

**Testimony of Marc M. Boutin, JD  
Chief Executive Officer  
National Health Council**

**Hearing on “Lowering the Cost of Prescription Drugs:  
Reducing Barriers to Market Competition”  
March 13, 2019**

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

Good morning Chairwoman Eshoo, Ranking Member Burgess, and distinguished members of the Subcommittee on Health. My name is Marc Boutin, and I serve as the Chief Executive Officer of the National Health Council (NHC).

I am honored to join the Subcommittee today to discuss the importance of a thriving generics and biosimilars market to promote competition to drive down costs and increase access for people with chronic diseases and disabilities. I am also here today to talk about specific anti-competitive practices that are causing a chilling effect on robust competition.

**Background on the National Health Council**

Founded in 1920, the NHC is the only organization that brings together all segments of the health community to provide a united voice for the more than 160 million people with chronic diseases and disabilities and their family caregivers. Made up of more than 125 diverse national health-related organizations and businesses<sup>1</sup>, the NHC's core membership includes the nation's leading patient advocacy organizations. Other dues-paying members include professional and membership associations; nonprofit organizations with an interest in health; representatives from the pharmaceutical, generic drug, health insurance, device, and biotechnology industries; and research, provider, and family caregiving organizations. Because of this diverse membership, the NHC can harness the collective expertise of the broader health community to address systemic issues that affect access to affordable, high-quality care for all patients, regardless of disease or disability. At the same time, while all NHC members are provided the opportunity to provide input into our public policy and education initiatives, control over the NHC's governance and policy-making process resides with our core membership of patient advocacy organizations.

In addition to membership dues payments, the NHC receives financial sponsorships<sup>2</sup> for programmatic activities from biopharmaceutical, generic drug, device, and insurance companies, and their trade associations. The NHC and our member patient organizations meet

---

<sup>1</sup> <https://www.nationalhealthcouncil.org/about-nhc/membership-directory>

<sup>2</sup> <https://www.nationalhealthcouncil.org/about-nhc/sponsors>

our Standards of Excellence<sup>®3</sup> requirements to ensure our work is transparent, independent, and mission-driven.

### **Rising health care costs create significant challenges for the patient community.**

Over the last few years, I have conducted numerous listening sessions with CEOs of patient organizations, asking them to describe the most significant challenges their constituents currently face. According to a recent poll by *Kaiser Health News*, almost half of people in poor health – our constituents – have a hard time paying for their medications.<sup>4</sup> While patient organizations care deeply about driving innovation to help their constituents improve how they feel, function, and survive, they are equally or more concerned about affordable access to high-value care. Even people with life-threatening conditions such as certain types of cancer, neurological, and rare diseases are finding significant access barriers to routine care, and those with historically inexpensive, yet effective, treatments like heart disease have found their costs rising dramatically.

Take for example the story of Mackenzie.

Mackenzie is a 32-year-old writer from North Carolina running her own small business. She has the common genetic condition called Familial Hypercholesterolemia (FH). She was born with cholesterol levels more than three times normal, putting her at very high risk for an early heart attack. FH caused her mother to have quadruple bypass at age 42, so Mackenzie works hard to keep her own cholesterol low. FH management requires medication, often with more than just a statin.

Mackenzie knew adding another medication, Zetia, to her statin treatment would help get her cholesterol closer to normal. She struggled with whether she could afford it on top of her existing medical bills. Mackenzie ended up paying \$60 out-of-pocket per month for Zetia on top of her other medicines - a real burden for a young professional just starting out. When the generic version – ezetimibe – became available at the end of 2016, the cost dropped to \$5 a month. Being able to afford the medication improved her health and reduced her stress, a pivotal factor in heart disease prevention.

Every day, people across the country are forced to make the difficult decision about filling their prescriptions, paying rent, or putting food on their tables. For the more than 160 million people in the US who live with a chronic disease or disability, we must do better. Reducing barriers to market competition is a much-needed step to reducing health care costs for people like

---

<sup>3</sup> The NHC has adopted a set of good operating practices to ensure that its member patient organizations maintain the highest standards of organizational effectiveness and public stewardship. To become a member of the NHC, patient advocacy organizations must meet the requirements set forth in the NHC's Standards of Excellence Certification Program<sup>®</sup>, which includes 38 standards covering the areas of governance, human resources, programs, fundraising, finance, accounting and reporting, and evaluation. Notably, these standards include requirements that any financial relationships with pharmaceutical manufacturers to be publicly reported, independent, and directed toward a mission-related benefit. <http://www.nationalhealthcouncil.org/resources/standards-excellence-certification-program>.

<sup>4</sup> Kirzinger, A, et al. KFF Health Tracking Poll – February 2019: Prescription Drugs. March 1, 2019

Mackenzie. However, this is just one component of a broader strategy to reduce health care costs, including, but not limited to, drug spending.

### **Increasing the availability of generic drugs and biosimilars reduces costs for patients.**

In the fall of 2016, the NHC evaluated nearly 200 policy proposals that aim to reduce the cost of health care. Based on that evaluation, we put forward a number of potential solutions we believe can help reduce health care costs, including drug prices, without limiting access, sacrificing quality, or hindering innovation.<sup>5</sup> Unfortunately, the vast majority of proposals that purport to reduce costs do so at the expense of access to care for those most in need.

More importantly, we also found that very few proposals are actually supported by evidence demonstrating they will in fact reduce costs. The one major exception is increasing competition, especially through generic-drug competition. Studies, including an analysis by the U.S. Food & Drug Administration (FDA), show that having multiple generic drugs on the market dramatically lowers drug prices.<sup>6,7</sup> Thus, it is imperative that we focus on policies that lead to greater availability and utilization of generics and biosimilars, as long as these policies consider clinical nuances to ensure people have access to the most appropriate treatments.<sup>8</sup>

In fiscal year 2018, due in-part to NHC-supported provisions included in the FDA Reauthorization Act, a record 1,021 generic drugs were approved or tentatively approved by FDA.<sup>9</sup> To ensure this trend continues, the NHC has supported FDA's efforts to reduce barriers to generic-drug approval. Additionally, we support proposed regulations being considered by the Administration to ensure patients are aware of the availability of generic drugs and lower-cost alternatives in public programs and encourage further action related to formulary transparency.

The NHC sees similar opportunities with biosimilars. While biologics provide tremendous value to patients, lack of competition in the marketplace has contributed to high prices for patients. Approximately 1-2% of the population use biologics, yet they account for nearly 40% of

---

<sup>5</sup> National Health Council. NHC Policy Proposals for Reducing Health Care Costs. 2017. <http://www.nationalhealthcouncil.org/healthcarecosts>.

<sup>6</sup> U.S. Food & Drug Administration. Generic Competition and Drug Prices. 2017. <https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm129385.htm>

<sup>7</sup> Alpern JD, et al. Trends in Pricing and Generic Competition Within the Oral Antibiotic Drug Market in the United States. Clin Infect Dis. 2017 Nov.

<sup>8</sup> For the vast majority of patients, generics work just as well as branded drugs. However, some patient populations have high levels of heterogeneity, resulting in instances where slight changes to formulations can have significant impacts on effectiveness and side effects. Similarly, while some biosimilars in certain disease states can be considered "interchangeable," switching in other disease states can have devastating consequences. Thus, it is important to consider safeguards to allow individuals to access branded treatments if they are more medically appropriate than a generic or biosimilar.

<sup>9</sup> U.S. Food & Drug Administration. Office of Generic Drugs. 2018 Annual Report. 2018. <https://www.fda.gov/downloads/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/Generics/UCM631997.pdf>

prescription drug spending.<sup>10</sup> A robust biosimilars market has the potential to reduce costs in our health care system and improve access and affordability for millions of patients. The NHC supports policy measures that encourage the development and adoption of biosimilar therapies, including recent steps taken by the FDA to improve the efficiency of the biosimilar approval process and to clarify development and approval requirements.

### **Anti-competitive business practices are preventing generic and biosimilar entry.**

The NHC keenly understands the need for intellectual property protections to drive innovation. Patents and FDA exclusivities reduce uncertainty for biopharmaceutical companies and investors. They provide incentives for companies to invest in research and development to bring lifesaving medicines to millions of patients who do not have effective treatments or cures. However, some companies have abused these laws.

I highlight two practices limiting the market entry of generic drugs and undermining the intent of current laws and regulations: First is the use of patent settlements (also called for “pay-for-delay” settlements) to prevent timely entry of generics and biosimilars into the market. Second is the use of the FDA’s Risk Evaluation and Mitigation Strategies (REMS) program to prevent generic manufacturers from acquiring needed reference materials to conduct testing necessary to secure FDA approval.

#### *Pay-for-Delay Settlements*

Patent settlements between brand and generic drug manufacturers may sometimes delay the entry of generics beyond when they would normally come onto the market. While there are instances where patent settlements between brand and generic manufacturers can reduce the cost of litigation and bring generics onto the market sooner, there are also instances in which the settlements are intended simply to block the entry of a generic drug to the market (those “pay-for-delay” settlements).

#### *Use of REMS to Delay Market Entry*

For drugs with known or potential risks, REMS is an important program that protects patient safety. However, the REMS program has been exploited by some brand manufacturers to block generic- and biosimilar-product developers from accessing sufficient doses of a brand product needed to conduct studies required for FDA approval of a new generic or biosimilar. The FDA has received more than 150 requests from generic drug developers seeking assistance in obtaining samples from brand companies, so many that the FDA has taken to making a list of these inquiries public.<sup>11</sup>

---

<sup>10</sup> Rand Corporation. Biosimilar Cost Savings in the United States. 2017.  
[https://www.rand.org/content/dam/rand/pubs/perspectives/PE200/PE264/RAND\\_PE264.pdf](https://www.rand.org/content/dam/rand/pubs/perspectives/PE200/PE264/RAND_PE264.pdf)

<sup>11</sup> U.S. Food & Drug Administration. Reference Listed Drug (RLD) Access Inquiries. Updated February 7, 2019.  
<https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/ucm607738.htm>.

A related issue occurs when brand and generic drug manufacturers must share a single REMS program. In this scenario, a generic drug manufacturer must reach an agreement with a brand manufacturer on a shared REMS program. According to the FDA, these negotiations may be used strategically by brand manufacturers to delay the market entry of a generic drug.<sup>12</sup>

These practices – and other techniques that delay generic and biosimilar entry – must be addressed by Congress. They prevent the potential cost-savings that can be achieved through the competition of multiple generics on the market. The end result is that people pay more at the pharmacy counter, preventing many of them from accessing meaningful care.

### **Other market forces are also limiting competition.**

Unfortunately, the tremendous recent increase in generic approvals have not always resulted in increased access. A recent report by the Kaiser Family Foundation found that 43% of generic drugs—about 700—approved by the FDA since January 2017 are still not on the market.<sup>13</sup> The report notes that part of the reason for this is the type of anti-competitive practices that we are discussing today. However, they also note other factors such as industry consolidation and business decisions not to manufacture specific products have resulted in many of the approved generics never making it to market.

While outside of the scope of today's hearing, Congress and the Administration must work to address significant misalignment of incentives and lack of transparency throughout the drug distribution system. As noted by FDA Commissioner Scott Gottlieb, when insurers and pharmaceutical benefit managers have greater incentive to include branded drugs and biologics on their formularies than generics and biosimilars<sup>14</sup>, we risk missing out on the promised cost savings generics and biosimilars could provide to the millions of people with chronic conditions who desperately need them.

### **Conclusion**

We commend the Health Subcommittee for shining a light on some of the practices that limit patient access to affordable medicines. We and our members stand ready to work with Congress on policies to reduce the costs of medicines. It is important we work together on policies that achieve cost reduction but not at the expense of access to effective medications. Such approaches often result in worse outcomes and increased costs for hospital, emergency

---

<sup>12</sup> U.S. Food & Drug Administration. Statement from FDA Commissioner Scott Gottlieb, M.D. on new steps to improve FDA review of shared Risk Evaluation and Mitigation Strategies to improve generic drug access. November 8, 2017.

<https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm584259.htm>

<sup>13</sup> Lupkin, S and Hancock, J. Trump Administration Salutes Parade of Generic Approvals, but Hundreds Aren't for Sale, Kaiser Health News. February 7, 2019.

<sup>14</sup> <https://www.fda.gov/newsevents/speeches/ucm599833.htm>

department, or other health care services.<sup>15</sup> Thus, a holistic approach that looks at total costs of care is needed.

Increasing competition in the drug market is an important step in the nation's effort to lower health care costs to increase patients' access to needed treatment. But, it should not be the only step. We call upon Congress to consider all the drivers of health care costs and craft holistic policies that can reduce the significant financial burden on people with chronic diseases and disabilities and their family caregivers.

Thank you for the opportunity to speak with you today and for joining us in making increasing access to affordable, sustainable, high-value health care a national priority. I look forward to working with you and welcome any questions you may have.

---

<sup>15</sup> Hsu J., et al. Unintended Consequences of Caps on Medicare Drug Benefits. N Engl J Med. 2006