

Administration approval, takes at least two years. In addition to the regulatory hurdles facing a potential entrant, manufacturing difficulties in producing generic injectable products, combined with the small size of the markets in question, makes additional entry unlikely to occur.

### Effects

The Proposed Acquisition would cause significant anticompetitive harm to consumers in the U.S. markets for the manufacture and sale of generic injectable phenytoin and generic injectable promethazine. In generic injectable pharmaceuticals markets, price generally decreases as the second, third, or fourth competitors enter. Thus, reducing the number of competitors to two and one in each market, respectively, would cause anticompetitive harm to consumers in these U.S. markets by increasing the likelihood that consumers would pay higher prices.

### The Consent Agreement

The proposed Consent Agreement effectively remedies the Proposed Acquisition's anticompetitive effects in the relevant markets by requiring Hikma to divest certain rights and assets related to generic injectable phenytoin and generic injectable promethazine to a Commission-approved acquirer no later than ten days after the acquisition. The acquirer of the divested assets must receive the prior approval of the Commission. The Commission's goal in evaluating a possible purchaser of divested assets is to maintain the competitive environment that existed prior to the acquisition.

The proposed Consent Agreement remedies the competitive concerns the acquisition raises by requiring Hikma to divest its generic injectable phenytoin and generic injectable promethazine products to X-Gen, which will purchase all rights currently held by Hikma. X-Gen is a New York-based generic injectable pharmaceutical company with 40 active products and an active product development pipeline. With its experience in generic injectable markets and strong ties to manufacturing partners, X-Gen is expected to replicate the competition that would otherwise be lost with the Proposed Acquisition.

If the Commission determines that X-Gen is not an acceptable acquirer of the assets to be divested, or that the manner of the divestitures is not acceptable, the parties must unwind the sale to X-Gen and divest the phenytoin and promethazine product lines, within six months of the date the Order becomes final, to a Commission-approved

acquirer. The Commission may appoint a trustee to divest the products if Hikma fails to divest the products as required.

The proposed Consent Agreement contains several provisions to help ensure that the divestitures are successful. The Order requires Hikma to take all action to maintain the economic viability, marketability, and competitiveness of the products until such time as they are transferred to a Commission-approved acquirer. In addition, the parties must supply X-Gen with phenytoin and promethazine pursuant to a supply agreement while Hikma transfers the manufacturing technology to X-Gen or a third-party manufacturer of X-Gen's choice.

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.

**Donald S. Clark,**

*Secretary.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

### Office of the Secretary

#### Delegation of Authority

Notice is hereby given that I have delegated to HHS' Operating and Staff Division heads and the Chair(s) of the HHS Innovation Council, or their successors, the authorities vested in the Secretary under Section 105 of the America COMPETES Reauthorization Act of 2010 (Pub. L. 111-358) (which added Section 24 of the Stevenson-Wydler Technology Innovation Act of 1980, 15 U.S.C. 3701 *et seq.*), as amended, to administer and fund prize competitions aimed at stimulating innovation. This delegation excludes the authority under Section 24(k)(3) to develop guidelines for the appointment of judges, which I hereby delegate to the Chair(s), HHS Innovation Council. Additionally, I reserve the authorities under Section 24(m)(3)(B) to approve an increase in the amount of a prize after initial announcement has been made and to approve the award of more than \$500,000 in cash prizes.

These authorities may be redelegated. The authorities granted herein shall be exercised in accordance with the Department's applicable policies, procedures, and guidelines. I hereby affirm and ratify any actions taken by you or your subordinates, which involve

the exercise of this authority prior to the effective date of this delegation. This delegation is effective upon date of signature.

**Authority:** 44 U.S.C. 3101.

**Dated:** April 22, 2011.

**Kathleen Sebelius,**  
*Secretary.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### HIT Standards Committee; Schedule for the Assessment of HIT Policy Committee Recommendations

**AGENCY:** Office of the National Coordinator for Health Information Technology, HHS.

**ACTION:** Notice.

**SUMMARY:** Section 3003(b)(3) of the American Recovery and Reinvestment Act of 2009 mandates that the HIT Standards Committee develop a schedule for the assessment of policy recommendations developed by the HIT Policy Committee and publish it in the **Federal Register**. This notice fulfills the requirements of Section 3003(b)(3) and updates the schedule posted in the **Federal Register** on October 8, 2010. In anticipation of receiving recommendations originally developed by the HIT Policy Committee, the HIT Standards Committee has created four (4) workgroups or subcommittees to analyze the areas of clinical quality, clinical operations, implementation, and privacy and security.

HIT Standards Committee's Schedule for the Assessment of HIT Policy Committee Recommendations is as follows: The National Coordinator will establish priority areas based in part on recommendations received from the HIT Policy Committee regarding health information technology standards, implementation specifications, and/or certification criteria. Once the HIT Standards Committee is informed of those priority areas, it will:

(A) Direct the appropriate workgroup or subcommittee to develop a report for the HIT Standards Committee, to the extent possible, within 90 days, which will include, among other items, the following:

(1) An assessment of what standards, implementation specifications, and certification criteria are currently available to meet the priority area;

(2) An assessment of where gaps exist (*i.e.*, no standard is available or harmonization is required because more than one standard exists) and identify