

supply that participate in the market. Market participants consistently characterize generic drug markets as commodity markets in which the number of generic suppliers has a direct impact on pricing. Customers and competitors alike have confirmed that the price of a generic pharmaceutical product decreases with the entry of the second, third, and even fourth and fifth generic competitor. Further, customers generally believe that having at least four suppliers in a generic pharmaceutical market produces the most competitive prices.

Evidence gathered during our investigation indicates that anticompetitive effects are likely to result from a decrease in the number of independent competitors in the markets at issue. The Proposed Acquisition, by reducing an already limited number of competitors or potential competitors in each of these markets, would cause anticompetitive harm to U.S. consumers by increasing the likelihood of higher post-acquisition prices. In the market for generic calcipotriene topical solution, Novartis and Fougera are two of only three suppliers. In the lidocaine-prilocaine cream 30 gram tube market, Novartis and Fougera are two of only three suppliers of the product, and the Proposed Acquisition would eliminate Fougera as an independent competitor to Novartis leaving only Hi-Tech. In the generic lidocaine-prilocaine cream 5–5 gram tubes market, the Acquisition would result in a merger to monopoly. In the generic metronidazole gel market, Novartis and Fougera are two of four competitors, and combined, Novartis and Fougera represent 55 percent of the market. In all of these markets, industry participants have indicated that the presence of Fougera as a competitor has allowed them to negotiate lower prices.

Finally, the Acquisition would eliminate significant potential competition between Novartis and Fougera in the market for the sale of diclofenac sodium gel. Novartis, through its agreement with Tolmar, was the first to file for an approval of a generic form of Solaraze with the FDA. Thus, Fougera's brand, Solaraze, is likely to face competition solely from Novartis for a significant period of time when generic competition is introduced into this market. As a result, the Acquisition would increase the likelihood that the launch of a generic diclofenac sodium gel product would be delayed or abandoned altogether and increase the likelihood that the combined entity would delay or eliminate the substantial price competition that would have resulted

from the entry of a supplier of a generic diclofenac sodium gel product.

The Consent Agreement

The proposed Consent Agreement effectively remedies the Proposed Acquisition's anticompetitive effects in the relevant product markets. Pursuant to the Consent Agreement, Novartis is required to return certain rights related to the relevant products to Tolmar no later than ten (10) days after the Acquisition. Specifically, the proposed Consent Agreement requires that Novartis: (1) Terminate its marketing agreement with Tolmar, thereby returning all of its rights to distribute, market, and sell the Marketed Divestiture Products back to Tolmar; and (2) return all rights to develop, distribute, market, and sell generic diclofenac sodium gel to Tolmar. Tolmar is the Colorado-based developer and manufacturer of the relevant generic products.

If Novartis does not fully comply with its obligations to return all rights to generic calcipotriene topical solution, generic lidocaine-prilocaine cream, generic metronidazole topical gel, and generic diclofenac sodium gel, the Commission may appoint a trustee to effect the return of such rights.

The proposed remedy contains several provisions to ensure that the transfer of rights back to Tolmar is successful. The Consent Agreement contains an Order to Maintain Assets that requires Novartis to continue to market the Marketed Divestiture Products in a manner that maintains the full economic viability and marketability of the businesses until Tolmar directs Novartis to cease marketing the Marketed Divestiture Products or Tolmar's new marketing partner commences the distribution, marketing, and sale of the Marketed Divestiture Products.

The Commission appointed William Rahe of Quantic Regulatory Services, LLC to act as an interim monitor to assure that Novartis expeditiously complies with all of its obligations and performs all of its responsibilities as required by the Consent Agreement. In order to ensure that the Commission remains informed about the status of the returned rights and assets, the Consent Agreement requires Novartis to file reports with the interim monitor who will report in writing to the Commission concerning performance by Novartis of its obligation under the Consent Agreement.

The purpose of this analysis is to facilitate public comment on the proposed Consent Agreement, and it is not intended to constitute an official

interpretation of the proposed Order or to modify its terms in any way.

By direction of the Commission.

Richard C. Donohue,

Acting Secretary.

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GOVERNMENT ACCOUNTABILITY OFFICE

Appointments to the Medicare Payment Advisory Commission

AGENCY: Government Accountability Office (GAO).

ACTION: Notice of appointments.

SUMMARY: The Balanced Budget Act of 1997 established the Medicare Payment Advisory Commission (MedPAC) and gave the Comptroller General responsibility for appointing its members. This notice announces the appointment of five new members and the reappointment of one existing member.

DATES: Appointments are effective May 1, 2012.

ADDRESSES: GAO: 441 G Street NW., Washington, DC 20548.

MedPAC: 601 New Jersey Avenue NW., Suite 9000, Washington, DC 20001.

FOR FURTHER INFORMATION CONTACT: GAO: Office of Public Affairs, (202) 512–4800.

MedPAC: Mark E. Miller, Ph.D., (202) 220–3700.

SUPPLEMENTARY INFORMATION: To fill this year's vacancies I am announcing the following:

Newly appointed members are Alice Coombs, MD, Critical Care Specialist and Anesthesiologist, South Shore Hospital; Jack Hoadley, Ph.D., Research Professor, Health Policy Institute, Georgetown University; David Nerenz, Ph.D., Director of the Center for Health Policy and Health Services Research, Henry Ford Health System; Rita Redberg, MD, Professor, Clinical Medicine, University of California at San Francisco Medical Center; and Craig Samitt, MD, President and Chief Executive Officer, Dean Health System, Inc.. Their terms will expire in April 2015. The reappointed member is Glenn M. Hackbarth, J.D., (chair).

(Sec. 4022, Pub. L. 105–33, 111 Stat. 251, 350)

Gene L. Dodaro,

Comptroller General of the United States.

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