital must then present any procompetitive rationale or justification for its conduct. In the context of economic credentialing, such a rationale or justification would likely be predicated on the potential harm caused by "freeriding." In securing medical staff

to a hospital's staff and facilities, though with the implicit expectation that he will provide economic support to the hospital through patient admissions or referrals. When a physician on staff becomes an investor in a competing facility, however, he has both the incentive and ability to engage in adverse selection. To the extent that the physician-investor denies the hospital profitable cases but continues to admit to the hospital uninsured or under-insured patients, his competing facility is effectively subsidized by the hospital.<sup>11</sup> The physicianinvestor may also be said to "free ride" on the non-investor physicians who are members of the medical staff to the extent that their profitable patient admissions serve to subsidize the uncompensated care extended by the hospital to the physician-investor's patients.

Free-riding by physician-investors thus can result in lower revenue and relatively higher costs for the community hospital. This loss of revenue, in turn, may jeopardize the ability of the hospital to provide a full range of clinical services to the extent that the lost revenue is needed to subsidize unprofitable services or programs.

Physicians often counter that the facility in which they have invested will effectively intensify competition because it will offer both patients and payers the choice of an additional, lower-priced facility due to its lower overhead. This rationale, however, seems to be merely a back-handed recognition of freeriding to the extent that the physician-owned facility is dependent on emergency or other clinical backup from a community hospital,

<sup>7.</sup> See, e.g., BCB Anesthesia Care, Ltd. v. Passavant Memorial Hospital Ass'n, 36 F.2d 664, 667 (7th Cir. 1994); Pontius v. Children's Hospital, 552 F. Supp. 1352, 1369-70 (W.D. Pa. 1982).

<sup>8.</sup> See Jefferson Parish Hosp. Dist. No. 2 v. Hvde. 466 U.S. 2, 26-29 (1984). 9. See generally ABA Section of Antitrust Law, Antitrust Law Developments, at 68-69 (5th ed. 2002)

<sup>10.</sup> FTC v. Indiana Federation of Dentists, 476 U.S. 447, 460 (1986).

<sup>11.</sup> Specialty hospitals often do not have emergency rooms that are used disproportionately by indigents and (low margin) Medicaid patients.

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full-service capabilities whose necessarily result in higher overhead costs. In addition, physicians often claim that the specialty facility in which they have invested has a more rapid turnaround time between cases as well as better outcomes. Any efficiencies that may be gained through specialization do not, however, negate the costs imposed on the community hospital as a result of free-riding.

To date, no court has conducted a full-blown, rule-of-reason analysis of economic credentialing restrictions. Nonetheless, in some non-antitrust cases, courts have been inclined to accept the argument that physician-investors have a strong economic incentive to engage in Drawing an analogy to the principles free-riding. In Mahan v. Avera St. of agency law, the court further Luke's,<sup>12</sup> for example, the South mused: Dakota Supreme Court held that a hospital's governing board had the authority under state law to impose a ban on extending privileges to physicians who were new to the community and had an investment interest in a competitor of the hospital. The defendant, Avera St. Luke's ("ASL"), had experienced a significant decline in orthopedic surgery procedures after a local orthopedic surgery group opened its own outpatient surgery center in competition with ASL. In response to this loss of revenue, ASL's board of trustees effectively closed the medical staff to applicants seeking privileges for orthopedic surgery and certain neurosurgery procedures. In rejecting the plaintiffs' claims, the court concluded that the hospital's actions were necessary to preserve In a similar vein, an Ohio state court its economic viability:

By preserving the profitable neurological services at ASL, the Board also insured that other

unprofitable services would continue to be offered in the Aberdeen area . . . . ASL cannot continue to offer unprofitable, yet essential, services including the maternity ward, emergency room, pediatrics and critical care units, without the offsetting financial benefit of more profitable areas such as neurosurgery. The Board responded to the effect the [outpatient surgery center] would have on the viability of . . . ASL's hospital and the health care needs of the entire Aberdeen community. These actions were within the power of the Board. It surely has the power to attempt to insure ASL's economic survival.<sup>13</sup>

How can a doctor who is part owner of the for-profit [outpatient surgery center] be expected to fulfill his or her duties towards his or her co-owners and in the same instance fulfill the duties towards the principal, ASL, who is a not for profit hospital? This does not imply ill-will on the part of the doctor, it simply faces fundamental medical issues such as at which institution does the doctor place his or her patients, [the physician-owned outpatient surgery center] or ASL? We have often stated that an agent cannot serve two masters. This rule applies to medical professionals as well.14

upheld the right of the defendant hospital, St. John, to terminate the privileges of physicians employed by a competitor, the Cleveland Clinic Foundation. St. John had adopted a Medical Staff Development Plan that effectively rendered any physicians employed by Cleveland Clinic ineligible for appointment or reappointment to the medical staff. This credentialing policy was in part a response to St. John's experience with physicians who had served on its medical staff but were employed by Cleveland Clinic. The evidence showed that virtually all of the Cleveland Clinic physicians' inpatient referrals were directed to Cleveland Clinic hospitals, even though St. John was closer to the outpatient facility at which those physicians practiced than any of the hospitals operated by Cleveland Clinic. In holding that St. John's credentialing policy was not arbitrary or capricious under Ohio law, the court concluded that the policy "a reasonable means of was protecting St. John's continued viability .... "<sup>15</sup> As in Avera St. Luke's, the court acknowledged the potential economic threat that arises when members of a hospital's medical staff have a financial relationship with that hospital's competitor.

#### B. Section 2 of The Sherman Act

Economic credentialing is more likely to be challenged under Section 2 of the Sherman Act, which prohibits monopolization, attempted monopolization, and monopolization by combination or conspiracy. Section 2 reaches unilateral as well as concerted conduct, but only where the hospital enjoys monopoly or near-monopoly power in the relevant market.

The offense of monopolization requires a threshold showing of monopoly power, which has been defined by the courts as the ability to control prices or exclude competi-

<sup>12. 2001</sup> S.D. 9, 621 N.W. 2d 150 (S.D. 2001).

<sup>13. 621</sup> N.W. 2d at 156.

<sup>14. 621</sup> N.W. 2d at 161 n.8.

<sup>15.</sup> Walborn v. UHHS/CSAHS-Cuyhoga, Inc., Case No. CV-02-479572, slip opinion at 30 (Cuyahoga Co. Com. Pls. June 16, 2003).

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heightened form of market power. Like market power, monopoly power may be established by direct evidence of supracompetitive pricing or restricted output, but is usually inferred from evidence of a high market share and market conditions conducive to anticompetitive behavior. A market share in excess of 70% is almost always sufficient to support an inference of monopoly power, while a market share of less than 40% virtually precludes such an inference.<sup>16</sup>

The offense of attempted monopolization requires, among other things, proof that the defendant, through its anticompetitive conduct, is likely to achieve a monopoly. This, in turn, essentially requires proof that the defendant has market power. А hospital that has a market share below 35% is not likely to be found to have market power necessary for attempted monopolization.

Many challenges to economic credentialing under Sherman § 2 are likely to fail because the relevant geographic market for hospital services will be found to be too broad to support allegations of monopoly or near-monopoly power. If payors and patients have practical alternatives to the credentialing hospital absent a physician-owned competing facility, then deterring the entry of such a facility would not to harm competition. appear Accordingly, hospitals in large metropolitan areas are likely to incur little risk of Sherman § 2 liability in adopting economic credentialing policies.

tion. Monopoly power is merely a In any event, proof of monopoly or near-monopoly power, by itself, is not sufficient to establish a violation of Section 2. Section 2 also requires proof that the firm seeking to achieve or maintain a monopoly has engaged in "predatory" or "exclusionary" conduct and that such conduct has caused competitive harm.

> Distinguishing exclusionary conduct from rough-and-tumble competition is one of the great challenges of antitrust practice: indeed, after more than one hundred years of antitrust jurisprudence, there is still no unified theory as to what constitutes exclusionary conduct within the meaning of Section 2 of the Sherman Act. The paradigmatic standard for distinguishing benign from exclusionary conduct was articulated by the Supreme Court nearly forty years ago:

The offense of monopoly under §2 of the Sherman Act has two elements: (1) the possession of monopoly power in the relevant market and (2) the willful acquisition or maintenance of that power as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident.<sup>17</sup>

This standard for exclusionary conduct has been criticized as "vacuous" because the concepts of "willful maintenance" of a monopoly and competition on the merits are mutually exclusive. For not example, a monopolist may use any number of procompetitive tactics - such as price reductions, product

innovation or service enhancement -- in order to prevail over an upstart competitor and preserve its monopoly. 18 Even the Supreme Court has conceded that, under its standard, it "is sometimes difficult to distinguish robust competition from conduct with long-term anticompetitive effects." 19

Because the Supreme Court's monopolization standard is incoherent, lower courts have been largely left to their own devices to formulate standards for distinguishing exclusionary conduct from that which can enhance competition. This has led to differing analytical standards and rulings that cannot be fully reconciled. Many of the better reasoned decisions, however, tend to focus on whether the defendant's conduct is calculated to improve its own efficiency - - in which case it should be deemed procompetitive - - or impair a rival's efficiency - - in which case it may be condemned as exclusionary.<sup>20</sup> In a similar vein, some courts have held that a monopolist engage competitively may in aggressive conduct so long as it would be economically rational for a firm to undertake such conduct regardless of its market position.<sup>21</sup> Under this standard, for example, discounts predicated price on volume normally would not be deemed to be exclusionary regardless of their impact on particular competitors because extending such discounts to meet or beat the competition would be deemed economically rationale behavior in any market context.<sup>22</sup> By contrast, conduct would be predatory or exclusionary in an antitrust sense

2. See Rocky Mountain Medical Center, Inc. v. Northern Utah Healthcare Corp., Cas. No. 00906627 (Dist. Ct., Third Jud. Dist., Salt Lake County, Utah) (Minute Entry, Jan. 26, 2004) (Summary judgment granted for defendant hospital which discounted rates based on composition of provider network).

<sup>16.</sup> See ABA Section of Antitrust Law, Antitrust Law Developments at 234-36 (5th ed. 2002).

<sup>17.</sup> United States v. Grinnell Corp., 384 U.S. 563, 570-71 (1966) (italics supplied).

<sup>18.</sup> See generally Elhauge, Defining Better Monopolization Standards, 56 STAN. L. REV. 253, 261-67 (2003).

<sup>19.</sup> Spectrum Sports, Inc. v. McQuillan, 506 U.S. 445, 458-59 (1993); Copperveld Corp. v. Independence Tube Corp., 467 U.S. 752, 767-68 (1984).

<sup>20.</sup> A straightforward example of impermissible, exclusionary conduct under this standard would be the defendant's systematic disruption of the business operations of its rival through the destruction of physical assets. See, e.g., Conwood Co., L.P. v. United States Tobacco Corp., 290 F.3d 768 (6th Cir. 2002), cert. denied, 123 S. Ct. 876 (2003).

<sup>21.</sup> See generally Concord Boat Corp. v. Brunswick Corp., 207 F. 3d 1039, 1062 (8th Cir.), cert. denied, 531 U.S. 979 (2000); Data Gen. Corp. v. Grumman Sys. Support Corp., 36 F. 3d 1147, 1182 (1st Cir. 1994)

where it would be economically unilateral refusal to deal. irrational for a firm to pursue such conduct except for its capacity to Any exception to the no-duty-to-deal harm to the competitive process pronouncement in Trinko would itself. example, may be found to be preda- where the alleged monopolist's tory and exclusionary where a firm behavior could not be readily that enjoys a dominant market posi- explained as efficiency-enhancing. tion calculates that it can drive a As noted above, however, economic new entrant out of business and credentialing would appear to be an thereafter recoup its profits in a efficiency-enhancing measure to non-competitive Under such circumstances, the that members of the hospital's medimonopolist's conduct can be ratio- cal staff who establish competing nally explained only in terms of its facilities will engage in free-riding to capacity to foreclose competition.

determination is nothing more than credentialing hospital's market posia refusal to deal. In Verizon Com- tion. munications, Inc. v. Law Offices of hospital might find it as necessary to Curtis V. Trinko,<sup>23</sup> Court reaffirmed that even a as would a major medical center. It monopolist has no general duty to follows that, because an economic deal with its competitors. The Court credentialing policy would appear to observed that a monopolist's refusal be an efficiency-based response to to deal with a competitor would be free-riding regardless of market actionable under Section 2 only in conditions, it cannot form the basis rare circumstances. "[A]t or near of "predatory" or "exclusionary" the outer boundary of Section 2 conduct within the meaning of Secliability"<sup>24</sup> was an earlier decision of tion 2. the Court, Aspen Skiing Co. v. Aspen Highlands Skiing Corp.,<sup>25</sup> in At least one pre-*Trinko* court seems which a large ski resort's refusal to to have indicated as much, in continue to offer a joint ski pass with concluding that a hospital's refusal its smaller competitor was held to to grant privileges to a physician constitute unlawful monopolization. was a legitimate response to the According to the Court, what made competition posed by a facility Aspen exceptional was defendant's discontinuance of a son v. Sacred Heart Hospital of Pen-"presumably profitable" course of sacola,<sup>27</sup> Dr. Williamson, a radiolodealing, suggesting "a willingness to gist, forsake short-term profits to achieve Hospital's denial of privileges to her anticompetitive an contrast, in Trinko, there was no competition in violation of Section 1 prior, mutually profitable course of of the Sherman Act. Dr. Williamson dealing between the parties, so as owned and operated an outpatient to permit an inference of anticom- radiology clinic in competition with petitive intent from the defendant's

Below-cost pricing, for seem to derive from circumstances environment. safeguard against the possibility the detriment of the hospital. The threat posed by free-riding, more-At its core, an adverse credentialing over, is not dependent on the Arguably, a small general the Supreme implement economic credentialing

> the owned by that physician. In Williamchallenged Sacred Heart end."<sup>26</sup> By as an unreasonable restraint on Sacred Heart Hospital. Her initial

application for privileges in the Department of Radiology was denied pursuant to an exclusive contract between the Hospital and other radiologists. Dr. Williamson subsequently applied for privileges in the Department of Internal Medicine, and the Hospital denied her application on clinical grounds.

Dr. Williamson asserted that the Hospital's grounds for denying her privileges were pretextual, and that the Hospital's true motivation for the denial was to impair her ability to compete with the Hospital in the market for outpatient radiological services. In granting summary judgment for the Hospital, the court seemed dismissive of the notion that the Hospital's denial of privileges could be found to be anticompetitive under any circumstances:

In light of the plaintiff's position in the market, granting her any type of privileges while she still operated her own clinic would put Sacred Heart in the position of supporting its main competition. Essentially, Sacred Heart would be competing with itself. Faced with this possibility, it clearly had a rational, procompetitive reason for acting independently to deny Dr. Williamson's request for privileges.28

Thus, consistent with the reasoning of Trinko, the court found that the Hospital's unilateral refusal to deal with a competitor was not exclusionary in an antitrust sense.

Opponents of economic credentialing tend to cite another pre-Trinko decision, Potters Medical Center v. City Hospital Association,29 in support of their position that privi-

<sup>23, 124</sup> S. Ct. 872 (2004).

<sup>24.</sup> ld. at 879.

<sup>25 472</sup> U.S. 585 (1985)

<sup>26, 124</sup> S. Ct. at 880.

<sup>27. 1993</sup> W L 543002 (N.D. Fla. May 28, 1993), aff'd, 41 F. 3d 667 (11th Cir. 1994).

<sup>28. 1993</sup> W L 543002 at p. 23. It should be noted that the court was addressing a conspiracy claim brought under Sherman §1, but its reasoning would appear to be equally applicable to a monopolization claim under Sherman §2. 29.800 F.2d. 568 (6th Cir. 1986).

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lege determinations can serve a monopolistic purpose. Potters Medical Center alleged that its only competitor, the larger City Hospital, had employed a variety of tactics to intimidate or coerce physicians not to practice at Potters. According to the complaint, City Hospital, among other things, refused to grant privileges to physicians who had privileges at Potters. In reversing the lower court's granting of summary judgment in favor of City Hospital. the Court of Appeals for the Sixth Circuit explained that "it is not unreasonable to assume that doctors, if they felt compelled to choose between Potters and the much larger, dominant City Hospital, would likely opt for the latter. It is conceivable that City Hospital sought to restrict physicians' staff privileges in order to foreclose competition from Potters in the hospital inpatient services market." 30

The Potters decision is short on analysis; the appellate court did not consider, for example, whether could be there а plausible efficiency-enhancing rationale for the defendant's restrictive credentialing policy. Nonetheless, it seems significant that the defendant's alleged credentialing policy was not directed at physicians who had invested in a competing facility. Indeed, nothing in the Sixth Circuit's opinion suggests that Potters was owned in whole or in part by local physicians and that City Hospital's restrictive credentialing policy was therefore motivated by a concern about potential harm caused by physician self-referral. Thus, the

credentialing policy under attack did not appear to have the saving grace of preventing the threat of free-riding effected through adverse selection, as might have been the case if the policy had been limited to physicians who had a financial interest in a competing health care facility. If the Potters ruling survives Trinko, it does so on the basis that there was no obvious efficiency-based rationale for the defendant's refusal to deal, which, when considered in the context of the broader pattern of coercive conduct alleged in the complaint, could have been found to impair the efficiency of a rival hospital and harm competition.

By contrast, credentialing policies and determinations that are predicated on the potential harm cause bv physician self-referral are efficiency-enhancing to the extent that they eliminate or curtail freeriding. There is mounting evidence that the potential harm posed by economic conflicts of interest is real: the MedPAC Report and other studies tend to substantiate that physicians favor facilities in which they have invested at the expense of full-service community hospitals at which they also practice. Because the free-riding rationale for economic credentialing would appear to be legitimate, it should serve to vitiate any claim that privilege determinations made pursuant to an economic credentialing policy are exclusionary within the meaning of Section 2. Indeed, in other contexts, courts have declined to characterize conduct as exclusionary where valid efficiency justifica-

tions have been advanced in support of such conduct.<sup>31</sup>

#### **IV. Conclusion**

The Federal Trade Commission and the Department of Justice recently observed that "[g]enerally speaking, antitrust law does not limit individual hospitals from unilaterally responding to competition . . . by terminating physician admitting privileges . . . " 32 While the federal antitrust agencies have also cautioned that they will take action if there is "specific evidence of anticompetitive conduct" to impede the entry of a physician-owned specialty hospital, they have not elaborated on the nature of the conduct or market conditions that could give rise to antitrust liability. It seems doubtful that the mere adoption of an economic credentialing policy, without more, would be sufficient to establish antitrust liability.<sup>33</sup> Such a policy is presumptively founded on an efficiency-based rationale - - the prevention of free-riding - - and thus should not be lightly condemned as exclusionary within the meaning of the Sherman Act. To the contrary, a hospital's refusal to deal with its physician-competitors seems intuitively unobjectionable, for, as one court colorfully put it, even a firm with market power has no duty "to cut its own throat" by subsidizing its competitors. 
<sup>34</sup>

<sup>30.</sup> ld. at 575.

<sup>31.</sup> Although the case law is not settled, the better rule would see to be that valid efficiency-enhancing restrictions and "exclusionary" conduct are mutually exclusive propositions under Section 2. Where the conduct in question is designed to prevent free-riding, several courts have recognized a valid business purpose that serves as a defense to a Section 2 claim. See, e.g., Morris Communications Corp. v. PGA Tour, Inc., 364 F3d 1288, 1295-1297 (11H Cir.), cert, denied, 125 S. Ct. 87 (2004) (PGA was justified in preventing media company from selling real-time golds core, compiled by system implemented by PGA); Trans Sport, Inc., v. Starter Sportswear, Inc., 964 F. 2d 186, 189-191 (2d Cir. 1992) (manufacturer was justified in preventing retailer from transshipping to other retailers) (Section 2 case). But see United States v. Microsoft Corp., 253 F. 3d 34, 59 (D.C. Cir. 2001) (en banc) (monopolization claims resolved by determining whether "the anticompetitive harm of the conduct outweighs the procompetitive benefit").

procompetitive benefit ). Courts, of course, will look beyond pretextual free-riding claims in finding that conduct may be exclusionary. See, e.g., Eastman Kodak Co. v. Image Technical Services, Inc., 504 U.S. 451 (1992). In that case, Kodak claimed the policies in question limiting the access of independent service organizations (ISOs) to replacement parts for its equipment (which made it more difficult for the ISOs to compete with Kodak in servicing this equipment) were necessary to prevent the ISOs from free-riding on the investments that Kodak had made in product development, manufacturing and equipment sales in order to take away Kodak's service revenues. 504 U.S. at 485. The Court summarized Kodak's argument to be that the ISOs were free-riding because they had failed to enter the equipment and parts markets, and declared that "this understanding of free-riding has no support in our case law." Instead, "one of the evils proscribed by the antitrust laws is the creation of entry barriers to potential competitors by requiring them to enter two markets simultaneously." Id. (citing Jefferson Parish). See also High Technology Careers v. San Jose Mercury News, 996 F.2d 987, 992 (9th Cir. 1993). 32. See Report by the Federal Trade Commission and Department of Justice, Improving Health Care: A Dose of Competition, Ch. 3 at 27 (July 2004).

<sup>33.</sup> Indeed, a recent consent decree governing the affiliation of two hospital systems expressly provides that the hospital may deny privileges to physicians by virtue of their financial interest in a competing health care facility. See Commonwealth of Pennsylvania v. Central Pennsylvania Health Services Corp., Cir. No. 04-252 J (W.D. Pa. 2004) (consent decree).