NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

Statement

Of

The National Association of Chain Drug Stores

For

United States House of Representatives
Energy and Commerce Committee
Subcommittee on Health

Hearing on:

Examining Implementation of the Biologics Price Competition and Innovation Act

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10:00 a.m.
Room 2123 Rayburn House Office Building

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Introduction

The National Association of Chain Drug Stores (NACDS) thanks the Subcommittee on Health for the opportunity to submit a statement for the hearing on "Examining Implementation of the Biologics Price Competition and Innovation Act." NACDS and the chain pharmacy industry are committed to partnering with Congress to provide affordable healthcare solutions to patients, including policies that promote access to cost-effective biosimilar medications.

NACDS represents traditional drug stores and supermarkets and mass merchants with pharmacies. Chains operate more than 40,000 pharmacies, and NACDS' chain member companies include regional chains, with a minimum of four stores, and national companies. Chains employ more than 3.2 million individuals, including 179,000 pharmacists. They fill over 2.9 billion prescriptions yearly, and help patients use medicines correctly and safely, while offering innovative services that improve patient health and healthcare affordability. NACDS members also include more than 850 supplier partners and over 60 international members representing 22 countries. For more information, visit www.NACDS.org.

Over the years, community pharmacies and pharmacists have worked to provide affordable medications to patients by dispensing generic versions of brand name drugs where generic products are available. These generic substitution practices have saved

patients and payors trillions of dollars.[1] On average, the retail price of a generic drug is 75 percent lower than the retail price of a brand-name drug.[2] Despite the pharmacy community having worked diligently to promote dispensing of cost-effective generic medications and to increase the rate of generic dispensing, overall drug costs continue to rise. This trend is in part attributable to expensive new biologic drugs that, up until now, have faced no generic competition in the market. While these new biologic drugs can drastically improve patients' health, they can also cost thousands of dollars per month. Unfortunately, high prices can place these medications out of reach for many patients.

With the enactment of the Biologics Price Competition and Innovation (BPCI) Act in 2010, Congress created the regulatory pathway for the Food and Drug Administration (FDA) to approve biosimilar versions of biological medications. With this framework now in place, NACDS continues to support the expeditious implementation of the BPCI Act to facilitate patient access to more affordable versions of biological medications.

Implementing the BPCI Act

Under the BPCI Act, FDA has been working to implement the drug approval pathway for biosimilars and has issued various draft and final guidance documents for the development and approval of biosimilar drugs. Ultimately, FDA's work in this area provided sufficient direction to allow for the first FDA biosimilar approval in the spring of 2015. In addition to this work, FDA has indicated that the agency will release several

[1] GPhA, Generic Drug Savings in the U.S. (September 2014)
[2] Congressional Budget Office (CBO), Effects of Using Generic Drugs on Medicare's Prescription Drug Spending (Washington, D.C.: September 2010).

guidance documents in 2016, including guidance for how biosimilar manufacturers can demonstrate that biosimilar products are "interchangeable" with their reference biological product. In particular, FDA guidance on interchangeability will be crucial to facilitate the availability of interchangeable biosimilar drugs that can be substituted at the pharmacy level to realize greater cost savings. For this reason, we support the expeditious release of the interchangeability guidance.

While NACDS generally supports FDA's work to implement the BPCI Act, we do have concerns with the agency's proposed new naming scheme for biological products as outlined in the draft guidance document titled "Nonproprietary Naming of Biological Products; Draft Guidance for Industry." Deviating from traditional naming practices for other drugs and medications, FDA's naming proposal for biological medications would assign all biological products a nonproprietary name comprised of a core name to be shared among reference biological products and associated biosimilar products, along with a four-letter suffix that is unique to each biological and biosimilar. FDA has not determined how it will apply this naming scheme to biosimilar products deemed interchangeable.

Essentially, FDA's proposed naming scheme would result in unique names for each biological product and their biosimilar counterpart, including potentially biosimilar products deemed interchangeable by FDA. Considering that all other substitutable drugs share a common nonproprietary name, we are concerned that FDA's new naming

proposal for biological products would lead to confusion among prescribers and dispensers that could result in serious patient safety issues.

NACDS supports naming policies for biosimilar drugs and biologics that are consistent with the naming conventions for brand and generic small molecule drugs. We encourage lawmakers to press FDA to adopt naming policies that are consistent with existing naming drug conventions and that support safe substitution practices for interchangeable biosimilars.

Medicare Part B Payment Policies for Biosimilar Biological Products

Reimbursement policies for biosimilar medications are also crucial to the development and uptake of these products. The Centers for Medicare and Medicaid Services (CMS) addressed reimbursement for biosimilar medications in the 2016 Physician Fee Schedule, which outlines payment policies under Medicare Part B. The 2016 Physician Fee Schedule specifies that reimbursement for biosimilar products will be based on the average sales price of all biosimilar products included within the same billing and payment code. However, it remains unclear whether this payment approach is intended to apply only to biosimilar products deemed interchangeable by FDA, or whether this would also include non-interchangeable biosimilars. CMS acknowledges this, noting that the 2016 Physician Fee Schedule final rule does not address whether a product's interchangeability status should be the basis for a different approach to Part B payment,

and that the agency would preserve their discretion to consider whether further refinements to the biosimilar payment policy may be necessary as the market develops.

It is critical that the reimbursement calculation only include interchangeable products. If CMS ultimately opts to blend biosimilar billing and payment codes to include both interchangeable biosimilars and non-interchangeable biosimilars, we believe this would create access barriers for patients at the pharmacy counter, lead to increased costs for healthcare payers, and result in inadequate reimbursement for pharmacies. If non-interchangeable biosimilars receive blended reimbursement from Medicare Part B, it could create a disincentive for manufacturers to develop new biosimilar products. Since non-interchangeable biosimilars are not automatically substitutable in the way that traditional small molecule generic drugs are, the costs of these biosimilar products may vary based on numerous factors. Blended reimbursement prevents manufacturers from setting appropriate prices relative to their individual costs, which could lead to fewer products in the marketplace resulting in fewer choices for beneficiaries and potentially reducing cost savings.

Limiting the number of choices available to the beneficiary will make it harder for prescribers and pharmacists to manage a patient's medication regimen. Furthermore, such a payment policy would put pharmacies at risk for being reimbursed at a price based on the lower, average cost of all products included in the code - which may not cover the cost of the dispensed product. The authority to substitute interchangeable biosimilar

products in the same manner as for traditional generics is the key to establishing a reimbursement policy that ensures patient access to these vital medications.

NACDS believes CMS should delay implementing a reimbursement policy until final guidance for interchangeable products is issued by FDA. Since FDA has not yet issued final guidance, it is premature and inappropriate for CMS to comment on the reimbursement of interchangeable biosimilars. The complex nature of biologicals warrants a cautious, balanced approach. We ask lawmakers to urge CMS to defer a biosimilar payment policy until clear standards are in place that will give patients and healthcare professionals confidence in biosimilar and interchangeability designations.

Conclusion

Thank you for the opportunity to share our views on issues relating to the implementation of the BPCI Act. We look forward to working with you on policies that impact patient access to affordable biological medications.