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Creative Health Benefits Solutions for Today, Strong Policy for Tomorrow

July 16, 2018

The Honorable Alex M. Azar II
Department of Health and Human Services
200 Independence Ave. SW
Room 600E
Washington, DC 20201

Submitted electronically via: <https://www.regulations.gov>

RE: HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs

Dear Secretary Azar:

We appreciate the opportunity to comment on the Administration's Request for Information (RFI) on the American Patients First Blueprint to Lower Drug prices and Reduce Out-of-Pocket Costs. We commend the Administration for taking on this important issue and being willing to conduct a re-examination of the entire drug pricing system as a whole, to identify opportunities for reform. We agree there is a need for improved competition, better negotiation, incentives for lower list prices, and lower out-of-pocket cost for consumers. Below, we will expand upon each of these strategies for reform.

The National Business Group on Health represents 421 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. Advancing better and more efficient payment policies is increasingly critical as rising costs affect the ability of beneficiaries, governments, insurers, and employers to afford care.

Improved Competition

Current permissive patent and exclusivity period protocols may unduly delay market entry of lower cost alternatives to brand medications.

After a generic or biosimilar is approved by the Food and Drug Administration (FDA), in many cases, it may still take years for less expensive versions to come to market. Often the delay is due to litigation by the manufacturer of the original drug over outstanding legal questions about whether patent protection can be extended through various secondary approvals for the original drug.

Determining when a patent term expires often requires specialized legal expertise. In fact, a publication by the Center for Drug Evaluation and Research (CDER) states that "patent" and "exclusivity" are two of

the most commonly searched terms on the FDA website,¹ which underscores both the complexity and value of these product protections to manufacturers, as well as the level of interest from outside stakeholders.

Beyond statutory extensions due to delays by the Patent and Trade Office (PTO) or the FDA, the life of a drug's overall patent protection can 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 ("patent estates").

The Business Group 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 interest in affordable medications.

In the attached addendum to our comments, specific patent abuses and other anticompetitive practices are explained in more detail. While these practices do not in effect extend original patents, they create patent estates, which increase the probability of litigation between brand and generic manufacturers. Additionally, building patent estates tends to run in congruence with applications for additional market exclusivity from the FDA.

The Federal Trade Commission (FTC) has identified other strategies that exist to reduce generic drug competition. Specifically, the Business Group agrees with the FTC's identification of the following additional impediments to generic entry, and encourages HHS to remain focused on:

- 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.²

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

However, some branded manufacturers have used 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

¹ Lal R. Patents and Exclusivity. CDER Small Business Chronicles.2015.

² "Pay for Delay," Federal Trade Commission, July 23, 2013, <https://www.ftc.gov/news-events/media-resources/mergers-competition/pay-delay>.

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 brand drug companies.³ ***We encourage regulators to limit the ability for these rules to be gamed. However, FDA or FTC cannot remedy this issue on their own. The agencies should also urge Congress to act by passing legislation to prevent the misuse of REMS and restricted distribution schemes to delay generic drug competition.***

Recommendations for Policy Makers

- **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;**
- **Develop sound policy that would discourage patent abuses such as “evergreening” and “product hopping.” These policies may include financial penalties, loss of exclusivity periods and/or reduced patent terms for other products;**
- **Eliminate pay-for-delay deals and/or implement penalty provisions for companies that engage in pay-for-delay deals;**
- **Reduce the market exclusivity for biologics from 12 years to 7 years; and**
- **Limit the ability for REMS rules to be gamed; urge Congress to act by passing legislation to prevent the misuse of REMS and restricted distribution schemes to delay generic drug competition.**

Better Negotiation & Incentives for Lower List Prices

In most other industries, prices are largely influenced by the traditional laws of supply and demand. The value placed on goods and services by the customers heavily determines market prices and manufacturers price accordingly to ensure a large market.

However, given the nature of health care, its inelastic demand, third party payment models, and asymmetric economic information, it is hard for customers—patients, insurers, employers, and governments—to determine value, let alone influence prices in a market-driven way. These phenomena disproportionately shift the influence to determine prices and define value to providers and suppliers. The pharmaceutical market is even more complicated because patents and exclusivity periods create temporary monopolies, for good reason, but it makes it all the more difficult for customers to determine value let alone have much influence on prices.

As they do in research and development in their own industries, employers recognize the significant investments drug makers commit to research and development. They also recognize that, as drug makers note, bringing a drug to market requires substantial capital and can take a decade or more, and that most drugs fail. And finally, employers also recognize that, of the drugs that make it to clinical trials in humans, less than 12 percent secure full FDA approval.⁴ Additionally, employers are even apt to

³ O Brill, Alex, Lost Prescription Drug Savings from the Use of REMS Programs to Delay Market Entry, Matrix Global Advisors (July 2014).

⁴ Stow T. The drug development and approval process is about much more than the final “okay”. The Catalyst. PhRMA.org. 2015.

accept that prices may be high for highly effective drug treatments, such as those for hepatitis C, and that selected drugs may add value to the health care system by saving money.⁵

Importantly, however, the increase in drug prices is not limited to the launch of new drugs but is aggravated by frequent price increases for drugs that have been on the market for many years. In addition, wide variation in charges for specialty drugs within and across sites of administration can tack on unnecessary and potentially exorbitant price inflators. The explosive growth in prices and spending for specialty pharmaceuticals has been alarming for quite some time, but has grown increasingly so in recent years, accelerated by the increase in vertical provider consolidation, which has contributed to growth in spending for specialty medications.

Given these concerns, **the Business Group agrees it is necessary to review public policies that influence the pricing, prescribing, and recommends adopting and reinforcing new public policies that would create more sustainable, affordable pricing:**

- **Remove uncertainties around risk-based and value-oriented contracting and implement indication-specific pricing and reference pricing in public programs;**
- **Limit the reach of Medicare Part D protected classes;**
- **Eliminate perverse payment incentives under Medicare Part B;**
- **Encourage the uptake of biosimilars; and,**
- **Reform permissive patent and exclusivity protocols.**

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

The fee-for-service model in which a set price is paid for a drug, irrespective of its health outcomes or its impact on the need for other health services now and in the future, is antiquated and inefficient. 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 or “risk-sharing” arrangements. Risk-sharing 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.

Risk-sharing agreements are a step toward creating a more sustainable pricing model for prescription drugs, particularly for expensive specialty medications. They distribute risks between payers and manufacturers more equitably and are likely to improve outcomes and the appropriate use of medications, and thus to improve quality. The attractiveness of risk-sharing arrangements are manifold, including creating a win-win-win situation for patients, manufacturers and payers—where incentives for employers, insurers, and plan participants all align toward appropriate, evidence-based use of expensive specialty medications.

While employers are optimistic about risk-sharing agreements, current policies inhibit the willingness of drug makers to enter these types of arrangements on a full-scale basis. Specifically, contracts in which manufacturers share in the financial risk if medications do not work as intended, may trigger provisions of the Medicaid “best price” program and it is not clear how such arrangements relate to this policy rule.

⁵ Osborn J. Desperately Seeking Price Reform: Pharma Needs To Embrace Transparency & Value To Protect Innovation. Forbes. 2015.

Although 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, which is an obstacle to these novel types of pricing arrangements.

We support the intent of risk-sharing agreements, as these types of interactions between insurers and manufacturers may have the effect of reducing prescription drug expenditures and overall medical costs for both public and commercial plans, although we recognize that more data are needed on the impacts. For these reasons, ***we believe it is critically important to remove barriers to VBP arrangements, particularly those constraining the creation of risk-based contracting.***

Value Frameworks and Innovative Pricing/Reimbursement

Four widely recognized value frameworks have been developed by the American Society of Clinical Oncology, the Institute for Clinical and Economic Review, the National Comprehensive Cancer Network, and Memorial Sloan Kettering Cancer Center. While each framework differs from the next, they share a goal to encourage shared decision-making between providers and patients, particularly when choosing high-priced drug therapies. Employers are encouraged that risk-based and value-oriented contracting may help slow rapidly escalating health care spending. With that in mind, we expect to see more employers seek opportunities to either directly engage in outcomes-based deals or encourage their plans to engage in these types of arrangements. We also encourage HHS and the congress to consider adopting value frameworks.

Indication-specific pricing holds the potential for increasing payment alignment for a drug with the value it delivers to a patient population by adjusting reimbursement to correspond with effectiveness of the medication at each indication.

With multi-indication drugs on the rise, many of which are high-priced specialty drugs, employers are willing to consider options through which pricing can better reflect differential benefit by indication. In March 2016, ICER detailed³³ 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. ***Three major models of indication-specific pricing were described, which could be considered by policy makers:***

1. Distinct product differentiation authorized and marketed under different brand names with different prices;
2. No brand differentiation, distinct, separate discounts are applied for each indication; and,
3. 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.

Reference Pricing

Specific to reference pricing, employers have successfully implemented this policy, particularly when generic alternatives to more expensive brand medications are available and for specialty medicines where price variation in site of administration exists. 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 9 reference-pricing policies from 6 countries.⁶ 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.

Recommendations for Policy Makers

- **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 and reduced costs;**
- **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 to improved patient outcomes;**
- **Consider how drug makers and payers can enter into other types of innovative VBP arrangements, such as indication-specific pricing; and,**
- **Implement reference pricing policies consistently across public programs, where possible and supported by clinical evidence.**

Limit Reach of Medicare Part D Protected Classes

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: 1) federal regulations require that plan formularies include drug classes covering all disease states, and 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; and 2) plans are also required to cover all drugs in six protected classes: immunosuppressants, antidepressants, antipsychotics, anticonvulsants, antiretrovirals, and antineoplastics.⁷ What’s more, the CMS has gone beyond the statute, requiring at least one drug in each subclass as well.⁸

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 16.8–33.2 percent of Part D drug costs and suggested that reversing just this one rule could decrease prices in these classes by 9–11 percent, for a projected Part D savings of \$511 million per year.⁹

The Medicare Payment Advisory Committee (MedPAC), which provides independent, nonpartisan policy and technical advice to the Congress on issues affecting the Medicare program and CMS, has twice recommended eliminating certain protected classes, but the proposals have twice been rejected.¹⁰ If

⁶ Marie Salter, “Reference Pricing: An Effective Model for the U.S. Pharmaceutical Industry?,” *Northwestern Journal of International Law & Business* 35, no. 2 (January 1, 2015): 413.

⁷ The Medicare Part D Prescription Drug Benefit. Kaiser Family Foundation 2015.

⁸ Outtersen K, Kesselheim AS. How Medicare Could Get Better Prices On Prescription Drugs. *Health Affairs*. 2009;28(5):w832-w841.

⁹ *Ibid.*

¹⁰ *Report to the Congress: Medicare Payment Policy*. The Medicare Payment Advisory Commission (MedPAC); 2014/03// 2014.

adopted, MedPAC suggested 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 pricing in the commercial market, including for employer plans. Medicare's rules and pricing for prescription drugs influences system-wide resource allocation and costs extend well beyond the share of health expenditures it finances directly due to its large beneficiary base and sheer volume of transactions.¹¹ Medicare Part D payment and plan design policies for prescription drugs greatly affects the private sector. One author has likened this phenomenon to "bargaining in the shadow of a giant."¹²

According to a 2014 report, the prices for drugs in the six protected classes showed a growth trend between 2006 and 2011 similar to that for all Part D drugs, rising by a cumulative 28 percent,¹³ 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 over 30 percent for antiretrovirals to increases of nearly 80 percent for antineoplastics.¹⁴

When generic substitutions were considered, prices in protected classes fell by a cumulative 2 percent over the six-year period, signaling that plan sponsors had successfully moved enrollees toward generics for these drugs when generic substitutes were available. MedPAC further noted that the drugs' protected status may limit the amount of rebates plan sponsors are able to obtain from manufacturers for drugs in these classes.¹⁵

Although there has been intermittent momentum to address the protected classes policy 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.

Recommendations for Policy Makers

- **Limit legislative and regulatory restrictions on formulary design within protected classes by modifying the Medicare Part D rules to remove those protected classes where sufficient generic competition exists;**
- **Evaluate the potential anticompetitive influence of protected classes on the commercial market, and specifically, evaluate the limitations imposed on private payers' ability to negotiate competitive prices for drugs in the protected classes due to market spillover; and,**
- **Work with stakeholders, including employers, to gain consensus around Medicare prescription drug policy changes that would remove additional hindrances to effective private payer pricing negotiation of these drugs, and then implement those changes.**

Eliminate Perverse Payment Incentives in Medicare Part B

As discussed above, most drugs in Medicare are reimbursed through Part D, its pharmacy benefit, but many specialty drugs are reimbursed through Part B, which is Medicare's medical benefit. This

¹¹ Clemens J, Gottlieb J. In the Shadow of a Giant: Medicare's Influence on Private Physician Payments. 2013/10// 2013. 19503.

¹² Ibid.

¹³ Ibid.

¹⁴ Ibid.

¹⁵ Ibid.

transactional difference takes place because specialty drugs often must be administered in a physician's office or hospital outpatient department. Because of this difference, Part B providers typically "buy and bill" for specialty drugs, meaning they buy the products in advance, store them according to the label specifications, and bill Medicare for reimbursement after administration to the patient. Provider reimbursement is calculated as ASP+6%, where ASP is "average sales price," which 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."¹⁶

This reimbursement model creates a three-part and cyclical incentive for prices to continuously inflate. First, it encourages manufacturers to set prices higher, to incent providers to select their drug, to 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.

Recommendations for Policy Makers

- **Eliminate financial incentives in Medicare for prescribing more expensive medicines, in more expensive settings; and,**
- **Encourage providers and manufacturers to share financial risk for the outcomes associated with the use of high-priced drugs when lower-priced alternatives are available.**

Reduce Patient Out-of-Pocket Spending

The Business Group believes that the policy recommendations above, if implemented will go a long way toward creating a more competitive market for pharmaceuticals that will also reduce costs for patients and payers. In addition, we believe that as employers increasingly offer high-deductible health plan options to employees and health care prices, including prices for prescription drugs continue to rise, the demand for price information and for quality information has never been higher. However, despite the growing popularity of health plan, PBM and Internet-based tools to compare health care services and providers, Americans need access to more comprehensive, real-time, price, quality and clinical effectiveness information about their medical care and prescription drugs. We strongly urge CMS to redouble its efforts to continue to support and improve public disclosure of price and quality data from the Medicare program to guide consumers.

Further, access to information about the price and quality of prescription drugs can help consumers make better and more informed choices. However, it is surprisingly difficult for consumers to get this information – especially in a readable, digestible and standardized format that allows for meaningful comparisons. The information void is particularly detrimental to informed choice in a market, particularly where the price of a specialty drug can vary considerably by site of service may not lead to higher quality or improved patient outcomes.

Thus, the Business Group believes that all health care providers and facilities should publicly disclose, in a user-friendly format, all comprehensive information about the relative price, quality, safety and efficacy of recommended treatments and prescription drugs.

The added benefit of providing transparency information, in addition to reducing out-of-pocket costs, is the potential to reduce overall expenditures through improved consumerism. A recent study by the

¹⁶ The Best Price Requirement of the Medicaid Rebate Program. The Academy of Managed Care Pharmacy (AMCP); 2009.

Employee Benefit Research Institute (EBRI)¹⁷ revealed, among other findings, that compared to people enrolled in traditional health plans (PPO, HMO, POS, etc.), high deductible health plan (HDHP) subscribers are more likely to engage in cost-conscious behavior, such as:

- Asking for a generic drug instead of a brand name drug (52% HDHP vs. 37% traditional)
- Talking to their doctor about treatment options and costs (43% vs. 32%)
- Developing a budget to manage health care expenses (28% vs. 22%)

Recommendations for Policy Makers

- **Continue to strongly support and improve CMS efforts to publicly disclose price and quality information for consumers and payers.**
- **Require that providers, facilities, and suppliers publicly disclose, in a user-friendly format, comprehensive information about the relative price, quality, safety and efficacy of recommended treatments and prescription drugs.**

Finally, in the 4th quarter of this year, we will launch the Pharmaceutical Supply Chain Leadership Forum (the “Leadership Forum”), an invitation-only initiative, which will convene stakeholders across the pharmaceutical supply chain. Given the attention and concern regarding drug pricing in Washington and the media, and among consumer groups and employers, we are creating this opportunity for key stakeholders to come together, offer our respective viewpoints, and coalesce around disruptive solutions that could potentially revolutionize the pharmaceutical supply chain.

This initiative recognizes that employers and patients seek a delivery model marked by transparency, affordability and access, and that a participatory process must be established to facilitate dialog and research, collect input, and make solutions-oriented recommendations. Further, the impetus behind this initiative draws upon the increased frustration by employers, policymakers, manufacturers, PBMs, health plans, the media, patients and public purchasers.

Through the leadership forum, we intend to host dialog around key issues noted in the blueprint, including, but not limited to, alternatives to the predominant supply chain models, the fiduciary status of PBMs and pharmaceutical rebates. We look forward to updating the agency on the work of the Leadership Forum – it is our hope that this group will recommend meaningful changes that the agency could consider implementing.

Thank you for considering our comments and recommendations regarding HHS’s blueprint. We look forward to reading the comments to the docket and following the agency’s progress on this issue. Please contact me or Steven Wojcik, the National Business Group on Health’s Vice President of Public Policy, at (202) 558-3012 if you would like to discuss our comments in more detail.

Sincerely,



¹⁷ “EBRI_IB_433_CEHCS.25May17.pdf,” accessed July 16, 2018, https://www.ebri.org/pdf/briefspdf/EBRI_IB_433_CEHCS.25May17.pdf.

Brian Marcotte
President and CEO

Addendum

Pharmaceutical Patent Abuses

“Evergreening” or “Product Hopping”

This term describes a practice in which a brand manufacturer makes minor or modest formulation changes that provide little to no therapeutic advantage to a brand medication’s formulation for the purpose of extending the life of both patent protection and FDA exclusivity. Companies have been known to introduce a nearly identical version of a brand-name drug before patent expiration and allow the original drug's patent to expire, promoting the “new” drug as an improvement over the previous brand-name drug. The Federal Trade Commission (FTC) and other government officials have flagged this practice as anti-competitive¹⁸, but it remains legal. In addition to using this method for piling up patents, FDA approval for a new use or a new formulation also triggers an additional three years of marketing exclusivity.

Label Patents

Refers to any patent that covers a method or product mentioned in the FDA-approved label. Label patents typically target a new patient population or a new indication, or include a new dosage form, dosing regimen or route of administration. The patent term for such new patents is 20 years from date of filing, which can significantly extend the period of exclusivity for the repurposed drug.¹⁹ Examples of label patents include:²⁰

- Administering a different dose to the elderly;
- Titration of dosage over a certain number of days;
- Titration pack with escalation dosages;
- Administering a drug without food;
- Administering a dosage form that achieves plasma level of X, measured Y hours after dosing;
- Administering with an anticonvulsant in patients at risk of seizure;
- Informing the caregiver or patient to avoid taking the approved drug with another drug;
- Offering a drug in combination with unique packaging;
- Offering a drug in combination with a delivery device, such as an; and
- Providing a unit dosage of a drug with particular dissolution values or resulting pK values.

30-Month-Stay

Refers to the burden placed on the generic drug manufacturer when bringing a potential generic entrant to market while operating under the assumption that a patent on the branded product is invalid; under those conditions, the generic manufacturer must file its application with a “paragraph IV certification,” stating the reasons the patent is invalid. At this juncture, an automatic 30-month-stay is initiated, preventing the generic from coming to market to allow for the resolution of litigation between the brand and generic manufacturers. Improper patent listings by branded manufacturers trigger frivolous 30-month-stays; – this practice has been flagged by the FTC and litigated extensively. Essentially, when

¹⁸ Royall, Sean M., Johnson, Ashleye, McKenney, Jason C. “Antitrust Scrutiny of Pharmaceutical “Product Hopping,” page 75. Antitrust, Vol. 28, No. 1, Fall 2013. © 2013 by the American Bar Association. Accessed July 17, 2017 via: <http://www.gibsondunn.com/publications/Documents/RoyallAntitrustScrutinyABA.pdf>

¹⁹ Israelsen N. New Patents for Old Drugs: Label-based strategies in the United States. Pharma Focus Asia. 2016.

²⁰ Ibid.

this is done, branded manufacturers list new patents after an application for a generic is filed, which grants the brand-named company additional 30-month stays of FDA approval of the generic’s application.²¹

Other Anticompetitive Practices

Pay for Delay

There are two main types of pay for delay deals: 1) those involving cash payments from brand manufacturers to generic manufacturers to delay generic market entry; 2) pay- for- delay scenarios that occur when a generic company agrees to delay introduction of a generic version of a brand- name drug in return for the brand- drug-maker’s agreement to refrain from marketing an authorized generic (a “no AG agreement”) version of the branded product during the “first filer” 180-day exclusivity period, a practice that the FTC does not condone.²²

Patent Trolling

Because of the sizable amount of money involved in certain patents, some investment firms acquire many patents and then assert rights against brand manufacturers, sometimes in a frivolous manner. This practice is referred to as “patent trolling.” The goal of many patent trolls is to extract cash settlements from manufacturers that want to avoid the expense of patent litigation.

²¹ Royall, Sean M ., Johnson, Ashleye, McKenney, Jason C. “Antitrust Scrutiny of Pharmaceutical “Product Hopping,” page 72. Antitrust, Vol. 28, No. 1, Fall 2013. © 2013 by the American Bar Association. Accessed July 17, 2017 via: <http://www.gibsondunn.com/publications/Documents/RoyallAntitrustScrutinyABA.pdf>

²² FTC Files Amicus Brief Explaining That “No-AG” Agreements Are Used by Drug Companies to Delay Generic Competition. August 13, 2012. Accessed July 12, 2017 via: <https://www.ftc.gov/news-events/press-releases/2012/08/ftc-files-amicus-brief-explaining-no-ag-agreements-are-used-drug>