Dissenting Statement of Commissioner Mozelle W. Thompson
Genzyme Corporation's Acquisition of Novazyme Pharmaceuticals Inc.
File No. 021-0026

A majority of the Commission voted today to close the investigation of Genzyme Corporation's 2001 acquisition of Novazyme Pharmaceuticals Inc. Although the Commission closed this investigation of a merger to monopoly in an innovation market,[1] in my view the Commission had reason to believe that Genzyme's acquisition of Novazyme violated Section 7 of the Clayton Act and Section 5 of the Federal Trade Commission Act. For that and the following reasons, I believe that the Commission should have issued an administrative complaint challenging the acquisition.

The basic facts of this matter are clear and for the most part uncontested. The Genzyme/Novazyme merger constitutes a consummated merger to monopoly in the research and development of a highly specialized drug, and entry of a new market participant is not likely to replace the innovation competition eliminated by the merger. The presumption of anticompetitive effects from this merger to monopoly has not been rebutted and is therefore sufficient to indicate that a Commission challenge is warranted. But further analysis of the Genzyme/Novazyme merger is helpful because it illuminates other issues important to innovation in America.

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[1] "An innovation market consists of the research and development directed to particular new or improved goods or processes, and the close substitutes for that research and development." U.S. Department of Justice and the Federal Trade Commission, *Antitrust Guidelines for the Licensing of Intellectual Property*, § 3.2.3 (April 9, 1995) (*Intellectual Property Guidelines*), *available at* http://www.usdoj.gov/atr/public/guidelines/ipguide.htm.

The Analysis of Innovation Mergers

In 1992, the Commission and the Department of Justice Antitrust Division issued the *Horizontal Merger Guidelines*,[2] which are now used by both agencies to analyze most mergers. Several years after these guidelines were issued, the Commission in 1996 held extensive public hearings on global and high-tech competition. The hearings included substantial testimony concerning "innovation mergers" – mergers that involve control of new ideas and product development. These hearings and further study eventually led to the development of the *Antitrust Guidelines for Collaborations Among Competitors* (or "*Joint Venture Guidelines*").[3] The *Joint Venture Guidelines*, which the agencies now use to analyze transactions such as collaborations in research and development ("R&D"), reflect the Commission's learning since the 1996 hearings and its more recent thinking about the role of innovation in the marketplace.[4] Among other things, the *Joint Venture Guidelines* establish that innovation collaborations that in effect amount to mergers, (*i.e.*, collaborations that are not merely narrow R&D joint ventures but are instead more complete and permanent integrations), will be analyzed using the *Horizontal Merger Guidelines*.[5]

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[2] U.S. Department of Justice and Federal Trade Commission, *Horizontal Merger Guidelines*, § 1.51 (April 2, 1992; revised April 8, 1997), *available at* http://www.ftc.gov/bc/docs/horizmer.htm.

[3] Robert Pitofsky, "Joint Venture Guidelines: Views from One of the Drafters," November 11 & 12, 1999, *available at* http://www.ftc.gov/speeches/pitofsky/jvg991111.htm.

[4] *See, e.g., Ciba-Geigy Limited, et al.*, 123 F.T.C. 842 (1997) (R&D of gene therapy to treat brain cancer); *The Upjohn Company, et al.*, 121 F.T.C. 44 (1996) (R&D of colorectal cancer treatments); *Glaxo PLC*, 119 F.T.C. 815 (1995) (R&D of migrane treatments); *American Home Products Corporation*, 119 F.T.C. 217 (1995) (R&D of vaccines for rotavirus).

[5] Federal Trade Commission and the U.S. Department of Justice, *Antitrust Guidelines for Collaborations Among Competitors*, §§ 1.3 and 4.3 (April 2000) ("*Joint Venture*

One important feature of the *Horizontal Merger Guidelines* is that they establish a rebuttable presumption of competitive effects for mergers if the change in, and resulting level of, market concentration is significant.[6] I see no compelling reason why innovation mergers should be exempt from the *Horizontal Merger Guidelines* or the presumption of anticompetitive effects for mergers to monopoly and other mergers as discussed therein.

The facts in this case further illustrate this point.

Genzyme's Acquisition of Novazyme Is Anticompetitive

The evidence gathered in this investigation establishes that: (1) the market should be defined as the market for the innovation of Pompe enzyme replacement therapies; (2) the geographic market is the world; and (3) entry is unlikely to deter or counteract the potential competitive effects. These elements of the merger analysis would likely not be susceptible to a serious challenge, and based on these facts alone, this merger to monopoly may be presumed anticompetitive under the *Horizontal Merger Guidelines*.[7] Moreover, the evidence is more than sufficient to find reason to believe that the Genzyme/Novazyme merger is anticompetitive,

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Guidelines"), *available at* http://www.ftc.gov/os/2000/04/ftcdojguidelines.pdf.

[6] U.S. Department of Justice and Federal Trade Commission, *Horizontal Merger Guidelines*, § 1.51 (April 2, 1992; revised April 8, 1997), *available at* http://www.ftc.gov/bc/docs/horizmer.htm. A merger to monopoly creates an HHI of 10,000; mergers that increase the HHI by more than 100 points to a post-merger HHI exceeding 1800 points are presumptively anticompetitive. The *Horizontal Merger Guidelines* address market power that adversely affects innovation: "Sellers with market power also may lessen competition on dimensions other than price, such as product quality, service, or *innovation*." *Horizontal Merger Guidelines*, § 0.1 (emphasis added). Because the presumption is rebuttable, merging parties may be able to overcome the presumption by presenting evidence relating to such issues as entry, effects, and efficiencies to the Commission. *See Horizontal Merger Guidelines*, § 1.51 c).

[7] *See Horizontal Merger Guidelines*, § 1.51.

irrespective of whether the Commission were to apply the guidelines' presumption to this particular merger.

The most significant single fact in this merger analysis is that the Genzyme/Novazyme combination brings together the only two companies in the world researching Pompe enzyme replacement therapies ("ERTs"). Pompe ERTs are designed to treat Pompe disease, a rare and fatal disease that affects up to 10,000 children and adults worldwide. Because of the rarity of the disease, Pompe ERTs will be subject to the Orphan Drug Act. This federal law provides seven years of market exclusivity to the first innovator to obtain U.S. Food and Drug Administration approval; but, the exclusivity may be broken by another innovator if it develops a superior product.[8]

The evidence shows that, between 1998 and 2001, Genzyme acquired control over the three other Pompe ERT R&D efforts in the world through joint venture or acquisition. Genzyme's 2001 acquisition of Novazyme completed its march to monopoly and eliminated any competition between itself and the only other remaining innovator.[9] This competition was important because it created a race between Genzyme and Novazyme to develop Pompe ERTs, thus increasing the pace of innovation. Now that Genzyme has acquired Novazyme, Genzyme cannot lose the innovation race as it has acquired the power to decide unilaterally and at any time

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[8] Pub. L. No. 97-414, 96 Stat. 2049 (1983) (codified as amended at 21 U.S.C. §§ 360aa-360ee (1988)).

[9] Innovator rivals in other Orphan Drug Act markets race to the market to gain exclusivity, thus confirming that innovation competition in Orphan Drug Act markets is just as important as in any other innovation market. *See infra* n.21.

whether to postpone or terminate its own research efforts or Novazyme's R&D project.[10]

Moreover, the Genzyme/Novazyme merger extinguished a second incentive. A non-merged Genzyme would have had the incentive not to only beat Novazyme to the market, but also to beat Novazyme to market with as great a lead as possible in case Novazyme successfully developed an exclusivity-breaking product. This second incentive would arise because Genzyme would recognize that it could gain a first-mover advantage; that is, Genzyme would be more likely able to gain and retain Pompe patients the greater the time interval between its entry and Novazyme's entry into the actual goods market.[11]

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[10] The pace of biotechnology research and development is sometimes difficult to predict; therefore, we cannot determine exactly how fast Novazyme could have progressed should it have chosen not to merge with Genzyme. What is clear, though, is that the development schedule of the Novazyme product has fallen four to six years behind Novazyme's pre-acquisition estimates and even behind Genzyme's initial projections.

Novazyme, before the acquisition, projected reaching clinical trials during "the end of 2001," and Genzyme, at the time of the acquisition, announced that the Novazyme Pompe product would reach clinical trials in "the first half of 2002." Interview of John Crowley, CEO, Novazyme (and other Novazyme officials) by International Pompe Association (May 21, 2001), *available at* http://www.worldpompe.org/internov.html ("Crowley Interview"); Genzyme Press Release, "Genzyme Completes Acquisition of Novazyme Pharmaceuticals," (September 27, 2001), *available at* http://www.prnewswire.com/cgi-bin/stories.pl?ACCT=105&STORY=/www/story/09-27-2001/0001580427 ("Genzyme Press Release"). Following the acquisition, Genzyme projected a Novazyme product launch first in 2005 and then revised the projection to sometime between 2009 and 2011. Genzyme Corporation, *Form 10-K for the Fiscal Year Ended December 31, 2001*, U.S. Securities and Exchange Commission File No. 0-14680, at GG-24; Genzyme Corporation, *Form 10-K for the Fiscal Year Ended December 31, 2002*, U.S. Securities and Exchange Commission File No. 0-14680, at GG-28; Genzyme Corporation, *Form 10-Q for the Quarterly Period Ended March 31, 2003*, U.S. Securities and Exchange Commission File No. 0-14680, at 77.

[11] This first-mover advantage results from the fact that some significant portion of Pompe patients who responded well to a new ERT that was approved for the market by the FDA would be understandably reluctant to switch treatments if a superior product subsequently reached the market. Of course, an independent Novazyme would have had the competing incentive to break a Genzyme exclusivity as soon as possible to minimize Genzyme's first-

Several other facts presented in this matter raise questions about Genzyme's true motives and the possible effects of the merger. First, Genzyme was willing to buy Novazyme for about $120 million,[12] a payment of considerable magnitude in exchange for an unproven company that had produced no product and whose research had not even reached the clinical trial stage. Second, the merged Genzyme/Novazyme pushed back the projected launch date for the Novazyme product four or more years.[13] Together, these facts raise the question whether Genzyme's sole motive was acquiring value found in Novazyme's R&D, or whether it had an interest in eliminating its only rival innovator. A third fact may also shine light on Genzyme's intent and the possible effects of the merger. Novazyme chose to take the relatively drastic step of merging with a direct competitor rather than pursuing any joint venture opportunities with Genzyme or another well-capitalized partner with biotech expertise similar to, or greater than, Genzyme's.

I am troubled by these facts and by the transaction's possible harm to innovation competition. We cannot foretell with certainty what this market would have brought in the absence of Genzyme's merger.[14] I do know, however, that the Novazyme acquisition affords Genzyme market power over Pompe ERT innovation and extinguishes any chance for competition to push innovation that could possibly bring the first or second Pompe ERT product

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mover advantage.

[12] Genzyme Press Release, *supra* n.10.

[13] *See supra* n.10.

[14] "Don't it always seem to go that you don't know what you've got till its gone?" JONI MITCHELL, *Big Yellow Taxi, on* LADIES OF THE CANYON (Reprise 1970).

to the actual goods market sooner.[15] This lost opportunity for innovation competition is more significant in this case because Novazyme's research path could conceivably have brought a superior product to this Orphan Drug Act market if it were placed in the hands of a biotech industry member other than Genzyme's. An alternative transaction thus could have resulted in either Novazyme's winning the initial race to market or Novazyme's breaking Genzyme's Orphan Drug Act exclusivity even if Genzyme had won the initial race.

Arguments Supporting the Merger Fail

In reaching this conclusion, I considered several arguments that could be raised to show why the Commission does not have reason to believe that the merger is unlawful. I believe that these arguments fall short for the following reasons.

First, it could be argued that the evidence from the time following the September 2001 merger does not support a determination that the merger has led to anticompetitive effects. The post-acquisition evidence, however, must be carefully evaluated according to the ultimate inquiry in merger analysis, which is "whether the merger is likely to create or enhance market power or to facilitate its exercise."[16] In evaluating the evidence relating to a consummated merger, the Supreme Court has cautioned against relying upon the fact that a firm refrained from

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[15] Although it may be helpful to consider separately the merger's potential impact on a relevant *goods* (as opposed to *innovation*) market, the Commission is not required as part of its analysis of innovation effects to consider the likelihood that the independent R&D programs would have resulted in the development of products for a goods market. *See Intellectual Property Guidelines*, § 3.2.3 (competitive effects for relevant goods, technology, and innovation markets are separately analyzed).

[16] *Horizontal Merger Guidelines*, § 0.2. The fact that this, or any, merger is consummated does not increase the evidentiary burden of finding a Clayton Act, Section 7 violation.

anticompetitive conduct following its acquisition of a competitor in an actual goods market:

> If a demonstration that no anticompetitive effects had occurred at the time of trial . . . constituted a permissible defense to a § 7 divestiture suit, violators could stave off such actions merely by refraining from aggressive or anticompetitive behavior when such a suit was threatened or pending.[17]

Relying upon such post-merger behavior is even more problematic in an innovation market because, in addition to the fact that the firm controls its own behavior, any reduction or delay of innovation would be inherently difficult to detect. This fact was specifically noted in the 1996 FTC staff report on the global and high-tech competition hearings, which observed that relying on post-acquisition evidence is difficult because "once a merger is consummated, the Commission cannot easily determine how quickly a new product would have been introduced absent the merger" or "what technological advances might have been achieved but for the merger."[18]

In this matter, the pre-merger evidence shows that Genzyme created or enhanced market power by acquiring Novazyme. My conclusion that this merger is anticompetitive is not changed by the fact that the evidence is insufficient to show whether Genzyme has thus far reduced the pace of Pompe ERT innovation due to the market power it gained with the merger. Indeed, the Commission could have found reason to believe that Genzyme unlawfully *created or enhanced* market power – whether or not there was evidence that Genzyme *exercised* market

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[17] *U.S. v. General Dynamics Corp.*, 415 U.S. 486 (1974) (footnote omitted); *see also FTC v. Consolidated Foods Corp.*, 404 U.S. 592, 598 (1965) ("[T]he force of § 7 is still in probabilities, not in what later transpired.").

[18] FTC Staff Report, *Anticipating the 21st Century: Consumer Protection Policy in the New High-Tech, Global Market Place*, Chapter Seven at 20 (Volume I, May 1996).

power during the period of time that its merger was under investigation.[19]

Second, several arguments might also be raised that in essence assert that the benefits of competition could be provided through a market incentive or other mechanisms that would regulate corporate behavior.[20] For example, it could be argued that the revenues Genzyme would have hoped to gain by completing its R&D and selling a Pompe ERT product on the market would have been a powerful incentive. This market incentive, the argument provides, would alone have prevented Genzyme from slowing the pace of innovation whether it became a monopolist or not. This claim fails because the evidence collected in this investigation showed that pre-merger competition did in fact bring an additional incentive to race in this particular innovation market.[21] It might also be argued that contingent payment provisions contained in the merger agreement would prompt former Novazyme shareholders in post-merger Genzyme positions to monitor Genzyme's efforts to develop the Novazyme product, thus thwarting any anticompetitive effects on innovation. But these $87.5 million payments, which are contingent upon receiving U.S. Food and Drug Administration approval to market products employing

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[19] *Horizontal Merger Guidelines,* § 0.2.

[20] Although it is not necessary to reach a conclusion that these arguments are not cognizable as a matter of law, I certainly have my doubts whether the Commission or any reviewing court would ever hold that these mechanisms could fully protect an innovation market from the adverse impacts of a merger to monopoly.

[21] Further, the investigation's witnesses pointed out three examples of other Orphan Drug Act markets where the presence or lack of competition affected the pace of innovation. In addition, a Federal district court recently observed that innovation competition occurred in yet another Orphan Drug Act market: "What ensued was a race for orphan drug approval since both Taxol and Paxene had been granted orphan drug designation; whichever drug was approved first would receive the seven-year period of market exclusivity." *Baker Norton Pharmaceuticals, Inc. v. U.S. Food and Drug Administration and Bristol-Myers Squibb Co.,* 132 F. Supp. 2d 30, 32 (D.D.C. 2001).

Novazyme's technology,[22] themselves provide Genzyme with a valuable incentive to delay the development of a Novazyme product. I also question whether monitoring could detect whether Genzyme's post-merger R&D efforts would be congruent to the level of efforts otherwise motivated by competition – a level that we will never be able to observe.[23] Accordingly, I do not believe that these contingent payment provisions constitute an adequate substitute for competition.

Further, it might be argued that Genzyme did not have the intent to slow the pace of innovation and/or the pre-merger pace of innovation would be maintained even in the absence of competition because Genzyme initially appointed the former Novazyme CEO to spearhead the Pompe program. The implicit reasoning would be that "formal" competition was not necessary because the former Novazyme CEO has personal incentives to maximize the pace of innovation. The facts show, however, that the executive could not exercise such influence over Genzyme's operation and left the company only a year after the merger.[24] For these reasons, any benefit that could be claimed from the appointment of the former Novazyme CEO to head the Pompe research is, at best, limited and, at worst, non-existent. More importantly, the Commission has long taken the position that, as a matter of law, possessing good motives is not a cognizable

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[22] Genzyme Press Release, *supra* n.10.

[23] *See supra* n.18. Moreover, I am not convinced that Genzyme or the shareholders believed that the payments were very likely and that Genzyme would have been concerned that one of its current executives would bring and win a breach of contract lawsuit.

[24] Geeta Anand, *Clinical Trials: For His Sick Kids, A Father Struggled to Develop A Cure,* The Wall Street Journal, August 26, 2003, at A1. The former Novazyme President is the father of two children unfortunately suffering from Pompe disease.

defense to an antitrust violation.[25]

The final argument that might be made in support of the merger is that the combination provides significant *merger-specific* efficiencies. Because we examined a consummated merger in this matter, we have the ability to evaluate specific claims of post-merger efficiencies and to determine whether there is in fact evidence to support such potential claims.[26] I believe that the evidence fails to support a determination that Genzyme's acquisition of Novazyme led to merger-specific efficiencies.

I do not believe that the merger provided any significant benefits to the Genzyme product in R&D. And, although I understand the argument that the merger may have been of some general benefit to the Novazyme R&D efforts, I found insufficient evidence of any *merger-specific* efficiencies because these benefits could have been created without the merger.[27] It is also possible that Genzyme and Novazyme would have achieved such benefits, while maintaining competition, if they had collaborated in a more narrow R&D joint venture.

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[25] "A firm, however well-intended, that lacks meaningful rivalry in its market simply cannot replicate the results of competition. Thus, as the Supreme Court has made clear, 'good motives will not validate an otherwise anticompetitive practice.'" Brief for Plaintiff-Appellant at Section II.A., Federal Trade Commission v. Butterworth Health Corp., et al., 1997-2 Trade Cas. (CCH) ¶ 71,863, 1997 LEXIS 17422 (6th Cir. 1996) (No. 96-2440) (*quoting* NCAA v. Board of Regents, 468 U.S. 85, 101 n.23 (1984)), *available at* http://www3.ftc.gov/bc/bbrepf~1.htm.

[26] As previously discussed, the Commission may choose to discount certain post-merger evidence. Specifically, the Commission may discount post-merger evidence demonstrating that the merger had no competitive effects if the merged firm had the ability to control this evidence. On the other hand, post-merger evidence relating to efficiency claims may be quite revealing because a merged entity has the incentive both to create efficiencies for its own benefit and to demonstrate them to the Commission.

[27] *Horizontal Merger Guidelines*, § 4.

Moreover, Novazyme could have collaborated with,[28] or could have been acquired by, another biotech firm. However, none of these practical alternatives were pursued.

For all of these reasons, I am satisfied that the Commission had reason to believe that the acquisition violated the Clayton and FTC Acts.

The Exercise of Prosecutorial Discretion

Beyond the legal issues in this matter, I believe this matter raises substantial competition policy issues. It could be argued that the Commission should exercise its prosecutorial discretion and not challenge the Genzyme/Novazyme merger even if the Commission had found reason to believe that the transaction was unlawful. An argument would be that litigation could disrupt Genzyme's efforts and ultimately harm Pompe disease patients, all without creating offsetting benefits because no meaningful and timely remedy is possible.

I am mindful of this concern. Even if some R&D activity were disrupted, however, the disruption would likely be limited and certainly not outweigh the innovation competition that is presently extinguished or the consequences of future loss that the public may experience because innovation may now not occur. Indeed, the very basis of modern antitrust jurisprudence is that competition has value. Exercising discretion not to bring a case would seem to discount this value. Nonetheless, there are several reasons that the impact of administrative litigation would not unduly harm innovation (assuming *arguendo* that it is good antitrust policy to accept business disruption as a good reason to refrain from challenging a monopolist we have reason to believe violated the antitrust laws).

First, pharmaceutical and other companies routinely litigate while engaging in R&D but

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[28] Crowley Interview, *supra* n.10.

nonetheless continue innovating. Genzyme itself has continued to operate while being involved in a number of legal controversies.[29] Second, while the legal issues could be complicated for a litigation based on an innovation market, the factual presentation in litigation could be somewhat streamlined in this particular case because, unlike some complex antitrust trials, the bulk of the facts here are fairly straightforward. For example, the challenged conduct (a merger) is undisputed; Genzyme likely could not factually dispute the alleged product and geographic market definitions; entry conditions are universally recognized as difficult; and the market structure is monopoly.

Of course, if the Commission had issued a complaint, Genzyme could always offer to settle administrative litigation in any number of ways. For example, it could offer to restore competition through divesting assets and/or licensing intellectual property. I acknowledge that remedies for consummated mergers can provide challenges that may or may not result in remedies equal to those that would have been provided by a pre-merger injunction or consent order. But imprecise or otherwise imperfect remedies for consummated mergers may still be able to replace some or all of the meaningful competition lost due to the merger.[30]

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[29] In addition to being investigated by the Commission (Pompe ERTs), Genzyme has recently been under investigation by the Office of Fair Trading in the United Kingdom (Cerezyme and other ERTs), and has been litigating a patent case against Transkaryotic Therapies, Inc. (Fabry ERTs) for the past three years. Genzyme Corporation, *Form 10-K for the Fiscal Year Ended December 31, 2002*, U.S. Securities and Exchange Commission File No. 0-14680, at 36.

[30] *See, e.g.*, MSC.Software Corp., Docket No. 9299 (August 14, 2002) (proposed consent order accepted for placement on public record for comment), *available at* http://www.ftc.gov/os/2002/08/mscsoftwareagee.pdf (ordering that a clone of the company's current software product be divested instead of those assets that the respondent acquired through the challenged acquisitions).

Even if this matter had been litigated to a Commission decision, an order at the end of the administrative trial would still benefit innovation in this market[31] because both research tracks are ongoing and the Novazyme product is now not projected to be introduced into the market for at least six more years.[32]

Conclusion

For all of these reasons, I voted against closing this investigation, and I would have voted to issue an administrative complaint challenging Genzyme's merger with Novazyme. Closing the investigation without issuing a complaint and leaving Genzyme with unfettered monopoly power could raise questions about the enforcement policies concerning innovation competition embodied in the *Intellectual Property Guidelines*, the *Joint Venture Guidelines*, and the *Horizontal Merger Guidelines*, as well as the Commission's long-standing merger enforcement efforts involving innovation markets. I believe that these policies are still good policies and protecting innovation competition has been a Commission success story over the past decade. Our actions have directly benefitted competition and consumers, and these actions have sent strong signals of support to innovators. In this matter, the failure to issue a complaint may lead the marketplace to draw a different conclusion.

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[31] Before the Hart-Scott-Rodino Antitrust Improvements Act of 1976, the federal antitrust agencies frequently struggled to find effective relief for unlawful consummated mergers. Bureau of Competition, Federal Trade Commission, *A Study of the Commission's Divestiture Process* 1 (1999). To ensure adequate opportunity for the Commission to obtain meaningful relief for consumers, it is critical that the Commission promptly review problematic consummated transactions that are not reported under the Hart-Scott-Rodino Act and aggressively seek appropriate remedies, either through administrative litigation or challenges in federal district court.

[32] *See supra* n.10.