January 25, 2018

The Honorable Alex Azar
Secretary, U.S. Department of Health and Human Services (HHS)
200 Independence Avenue, S.W.
Washington, D.C. 20201

Submitted electronically via: CompetitionRFI@hhs.gov

RE: Promoting Healthcare Choice and Competition Across the United States

Dear Secretary Azar:

The National Business Group on Health (NBGH or the “Business Group”) appreciates the opportunity to comment on HHS’ Request for Information (RFI) on promoting healthcare choice and competition across the United States. In particular, the Business Group appreciates providing the agency with employers’ perspectives on consolidation in healthcare markets and abuses of market power, and the need for improved consumer access to quality information needed to make informed healthcare decisions. Additionally, for consideration, we offer our perspective on needed reforms to increase competition in the prescription drug market, as soaring prices for prescription drugs must be considered within the overall context of healthcare choice and competition.

The National Business Group on Health represents 419 primarily large employers, including 74 of the Fortune 100, who voluntarily provide group health and other employee benefits to over 55 million American employees, retirees, and their families. Being mostly self-funded, our employer members as well as many other employers, have a vested interest in more effective, efficient health care and promote health plan designs that encourage delivery of the right care at the right time and in the right place; an emphasis on promoting health and primary and preventive care; improving value while reducing the cost of care; and, delivering services to the highest level of customer satisfaction.

I. Consolidation in Health Care Markets & Abuses of Market Power

Some consolidation in the very fragmented market for health care in the US may be necessary and appropriate to increase care coordination and integration of health care and drive efficiencies. However, as in any market, excessive consolidation can lead to consumers paying higher prices than in markets with sufficient competition.

Merging companies often tout benefits including cost savings and increased care coordination, but serious concerns about market power also need to be raised. In the Business Group’s Large Employers’
2018 Health Care Strategy and Plan Design Survey\(^1\), employers were asked about the inappropriate/inefficient use of the health care system as a cost driver, and they ranked it fifth overall. Additionally:

- 62% of large employers are concerned about increased costs due to provider consolidation.\(^2\)
- While only a few employers see provider consolidation as one of the top drivers of health care trend, they are keeping an eye on consolidation.\(^3\)
- 90% of markets are highly concentrated for hospitals, with the fastest rise associated with primary care doctors.\(^4\)
- Primary care physician market concentration is being driven by hospitals, when analyzed by looking at the percentages of primary care physicians working in organizations, by ownership.\(^5\)
- Four studies that evaluated the association between mergers and medical prices have demonstrated that price increases ranging from 20% to 45% occur following consolidation.\(^6\)

In particular, the race for vertical integration in the hospital and provider communities has led to an increase in reimbursement rates at off-campus hospital outpatient departments (HOPDs), not necessarily linked to an increase in resources expended for same services or overall improvement in quality of patient care. According to MedPAC, Medicare may pay nearly 80% more to HOPDs than ambulatory surgery centers (ASCs) for the same procedure. The location where the services are delivered, the costs of operating in that setting, and the different patient populations served are all factors that determine the rate, such that the same service provided in a variety of clinical settings may sometimes be paid at dramatically different rates. However, oftentimes, the more costly setting is not warranted by a patient’s level of risk.

MedPAC has identified 66 outpatient service payments—including three groups of cardiac imaging services—for which equalizing reimbursement rates would save $900 million annually.\(^7\) The report also identified 12 groups of services commonly performed in ASCs that would generate about $600 million in annual savings if HOPD rates are lowered to the level of ASCs.\(^8\)

In addition, variable rates for the same services in HOPDs, including in physician practices acquired by hospital systems, vs. independent physician offices is a growing issue. The Government Accountability

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1 The Large Employers’ 2018 Health Care Strategy and Plan Design Survey was conducted between May and June 2017. A total of 148 large employers participated in the survey. Collectively, respondents represent a wide range of industry sectors and offer coverage to more than 15 million employees and their dependents. Two-thirds of respondents belong to the Fortune 500 and/or the Global Fortune 500, and 42 belong to the Fortune 100. The survey can be accessed here: https://www.businessgrouphealth.org/pub/?id=62A23B83-DC87-F58C-38FB-881AF80C8272
2 Ibid.
3 Ibid.
5 Ibid.
8 Ibid.
Office (GAO) has noted that payment differences have encouraged hospitals to acquire physician practices, leading to higher rates for office visits. Select examples, according to the Medicare Payment Advisory Commission (MedPAC), include:

- Medicare reimburses $453 for a level II echocardiogram performed in an off-campus HOPD vs. $189 in a doctor’s office.
- Similarly, Medicare reimburses $1,383 for a colonoscopy performed in an off-campus HOPD vs. $625 in a doctor’s office.

The GAO report stated that such payment variations "urgently need to be addressed because many ambulatory services have been migrating from physicians’ offices to the usually higher-paid outpatient department settings, as hospital employment of physicians has increased." Government can play an effective role in addressing higher prices that come from consolidation by pursuing policies that foster increased competition in health care markets. Specifically, HHS should support efforts at the Federal Trade Commission (FTC) to:

1) Increase scrutiny of:
   - **Vertical consolidation**, where companies in different lines of work, often offering complementary services, consolidate or integrate. As an example, when a hospital system acquires a post-acute care facility or physician practices;
   - **Horizontal consolidation**, where two similar companies consolidate, such as two hospitals; and,
   - **Cross-market consolidation**, where companies operating in different geographic or product markets, consolidate or integrate.

   Further, it is critically important to scrutinize future mergers because of their impact on an already excessively concentrated healthcare marketplace. The Federal Trade Commission (FTC) cites an 18% increase in hospital mergers in 2015 over the prior year, and 70% more mergers and acquisitions than in 2010, with 102 of those transactions involving 265 hospitals around the country in 2015 alone.

2) Lower the threshold for mandatory reporting of planned transactions involving acquisition of provider practices, given that most of these transactions fall below the current threshold, particularly if the health system has more than a 30% or other appropriate percentage of the primary care market in a given service area.

3) Increase monitoring and evaluation of post-merger market impacts and strengthen enforcement actions where anti-competitive harms occur.

Within HHS, HHS should prioritize the following:

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10 Ibid.
4) **Explore and expand the implementation of rate parity to providers, for same services, regardless of the practice location.**
   - We believe that financial incentives should not influence the site of care when multiple settings are appropriate for patients and do not adversely affect the quality of care. Following this payment policy would encourage competition, reduce expenditures for Medicare beneficiaries, and strengthen incentives to provide services at the lowest-cost sites of care that are appropriate.

5) **Mitigate unintended consolidation incentives within provider payment reform policies.**
   - Consider ways to increase independent provider participation in alternative payment models, including groups with fewer than 10 providers, and those in rural areas.

6) **Promote use of services by lower cost providers and facilities where appropriate through Medicare policy.**
   - Nurse practitioners (NPs), physician’s assistants (PAs), urgent care, and retail clinics, all as examples, can provide many primary and preventative services more efficiently, at lower cost, and more conveniently for patients.

II. **Transparency: Improved Consumer Access To Quality Information**

The Business Group strongly supports reforms and efforts to create a culture of healthcare price and quality transparency, for which the legal framework already exists. We believe that efforts to increase transparency reduces healthcare costs and increases quality by allowing patients to compare prices and quality. Further, increased transparency fosters competition between providers and hospitals, and is foundational to improved consumerism. Finally, the structure of consumer directed health plans has created demand for more healthcare transparency, especially as it pertains to costs of services and out-of-pocket expenses.

Despite the growing popularity of Internet-based tools to compare health care services and providers, Americans need enhanced access to comprehensive, real-time, price, quality and clinical effectiveness information about their medical care and prescription drugs. Thus, below we make recommendations to enhance price transparency.

**CMS and HHS should continue their efforts to lead and support the development of reporting meaningful price and quality measures.**

1) **HHS should continue to support efforts to establish core measure sets of quality outcome metrics as well as measures of cost and efficiency – these allow consumers to make meaningful comparisons.**

2) **CMS should continue to release to the public and make broadly available for analysis Medicare physician claims and hospital payment data as well as information on quality.**

Additionally, the Business Group recommends that all health care providers and facilities should publicly disclose, in a user-friendly format, all relevant information about the relative price, quality, safety and efficacy of recommended treatments and prescription drugs.
3) Require outpatient facilities and physician offices to disclose whether they are billing as providers or as facilities, and require them to disclose the differential prices (facility fees) prior to patients’ receipt of services and preferably at the time they schedule appointments.

4) Similarly, CMS should make publicly available transparency information on prescription drugs provided in the hospital outpatient and inpatient settings for Medicare patients.

Access to information about the price and quality of healthcare services can help consumers make better and more informed choices about their care, thus creating a functional, competitive market. However, it is surprisingly difficult for consumers to get this information – especially in a readable, digestible and standardized format that allows for meaningful comparisons across care categories. In fact, even today, the majority of patients rarely know the true cost of care let alone how much they need to pay until after they have received it.

This information void is particularly detrimental to informed choice in a market where the price—and quality—of a particular service can vary considerably by provider, geography, network and site of service, even for common procedures and even prescription drugs. What’s more, it has become increasingly evident over time that higher prices for either prescription drugs or other medical services do not necessarily equate to higher quality or improved patient outcomes. Additionally, below we list supporting imperatives for increasing price transparency.

**Transparency Helps Consumers Make More Efficient, Appropriate Care Choices and Increases Patient Satisfaction**

- The Dartmouth Institute’s work on variations in health care indicated that giving consumers information on the relative costs and outcomes of treatment options results in higher patient satisfaction and more efficient, appropriate health care choices. Also, [2013 research](#) by the Robert Wood Johnson Foundation on Shared Decision-Making (SDM) showed that informed patients using SDM opt for less invasive and less costly treatment options—including a 25% decrease in preference-sensitive surgical treatments.

**Price Transparency Is a Fundamental Component of Consumer-Driven Care**

- As more Americans pay out-of-pocket for a greater percentage of their health care, they are demanding more information about the relative prices of health care and treatment options, to make informed economic decisions about their care. Price and quality information will help consumers make decisions based on value.

**Transparency Helps to Identify and Reward Performance**

- Increasingly, purchasers are providing additional payments to physicians, hospitals and other health care professionals identified as providing superior quality and more efficient care. Enhanced efforts related to transparency of clinical and price information will make it easier to reward providers who provide high value and high quality care.

**Transparency Will Promote Evidence-Based Medicine**

- Purchasers, consumers, and providers need information comparing the relative effectiveness of alternative treatment options. Although research by the Agency for Health Care Research and Quality (AHRQ) and the Patient-Centered Outcomes Research Institute (PCORI) has begun to fill that voice, much more comparative effectiveness research is needed. More and better
information about how well a health care intervention works will promote more outcomes-based adoption of innovations and disuse of existing, ineffective options.

**Transparency Could Help Control Health Care Cost Increases**
- Enhanced transparency would enable consumers to find high quality providers, who deliver more efficient care, which could result in significant savings nationally. Price transparency will also help people become more aware of the true cost of their health care. This knowledge may encourage consumers to be more prudent in accessing health care unnecessarily. In addition, as people begin to understand the cost implications, they will likely focus more on wellness and healthier lifestyles.

**Transparency Is Critical to Increase Competition in Health Care**
- Finally, transparency of information will help to create a truly competitive health care marketplace. With access to key information, purchasers and consumers can compare truly costs and quality, which can help drive improvement and competition based on excellence of care.

**III. Increase Competition in The Prescription Drug Market**

Given growing public and political pressure, along with employers’ growing concern over their ability to sustain trends in spending for specialty medications over the long term, the Business Group believes it is necessary to review public policies that influence the pricing, prescribing and administration of specialty medications and recommends adopting and reinforcing new public policies that would create more sustainable, affordable pricing. Specifically, the Business Group recommends the following:

1) **Remove Uncertainties Surrounding Risk-based and Value-Oriented Contracting and Implement Indication Specific Pricing and Reference Pricing in Public Programs.**
2) **Limit the Reach of Medicare Part D Protected Classes.**
3) **Eliminate Perverse Payment Incentives Under Medicare Part B.**

**Remove Uncertainties Surrounding Risk-based and Value-Oriented Contracting and Implement Indication Specific Pricing and Reference Pricing in Public Programs**

How consumers use health care has changed significantly over the past several decades, but how they pay for services has not kept pace. Specifically, the fee-for-service model in which a set price is paid for a drug, irrespective of its health outcomes, is antiquated and inefficient.

**Value-Based Contracting and Medicaid Best Price**

In the face of these outdated payment policies, industry stakeholders are already experimenting with innovative, value-oriented solutions, often thought of under an umbrella concept commonly referred to as value-based payment (VBP) arrangements. VBP arrangements seek to more concretely tie payments to improved patient outcomes by implicitly tying reimbursement amounts to drug-associated patient outcomes and/or improvements in quality of life.

However, current policies inhibit the willingness of drug makers to enter into these types of arrangements on a full-scale basis, largely out of fear of their impact on current laws. Specifically, risk-based contracting, in which manufacturers share in the financial risk if medications do not work as intended, may trigger provisions of the Medicaid “best price” program. At this point, it is not clear how such arrangements relate to this policy rule.
The anticompetitive nature of the Medicaid best price program has been well documented by the U.S. Government Accountability Office (GAO), the Congressional Budget Office (CBO) and academic economists. Apart from historical arguments against the best price policy, the program also imposes an impediment for drug makers to experiment with payers in new, innovative VBP arrangements because of the potential implications. Though manufacturers have increasingly shown a willingness to take on risk and potentially reimburse or rebate payers when a product fails to execute against pre-contracted outcomes, they have concerns that those rebates or reimbursements could trigger manufacturer obligations to Medicaid under the best price program.

**Indication-Specific Pricing**

Other innovative approaches to ensure appropriate value payments for drugs, and thus increase competition, may be to explore indication-specific pricing and reference pricing models in public programs, concepts the Business Group strongly supports.

With multi-indication drugs on the rise, many of which are high-priced specialty drugs, employers are interested in considering options that allow pricing to better reflect differential benefit by indication, another option for increasing more competitive drug pricing. In March 2016, ICER detailed various models of indication-based pricing for pharmaceutical drugs, outlined the risks and benefits of these models for both payers and manufacturers, and made specific policy recommendations for how these types of agreements could be implemented. In particular, three major models of indication-specific pricing were described, which could be considered by policy makers:

- Distinct product differentiation, authorized and marketed under different brand names with different prices;
- No brand differentiation, but distinct, separate discounts applied for each indication; and
- No brand differentiation; a single “weighted-average” price is developed using estimates of indication use across the population, with possible retrospective reconciliation through rebates based upon actual use.

Though employers recognize that there may be substantial implementation challenges to indication-specific pricing policies, we are encouraged by CMS’s previous willingness to pilot this tool through the Medicare Part B program. We recommend that CMS maintain an open dialogue with employers and other payers, as well as with manufacturers and providers, to identify opportunities for additional legislative changes to federal reimbursement policies that obstruct indication-specific pricing agreements.

**Reference Pricing**

Employers have successfully implemented reference pricing, particularly when generic alternatives to more expensive brand medications are available, for specialty medicines, and where there is documented price variation based on site of administration. As policy makers contemplate reference pricing policies for pharmaceuticals, one potential academic resource for reference is the Northwestern Journal of International Law and Business, which synthesized 16 studies describing

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nine reference-pricing policies from six countries. The synthesis found that reference pricing “led to decreases in drug prices and increases in utilization of targeted medications, while also reducing payer and patient expenditures.”

The synthesis further suggested there was no increase in the use of medical services, such as physician office visits and hospitalization. Therefore, CMS and HHS should:

- Consider exemptions for value-based contracts from Medicaid best price requirements and clarify how drug makers and payers can conceive of value-based contracts without triggering broader Medicaid best price program implications.
- Allow for variable pricing, where the price better reflects the evidence for benefit.
- Evaluate the usefulness and application of the existing developed value frameworks and their potential to impact drug pricing in public programs, as well as their overall utility to the health care system.
- Directly link reimbursement and improved patient outcomes.
- Consider how drug makers and payers can enter into other types of innovative VBP arrangements, such as indication-specific pricing.
- Implement reference pricing policies supported by clinical evidence consistently across public programs, where possible.

**Limit Reach of Medicare Part D Protected Classes**

Plans participating in Medicare Part D must offer either a defined standard benefit or an alternative benefit equal in value (“actuarially equivalent”) or provide enhanced benefits. While formulary design is a widely used private-sector tool for controlling private payer drug costs, Medicare has limited the freedom of Part D plans to control their formularies through specific rules, two of which substantially impact the price of drugs:

- Federal regulations require that plan formularies include drug classes covering all disease states, with a minimum of two chemically distinct drugs in each drug class—a policy construct that allows drug makers to manipulate pricing based on artificial market share.
- Plans are also required to cover all drugs in six protected classes: immunosuppressants, antidepressants, antipsychotics, anticonvulsants, antiretrovirals and antineoplastics. What’s more, CMS has gone beyond the statute, requiring at least one drug in each subclass as well. These rules limit the negotiating power of Part D plans and make drugs in those classes more expensive. Specific to the six protected classes, a Milliman study found that they accounted for between 16.8% and 33.2% of Part D drug costs. The study suggested that reversing just this one rule could decrease prices in these classes by 9%–11%, for a projected Part D savings of $511 million per year.

The Medicare Payment Advisory Committee (MedPAC), which provides independent, nonpartisan policy and technical advice to Congress on issues affecting the Medicare program and CMS, has twice recommended eliminating certain protected classes, but the proposals have been rejected.

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17 Ibid.
both times. This is unfortunate, because if adopted, MedPAC believes that the proposed changes to the Part D program could increase the payers’ negotiating ability to lower prices of medicines in the protected classes.

This potential change would be significant not only for the Medicare program, but also for more competitive pricing in the commercial market, including for employer plans. Medicare’s rules and pricing for prescription drugs influence system-wide resource allocation. Medicare costs extend well beyond the share of health expenditures it finances directly due to its large beneficiary base and sheer volume of transactions. Medicare Part D payment and plan design policies for prescription drugs greatly affect the private sector. One author has likened this phenomenon to “bargaining in the shadow of a giant.”

According to a 2014 report, between 2006 and 2011, the prices for drugs in the six protected classes showed a trend similar to that for all Part D drugs, rising by a cumulative 28%, driven primarily by two classes of drugs where generic competition was available: 1) antidepressant medications, which accounted for about half of the volume in the six classes; and 2) anticonvulsants, which accounted for about a quarter of the volume. Meanwhile, the same report notes that other classes made up almost entirely of brand-name drugs saw rapid growth in prices, ranging from increases of more than 30% for antiretrovirals to increases of nearly 80% for antineoplastics.

When generic substitutions were considered, prices in protected classes fell by a cumulative 2% over the six-year period, signaling that plan sponsors had successfully moved enrollees toward generics when they were available. But, MedPAC further noted that the drugs’ protected status may limit the number of rebates plan sponsors are able to obtain from manufacturers for drugs in these classes. Although there has been intermittent momentum to address the protected classes policy in order to save money in the Medicare program, there is no recognition by policy makers that current law limits private payers’ ability to negotiate lower prices for certain drugs. And, despite its regulatory authority, CMS has been hesitant to implement changes that meet with opposition from drug manufacturers.

- Following the independent MedPAC committee’s recommendations, HHS should work with Congress and CMS to limit legislative and regulatory restrictions on formulary design within protected classes by modifying the Medicare Part D rules to remove drugs from those protected classes where sufficient generic competition exists, a change that would give private plans more freedom to control their formularies and negotiate for expanded manufacturer rebates.
- Specifically, HHS should encourage CMS to resubmit its proposal to remove antidepressants, antipsychotics and immunosuppressants for transplant rejection from

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20 Ibid.  
21 Ibid.  
22 Ibid.  
23 Ibid.
the list of protected classes because, in these classes, price reductions have been more closely linked to the availability of generics than to their status as “protected.”

- At a minimum, policy makers should evaluate the potential anticompetitive influence of protected classes on the commercial market, and specifically, they should evaluate the limitations imposed on private payers’ ability to negotiate competitive prices for drugs in the protected classes due to market spillover.
- Policy makers should work with stakeholders, including employers, to gain consensus for Medicare prescription drug policy changes that would remove additional hindrances to effective private payer pricing negotiation of these drugs. Then policymakers should work to implement those changes.

Eliminate Perverse Payment Incentives in Medicare Part B

Under Medicare Part B’s “buy and bill” system, provider reimbursement is calculated as ASP+6%, where ASP, or “average sales price,” is calculated by CMS from manufacturer-reported prices for “sales to all purchasers,” excluding sales that are exempt from Medicaid “best price” and sales at “nominal charge.” This reimbursement model creates a three-part, cyclical incentive for prices to continuously rise. First, it encourages manufacturers to set prices higher and to incent providers to select those drugs—and receive a higher reimbursement. Second, it also creates an incentive for providers to continuously select higher-priced drugs, even when lower-cost alternatives might be available. Third, it incents the delivery of these medications in higher-priced settings, such as hospital outpatient departments.

HHS and CMS should:
- Eliminate financial incentives to providers who participate in Medicare to prescribe more expensive medicines, in more expensive settings; and,
- Encourage providers and manufacturers to assume financial risk with regard to high-priced drug utilization.

The Business Group has also recently provided comments to both the Food and Drug Administration (FDA) and the FTC, to urge increased competition in the prescription drug market. We implore HHS to additionally consider its role in increasing competition in this industry. Below, we provide background and recommendations for how the agency could work with other appropriate policy makers to increase competition in the prescription drug market.

The Drug Price Competition and Patent Term Restoration Act (known as the “Hatch-Waxman Act”) was crafted by Congress with competing goals in mind, to both 1) spur generic drugs to market, and 2) encourage brand drug development. The legislation provides a number of incentives for generic manufacturers to enter the market where the brand drug is off patent, including:

- The ability to file an Abbreviated New Drug Application (ANDA);
- A 180-day exclusivity period for the first-filed generic drug product;
- A safe-harbor from infringement when performing testing for regulatory review;
- The ability to file declaratory judgment actions to resolve potential patent disputes; and

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• The ability to file a counterclaim to a patent infringement action seeking to de-list patents from the Orange Book.

However, the above noted incentives were included in Hatch-Waxman along with arguably equal incentives for brand preservation in the pharmaceutical market:

• A patent term extension based on the length of FDA’s regulatory review;
• A definition of the scope of rights under the extended patent;
• Non-patent-based exclusivities;
• A mechanism for increasing the public notice of patents and patent challenges; and
• An automatic injunction precluding premature FDA approval of a generic drug.

Similar to the Hatch-Waxman Act, the Biologics Price Competition and Innovation Act (BPCIA) passed in 2010. The BPCIA established a pathway for the development of biosimilar drugs to compete with branded biologics – often specialty drugs – to introduce competition in the biologics market and thus, put downward pricing pressure on the expanding market of these complex and expensive drugs.

As Chairman Ohlhausen pointed out at the FTC’s November 8, 2017 workshop, when a branded drug’s patent expires, the first generic drug entry into the market generally offers a 20-30% discount, with subsequent entries lowering the price up to 85% or more. This data underscores the importance of ensuring that market forces are working and that there are no undue barriers that exist to prevent competition, which were foundational visions of the above noted pieces of legislation.

However, after a generic or biosimilar is approved by the FDA, in many cases, it may still take years for the cheaper versions come to market. This is largely because of litigation brought by the manufacturer of the original drug, based on outstanding legal questions about whether the patents can be extended through various secondary approvals for the original drug. For example, the original patent for Humira, a biologic used to treat various types of arthritis, Crohn’s Disease and other ailments, was set to expire in 2016, but its manufacturer has indicated that it has add-on patent protection from 70+ ancillary patents, which can extend the patent through 2022, and potentially beyond. These claims, however, seem to be unsubstantiated following an evaluation of the Patent Application Information Retrieval (PAIR) database housed at the Patent Trademark Office (PTO).25

Why the discrepancy? Deciphering and understanding patent and exclusivity terms of pharmaceutical products is complicated because the two are intertwined and work in complementary, yet distinct, ways. And as these product protection terms have become increasingly important to market share and profitability, they are fiercely protected by the pharmaceutical industry, resulting in “patent estates,” or “patent blockades,” on top-grossing products.26 These are multiple patents for one product, covering different indications, delivery methods, and/or combinations of the product. Thus, coming to an accurate determination of when a patent term expires often requires specialized legal expertise. A publication by the Center for Drug Evaluation and Research (CDER), part of the FDA, states that “patent”

and “exclusivity” are two of the most commonly searched terms on the FDA website, which underscores both the complexity and value of these product protections to drug manufacturers, as well as interest from outside stakeholders.

In a nutshell, market exclusivity is driven by 1) monopoly rights awarded following the FDA’s approval of a new drug product and 2) the patents associated with the product. Thus, drug makers’ ability to sustain high prices in the United States hinges on the monopolistic character of the pharmaceutical market, driven by these patent and exclusivity protections, which insulate products from competition and artificially boost the industry’s negotiating power.

Apart from the above statutory extensions, the life of a drug’s overall patent protection can additionally be extended by applying for secondary patents through new formulations of the drug, new routes of administration, new indications, or uses of the drug in combination with another drug. NBGH agrees that an appropriate period of protection is essential to promoting investment in innovation and the discovery of new medicines, but we also believe a balance must be struck between both the right to enjoy the benefits as a creator of intellectual property and society’s right to have affordable, adequate health and medical care. As mentioned previously, patents and exclusivity periods afforded to drug manufacturers by the PTO and the FDA are intended to reward innovators for their contributions. The expiration of patents theoretically yields generics and biosimilars, which benefit consumers.

Unfortunately, what we sometimes see is repeated and anticompetitive exploitation of the patent system, in which some drug makers game the process, thereby extending their monopoly market terms, which directly contributes to the unaffordable and unsustainable high-priced prescription drug market. While these practices do not in effect extend an original patent, they do create patent estates, which increase the probability of litigation between branded and generic manufacturers and permit the branded manufacturer to continue to promote its product. Additionally, building these patent estates tends to run in congruence with applications for additional market exclusivity from the FDA.

FDA Commissioner Gottlieb has discussed the FTC and FDA’s shared goal of ensuring that consumers benefit from greater competition in the prescription drug market and has made commitment to explore exclusivity and patent abuses, and we commend both agencies for this collaborative work because there is a limit to what any single entity can do on its own. We further encourage HHS to partner with FTC, FDA, the PTO, and members of Congress to:

4) Eliminate or limit additive patent extensions and exclusivity periods that serve only to extend monopoly power, especially where there is limited or no additional company investment or patient value produced.

5) Develop sound policy that would discourage patent abuses such as “ever-greening” and “product hopping.” These policies may include financial penalties, loss of exclusivity periods and/or reduced patent terms for other products.

6) Reduce the market exclusivity for biologics from 12 years to 7 years.

29 Ibid.
The Business Group also agrees with the FTC’s identification of the following additional impediments to generic entry:

- Pay-for-delay deals; and
- Abuse of the Risk Evaluation and Mitigation Strategies (REMS) program through the FDA.

We commend the FTC for prioritizing pay-for-delay deals, a costly legal tactic that some brand manufacturers have been using to delay market entry of lower-cost generic alternatives. According to one study, these anticompetitive deals cost consumers and taxpayers $3.5 billion in higher drug costs every year.

7) **HHS should work with sister agencies to urge the Congress to pass legislation that would ban pay-for-delay arrangements and thus, protect payers and consumers from these costly arrangements.**

Another area where the current regulatory system presents opportunities for branded firms to delay generic entry is in situations where the branded pharmaceutical is subject to a restricted distribution system. The FDA is authorized to require REMS programs, which restrict distribution of certain pharmaceuticals in order to safeguard the public and prevent potential abuse or diversion. But, even if the FDA does not require REMS for a particular drug, the manufacturer can voluntarily adopt a restricted distribution policy using exclusive contracts with distributors or specialty pharmacies to limit access to the product.

Some branded manufacturers have used these restricted distribution programs to delay generic entry in two ways: by refusing to provide samples to the generic manufacturer, leaving it unable to perform the preclinical and clinical testing the FDA requires to establish that the generic version is biologically equivalent to the branded drug; or by preventing the generic from joining the existing REMS distribution system, so the FDA cannot approve the generic manufacturer’s Abbreviated New Drug Application (ANDA).

One study estimates that Americans have lost $5.4 billion annually due to higher prices for prescription drugs because of REMS manipulation by branded drug companies.30

8) **We encourage HHS to take action limiting the ability for REMS to be gamed, and we commend FDA’s and FTC’s engagement and encourage continued oversight of potentially anticompetitive actions. However, the agencies cannot remedy this failure on their own. The agencies should also urge Congress to take action by passing legislation to prevent the misuse of REMS and restricted distribution schemes to delay generic drug competition.**

Pharmacy Benefit Managers (PBMs) and Group Purchasing Organizations (GPOs) play important roles in keeping prices low for prescription drugs and other health care services. However, the concentration of the PBM market – notably, the three largest PBMs have approximately 75% market share – has raised important antitrust and drug pricing concerns for large employers. Moreover, the 15 largest firms generated more than $270 billion in revenue in 2015 through retail and mail-order pharmacy, compared to $48 billion in revenue for independent pharmacies. As a related topic, the FTC should also consider

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30 O Brill, Alex, Lost Prescription Drug Savings from the Use of REMS Programs to Delay Market Entry, Matrix Global Advisors (July 2014).
other players within the supply chain and the impact that consolidation in those spaces has on drug pricing as well. For example, the three largest U.S. distribution companies account for more than 85% of the market share, with an estimated combined drug distribution revenues of $378 billion in 2015. As well, the top tier of dispensing pharmacies account for about 62% of U.S. prescription dispensing revenues in 2016.31

The financing and distribution of pharmaceuticals in the United States is complex, involving manufacturers, distributors, retailers, payers, pharmacy benefit managers, and, most importantly, patients. Given the substantial consolidation and vertical integration of many sectors of this system over the past decade, policy makers should:

9) Increase scrutiny of consolidation within the PBM, retailer, wholesaler and distributor markets to better understand the impact such consolidation would have on drug pricing throughout the supply chain;

10) Increase scrutiny of vertical consolidation (hospital and health system) acquisition of physician practices, particularly as they affect access to and pricing of Part B medications;

11) Lower the threshold for mandatory reporting of planned transactions involving acquisition of provider practices, given that most of these transactions fall below the current threshold, particularly if the health system has more than a 30% or other appropriate percentage of the primary care market in a given service area; and,

12) Increase monitoring and evaluation of post-merger market impacts and strengthen enforcement actions where anti-competitive harms occur.

In closing, we commend the agency for seeking out ways to facilitate a more competitive health care market for consumers. Government policies should facilitate and reinforce competition. When they do not, they need to be reexamined and modified. We look forward to continued partnership as the agency works to transform the nation’s health care system into one that is renowned for high-quality and high-value care, through improvement initiatives which pursue a broader system of linked goals. Again, thank you for the opportunity to comment. Please contact me or Steven Wojcik, the National Business Group on Health’s Vice President of Public Policy, at (202) 558-3012, if you want to discuss our comments in further detail.

Sincerely,

Brian Marcotte
President and CEO