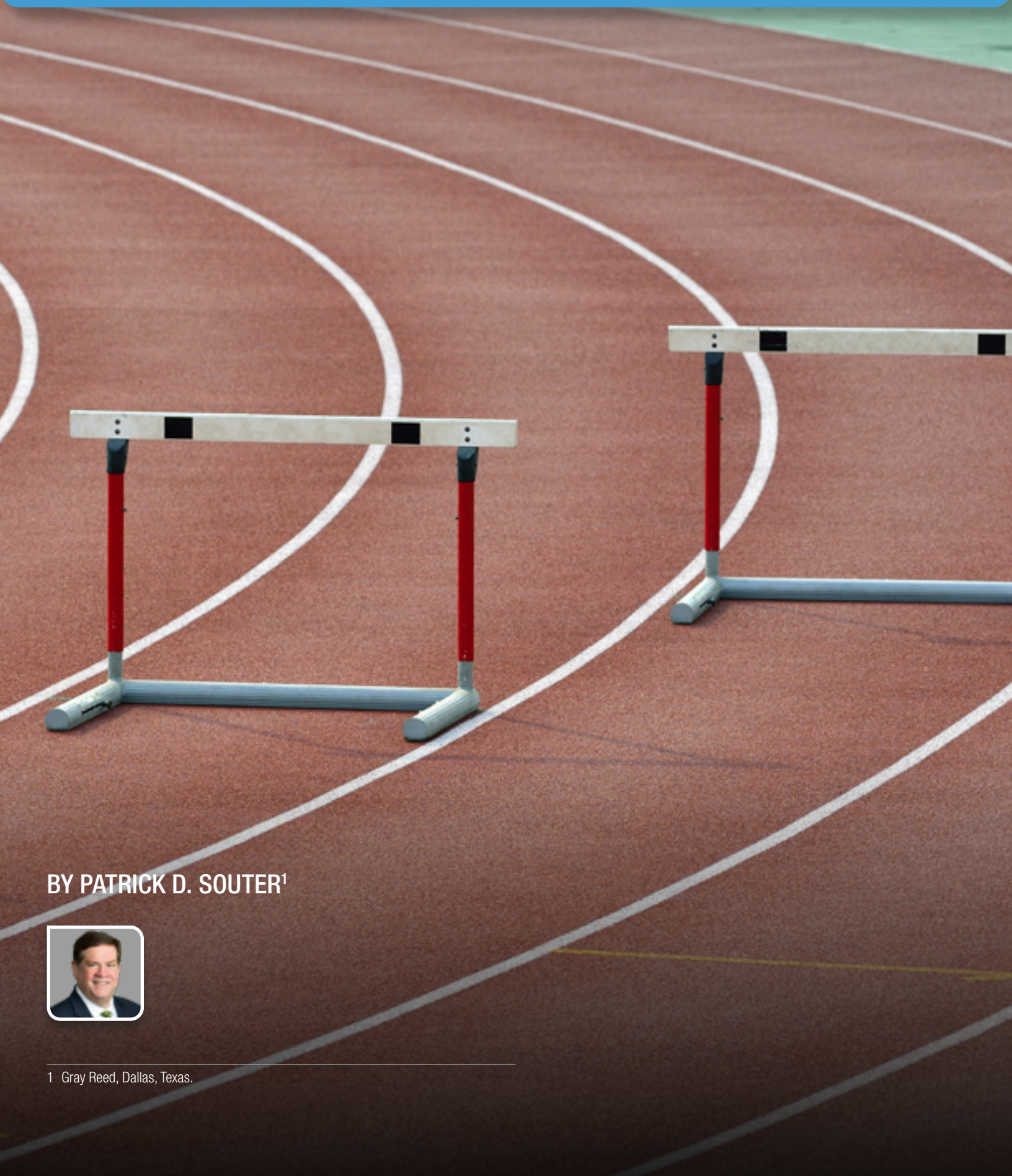
THE EVOLUTION OF ANTITRUST ANALYSIS FOR THE HEALTHCARE INDUSTRY: IS IT FOR THE BETTER OR WILL IT RESULT IN UNNECESSARY HURDLES



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THE EVOLUTION OF ANTITRUST ANALYSIS FOR THE HEALTHCARE INDUSTRY: IS IT FOR THE BETTER OR WILL IT RESULT IN UNNECESSARY HURDLES

By Patrick D. Souter

The healthcare industry is comprised of numerous types of providers and suppliers who are generally considered competitors from an antitrust standpoint, but their collaboration has been accepted in certain circumstances by governmental regulators due to the benefits derived by the patients from such arrangements without being detrimental to competition. For decades these healthcare market participants were able to utilize multiple policy statements and guidance issued by the United States Department of Justice and Federal Trade Commission to assist in properly developing various business arrangements and exchanging information among competitors. Additionally, these authorities provided a guidebook whereby the parties were able to determine whether federal antitrust laws were negatively implicated in the process. However, the United States government has recently taken action to withdraw this guidance and revise the method by which healthcare business arrangements are reviewed. The end result is that valuable resources long relied upon by healthcare market participants are no longer available for legal authority in conjunction with the federal government's heightened level of scrutiny in the analysis of such proposed transactions.

I. INTRODUCTION

On July 9, 2021, the healthcare industry was provided the first official pronouncement by the Biden Administration of how antitrust analysis and enforcement would substantially deviate from that which industry participants had relied upon the previous three decades. The new analysis would be much more aggressive in its approach than that utilized from a historical antitrust perspective. The Executive Order on Promoting Competition in the American Economy[2] ("Executive Order") established a "whole-of-government effort" to promote competition in certain industries the Biden Administration asserts are the most pressing areas of problematic competition. The Executive Order includes 72 initiatives to be pursued by more than a dozen federal agencies when addressing concerns on negative impacts to the marketplace. Healthcare is spotlighted as one on those problematic industries where a drastic overhaul of antitrust enforcement is believed to be necessary to improve competition. It also encourages those federal agencies involved in antitrust matters to focus their efforts on key industries and underlying markets where there may be problematic competition issues and coordinates other agencies' ongoing response to consolidated business arrangements.

Healthcare was identified for new, heightened antitrust enforcement since "… lack of competition in healthcare increases prices and reduces access to quality care."[3] One of the four healthcare industry segments that was specifically focused on was hospital consolidations.[4] The United States Department of Justice ("DOJ"), and Federal Trade Commission ("FTC") (collectively, "Agencies"), like other governmental agencies, commonly issue guidance documents and other resources to educate and inform stakeholders on how these agencies will apply antitrust laws in certain arrangements. Much of this guidance will be applicable across a wide array of industries but there are instances where these materials will be industry-specific due to the differences in one industry versus the others. Healthcare is an example of a standalone industry due to the type of stakeholders involved in a patient's care and the unique way healthcare should be delivered for those patients to receive optimal results. The Executive Order was the precursor of the DOJ and FTC eliminating such guidance that was compiled through Agency policies ("Policy Statements") that established what was referred to as "Antitrust Safety Zones."

The guidance offered through each of these Policy Statements was not intended to create laws, regulations, or other legal doctrines. Rather, the purpose was to provide insight on how the Agencies would examine and apply existing antitrust laws and the interpretation by the courts in those instances where joint arrangements might be questioned. There are various methods of antitrust analysis based upon a particular arrangement and the impact of the Policy Statements allowed for consistent review and interpretation of the applicable laws and regulations:

> The Healthcare Statements provide for flexible analysis and allow for consideration of procompetitive justifications in appropriate cases of potentially procompetitive joint behavior that otherwise might receive per se condemnation. This approach illustrates the reluctance of Agencies, as well as the courts, to apply the per se rule to condemn collaborative conduct among health care providers where, despite the elimination of some price competition among providers, there also is a reasonable likelihood that the conduct may be part of a larger, potentially, procompetitive, endeavor.[5]

Therefore, when healthcare market participants were contemplating a proposed transaction that may result in antitrust scrutiny, the guidance allowed for established considerations to be taken into account and Policy Statements on how those considerations should be addressed. These authorities provided for a commitment by the Agencies not to challenge conduct that met the Policy Statements and provided consistency in antitrust analysis and enforcement.

However, in less than a year, the Biden Administration's antitrust overhaul initiative as set forth in the Executive Order has resulted in federal authorities completely dismantling a consistent approach to healthcare mergers, consolidations and working relationships. This guidance has been utilized for decades for not only hospitals and health systems but healthcare providers, suppliers, and payors. More specifically, antitrust guidance and safety zones authorities have been eliminated wholesale and new approaches to antitrust analysis and enforcement announced for a more stringent, case-by-case analysis and not just for hospital mergers as the Executive Order stated. Rather, the Agencies' actions due to the Executive Order will result negatively impact the entire healthcare industry.

2 Fact Sheet: Executive Order on Promoting Competition in the American Economy (July 9, 2021).

3 *Id.*

4 The other three industry segments were prescription drugs, hearing aids and health insurance.

5 Cristine L. White, Saralisa C. Brau & David Marx, Jr., Antitrust And Healthcare: A Comprehensive Guide 59 (2d. ed 2008).

II. THE CREATION OF ANTITRUST SAFETY ZONES

The Clinton administration, through the DOJ and FTC, initiated steps on September 15, 1993, to make healthcare more accessible and affordable for all by issuing guidance to healthcare facilities and providers for their use in structuring mergers, joint ventures, and other contractual arrangements.[6] Interestingly, the basis for the Clinton Administration initiatives are the same utilized for the Biden Administration initiatives but the end results are diametrically opposed from each other.

The Agencies issued their Policy Statements addressing six specific areas of healthcare arrangements: (i) hospital mergers; (ii) hospital joint ventures involving high-technology or other expensive medical equipment; (iii) physicians' provision of information to purchasers of health care services; (iv) hospital participation in exchanges of price and cost information; (v) health care providers' joint purchasing arrangements; and (vi) physician network joint ventures (collectively, the "1993 Statements"). These policy statements established Antitrust Safety Zones setting forth circumstances in which the Agencies would not challenge the certain aforementioned arrangements. Additionally, the Agencies also committed to expediting requests for FTC Advisory Opinions,[7] and DOJ Business Reviews[8] when requested by those contemplating arrangements that may implicate antitrust enforcement activity. The 1993 Statements were not intended to be static. Rather, they would be revisited with the evolution of the structure of the healthcare industry.

The Agencies revised the 1993 Statements one year later "… designed to encourage agreements that promote efficiency in the health care industry and lower health care costs to consumers."[9] These revisions expanded the guidance to nine enforcement policies that included new guidance on hospital joint ventures, the provision of fee-related information to purchasers and creating healthcare networks. It also provided additional guidance on the topics previously addressed in the 1993 Statements as well as creating new guidelines for hospital joint ventures involving specialized clinical services, analytical principles relating to multi-provider networks and providers' collective provision of fee-related information.

The Agencies issued the next set of Statements of Antitrust Enforcement Policy in Health Care in 1996[10] that expanded on the revised 1993 Statements safety zones and included guidance pertaining to physician network joint ventures, clarified and expanded the Agencies' 1993 guidance to new healthcare arrangements and business models, offered hypothetical scenarios to clarify the agencies' application of the enumerated safety zones, and explained how the agencies would analyze conduct falling outside of the safety zones.

The last significant development relating to the Agencies' policy statements occurred in 2011 with the issuance of Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program (the "2011 Policy Statements").[11] The Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act of 2010 (collectively, the "Affordable Care Act")[12] allowed for healthcare providers to utilize an Accountable Care Organizations ("ACO") as a method of healthcare delivery system reform that allowed for healthcare providers and affiliated stakeholders to service Medicare fee-for-service beneficiaries and share in the savings generated if certain metrics were met from an organization participating in the Medicare Shared Savings Program.[13] The 2011 Policy Statement also provides more latitude so as to allow for ACO-type arrangements operating in a private sector such as similar types of arrangements with commercial payors when those stakeholders are participating in the Medicare Shared Savings Program.

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6 Press Release, U.S. Dep't of Justice, Antitrust Enforcement Policy Statements Issued for Health Care Industry (Sept. 15, 1993).

7 The FTC may issue Advisory Opinions that contains advice in the form of an opinion if it is practical for the FTC to render such a request, is made of an actual, proposed business arrangement and not require extensive investigation, clinical study, testing, or collateral inquiry. It may not issue an opinion if the request is based upon a hypothetical question.

8 The DOJ may issue a similar type of review like that of the FTC Advisory Opinion under similar circumstances.

9 Press Release, U.S. Dep't of Justice, New Antitrust Enforcement Policy Statements Issued for Health Care Industry (Sept. 27, 1994).

10 Statements of Antitrust Enforcement Policy in Health Care Issued by the U.S. Dep't of Justice and Federal Trade Commission (Aug. 1996).

11 Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program issued by the Federal Trade Commission and U.S. Dep't of Justice (Oct. 20, 2011).

12 The Patient Protection and Affordable Care Act, Pub. L. 111-48, 124 Stat. 119 (2010), and the Health Care and Education Reconciliation Act of 2010, Pub. L. 111-52, 124 Stat. 1029 (2010) commonly referred to as "ObamaCare."

13 Patient Protection and Affordable Care Act § 3022, 124 Stat. at 395-99.

III. DOJ'S WITHDRAWAL OF THE THREE HEALTHCARE POLICY STATEMENTS

On February 2, 2023, Principal Deputy Assistant Attorney General of DOJ's Antitrust Division, Doha Mekki, announced in a speech that the DOJ was withdrawing the three Policy Statements with no immediate plans to replace them.[14] Deputy AAG Mekki reasoned that such withdrawal was necessary since the Policy Statements "… no longer reflect market realities or the Division's current enforcement posture."[15] Specifically, the Deputy stated:

> Much has changed in the health care industry over the 30 years since these statements were issued. The delivery of health care products and services have changed. In many respects, our understanding of health care economics has evolved for the better. Increasingly health care is a data intensive industry that relies on the power of machine learning, artificial intelligence, and other advanced tools to develop or deliver products or services. Some markets are increasingly multi-sided. These realities affect how buyers or sellers transact business, which may bear on important dimensions of competition in this industry.
>
> Moreover, a wave of consolidation in the health care industry has brought together industry participants who once served distinct or adjacent functions. As just one example, large health insurance companies now own providers, PBMs, health data analytics companies, and acute care clinics. If the concept of industry roll up was not in our lexicon then, it is more commonplace now. In many cases, these combinations and other entanglements may have changed the underlying incentive structures in the industry.[16]

Deputy AAG Mekki reasoned that due to the evolution of the healthcare marketplace and outdated nature of many statements reflected in those documents, the DOJ was no longer confident that the guidance fully reflects market realities, the risk of serious competitive harm, or the full scope of liability under the antitrust laws.

The next day, following through on the Deputy's statements, the DOJ issued a press release formalizing the withdrawal of the Policy Statements.[17] The FTC, which usually is responsible for investigating healthcare related activities such as hospital mergers, has yet to withdraw its support for the three Policy Statements. However, the FTC did issue a new Policy Statement that will impact its analysis of healthcare transactions and seems to be an indicator that it will move another direction in analysis and enforcement of the antitrust laws in the healthcare industry.

IV. FTC'S NEW POLICY STATEMENT REGARDING UNFAIR METHODS OF COMPETITION

On November 10, 2022, the FTC issued its Policy Statement Regarding the Scope of Unfair Methods of Competition Under Section 5 of the FTC Act[18] that alters how the Agency will review arrangements that traditionally were analyzed under more traditional principles. The FTC has indicated its intent to use Section 5 of the Federal Trade Commission Act[19] ("Section 5") as the sole basis to pursue cases that are outside other antitrust laws such as the Sherman Act[20] and Clayton Act[21] where unfair methods of competition negatively impact competition. Additionally, the FTC indicates reviewing conduct that tends to foreclose or impair market participants opportunities, reduce competition, reduce opportunities for choice in the marketplace and otherwise negatively harm consumers. This method of analysis will result in the FTC moving away from utilizing the long-standing *rule of reason* analysis as utilized by the judiciary in reviewing Sherman Act violations and further evidence that one should be leery of relying upon the DOJ's withdrawn Policy Statements in addressing Section 5 antitrust concerns.

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14 Doha Mekki, Principal Deputy Assistant Attorney General, Antitrust Division, Remarks at GCR Live: Law Leaders Global 2023 (Feb. 2, 2023), https://www.justice.gov/opa/speech/principal-deputy-assistant-attorney-general-doha-mekki-antitrust-division-delivers-0.

15 *Id.*

16 *Id.*

17 Press Release, U.S. Dep't of Justice, Justice Department Withdraws Outdated Enforcement Policy Statements (Feb. 3, 2023).

18 Fed. Trade Comm'n, Policy Statement Regarding the Scop of Unfair Methods of Competition Under Section 5 of the Federal Trade Commission Act (Nov. 10, 2022).

19 15 U.S.C. §45.

20 15 U.S.C. §§ 1–7.

21 15 U.S.C. §12-27.

V. WHAT DOES THIS MEAN FOR HEALTHCARE ANTITRUST ANALYSIS?

Healthcare marketplace stakeholders no longer have the level of guidance it previously had to rely upon when structuring transactions or even when contemplating whether they are advisable to consider. The "whole-of-government" approach referenced in the Executive Order forebodes many new, aggressive enforcement actions with a coordination among governmental authorities that traditionally have not jointly participated in such activities. These new initiatives should result in the following considerations to be contemplated early in the transaction process:

(i) Anticipation that there will be an expanded scope of scrutiny resulting in broader, more comprehensive investigations from one or more governmental authorities;
(ii) Recognize that a more focused investigation and analysis of the relevant geographic marketplace, including one that is much narrower than traditionally used, may be utilized in the analysis to ensure that an appropriate market analysis occurs;
(iii) Prepare in advance the need to present to the authorities more thorough information early in an antitrust review to assist in expediting the process;
(iv) Understand that a more individualized case-by-case analysis will result in greater uncertainty than what was encountered when the Policy Statements were in effect due to lack of Antitrust Safety Zones; and
(v) Expect to incur significant more expense in dealing with governmental authorities since it will be much more involved and time consuming.

While the healthcare industry has lost a valuable resource in consideration of and structuring transactions, it does not mean that traditional business arrangements that previously cleared antitrust scrutiny will not continue to do so. Rather, the Agencies will be more sensitive and focused of the impact of a healthcare transaction to ensure that not only at the time of the transaction but on a long-term going-forward basis it does not result in a negative impact in the delivery of healthcare.

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