LEUKEMIA & LYMPHOMA SOCIETY®

July 16, 2018

The Honorable Alex Azar
Secretary
United States Department of Health and Human Services
200 Independence Ave, SW
Room 600E
Washington, DC 20201

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

Dear Secretary Azar:

The Leukemia & Lymphoma Society (LLS) is committed to working with all stakeholders to strengthen the healthcare system by breaking down barriers that stand between patients and necessary care while simultaneously reforming incentives to reduce the overall cost of cancer care. LLS serves the needs of blood cancer patients by working to find cures for leukemia, lymphoma, Hodgkin's disease, and multiple myeloma, and by ensuring that blood cancer patients have sustainable access to quality, affordable, coordinated healthcare. We appreciate the Trump Administration's stated commitment to lowering the cost of care and reducing out-of-pocket costs for patients, and we welcome the opportunity to offer the following comments.

The cost of care, particularly cancer care, is rising at an alarming rate. In response to this trend, both public and private insurers are shifting a greater portion of healthcare costs onto patients with serious health conditions like cancer. As a result of these growing out-of-pocket costs, patients are often unable to afford necessary care, choosing to delay or forego treatment due entirely to cost. If these trends continue unabated, it will lead to higher premiums for all consumers and insurmountable cost sharing for patients who need to use essential, even lifesaving, care.

LLS is eager to work with the Administration and other stakeholders to find solutions that bend the cost curve to make the healthcare system more sustainable, as we believe a more sustainable system will provide better access to care for cancer patients. Yet, it is imperative for policymakers to ensure that policy proposals aimed at bending the cost curve also contain sufficient guardrails to protect against inadvertent harm to patients.
We believe that for policy solutions to provide meaningful improvements they must meet certain criteria, as follows:

- Policies must guard against increases to patient out-of-pocket costs. The Administration should be mindful that, without sufficient guardrails, some of its proposals to lower drug prices and reduce out-of-pocket costs could inadvertently

Office of Public Policy
10 G Street NE, Suite 400
Washington, DC 20002
www.LLS.org

increase patient costs and erect new barriers between cancer patients and the treatments they need.

- Reforms must protect patients' appropriate access to meaningful coverage. As we describe in our Principles for Meaningful Coverage,[1] for coverage to be "meaningful," patients, regardless of their health status, must be guaranteed access to insurance that is stable, affordable, and high quality. Cancer patients' lives depend on having access to meaningful health insurance coverage. For many cancer patients, even a short interruption or delay in their access to coverage can have dire consequences for their treatment and outcomes.
- Policy changes should incentivize the development and prescribing, when appropriate, of new, innovative treatments. Policy proposals must ensure that changes do not discourage valuable innovations, as the development of and access to new safe and effective treatments is critically important to the health outcomes of cancer patients.

LLS is pleased that the Administration's Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs endorses several reforms that LLS has identified as opportunities to lower the cost of cancer care. When LLS released its Cost of Cancer Care recommendations last year, we called upon policymakers to equalize payments in different care settings in order to lower patient and insurer costs, promote competition once a drug is no longer under patent, reform the financial incentives in Medicare Part B, and empower patients through transparency about the cost of their treatment options. The Administration's Blueprint has offered reforms in all these areas, and LLS will continue to provide the cancer patient perspective as the Administration considers advancing policies to address these issues.

LLS strongly urges the Administration to consider and incorporate the patient perspective as it works to identify potential solutions and ensure patients retain adequate protection. In addition, it is critical that the Administration empower patients by providing consistent and clear communication as it moves forward with reforms.

LLS seeks to comment on the HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs across topics laid out by the Administration, including increasing competition and reducing patient out-of-pocket costs. We are encouraged by a number of the potential policy solutions that the Administration is exploring. However, we note that no single policy change can bring about systemic and lasting improvement. Rather, the Administration must pursue a comprehensive package of reforms to realign incentives and protect patients from higher out-of-pocket costs. In addition, as the Administration seeks to lower costs, it must pursue complimentary polices that ensure that lower out-of-pocket costs do not come at the expense of high-quality care.

[1] Available at http://www.lls.org/cancercost/Principles

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REFORMING MEDICARE PART B

LLS shares the Administration's view that the incentives in the buy and bill system governing reimbursement for drugs provided under Medicare Part B must be changed. In particular, LLS believes that policymakers should realign this system to prevent financial incentives that increase provider revenue based on the price of the underlying medication. Such reforms have the potential to reward value and eliminate unnecessary spending, without adversely affecting patient access to vital medications in the outpatient and physician office settings. With that said, millions of patients depend on drugs they receive through the Part B benefit, and reform must be pursued in a transparent and evidence-based manner to ensure minimal disruption in their care. Moreover, policies should be mindful that any new incentive structures do not create or allow for a different but equally problematic set of inadvertent or perverse incentives.

Transitioning Medicare Part B Drugs into Part D

As mentioned previously, we agree that the current system must be reformed. However, we strongly believe that without significant reforms to the Medicare Part D program (e.g. addressing disparities in out-of-pocket requirements, or protecting against the inappropriate use of utilization management tools) CMS should not move ahead with any proposal to transition certain drugs from Medicare Part B into Part D. Research from Avalere Health finds that, as of 2016, the average out-of-pocket costs for new cancer therapies were 33 percent higher in Part D than in Part B.[2] In addition, the Administration has acknowledged, that higher out-of-pocket costs have long been associated with a greater likelihood that patients will not adhere to their treatment regimen or abandon treatment altogether, leading to worse health outcomes and increased long-term costs for the system overall.[3] Moving ahead with this proposal would likely negatively impact a patient's ability to access needed care—particularly those patients whose treatment includes more than one high-cost drug—without achieving the Administration's goal of lowering costs.

Site-Neutral Payment Policies

LLS appreciates the Administration's attention on this issue and believes that site-neutral payment, if correctly designed and implemented, can create incentives for providers to make decisions that lower the cost of care for patients and taxpayers. In particular, realigning reimbursement incentives through site-neutral payment can ensure that the reimbursement system does not drive consolidation decisions and that consolidations do not increase patient and system costs. This is significant particularly as consolidation

[2] Avalere Health. 2016. Average OUT-OF-POCKET Costs for New Cancer Therapies 33% Higher in Part D than in Part B. Link.

[3] Journal of Clinical Oncology. December 20, 2017. Association of Patient Out-of-Pocket Costs with Prescription Abandonment and Delay in Fills of Novel Oral Anticancer Agents. https://ldi.upenn.edu/brief/association-patient-out-pocket-costs-prescription-abandonment-and-delay-fills-novel-oral.

between hospital and physician office settings continues to rise. For example, according to the Government Accountability Office (GAO), between 2007 and 2013, the number of vertically consolidated hospitals increased from nearly 1,400 to 1,700, while the number of vertically consolidated physicians nearly doubled from about 96,000 to 182,000.[4] In addition, a Milliman study on the cost drivers of cancer care found that the portion of chemotherapy infusions delivered in hospital outpatient settings increased from 15.8 percent in 2004 to 45.9 percent in in 2014 in the Medicare population.[5]

Further, as the trend toward consolidation continues to rise, site-neutral payment policies should ensure consistent quality of care across settings. With concerns around disproportionate reimbursement rates across the hospital and office settings, MedPAC has argued that site-neutral payments, which base the payment on the rate provided to the less costly setting, can save money for Medicare, reduce cost sharing for beneficiaries, and limit non-clinical incentives to provide services in more expensive settings—all without compromising beneficiary access to care or health outcomes. Specifically, a MedPAC study found that, for select conditions, characteristics of beneficiaries admitted to skilled nursing facilities (SNFs) and inpatient rehabilitation facilities (IRFs) in the same market were similar, and that health outcomes were nearly identical. MedPAC has since recommended site-neutral payments for select conditions between post-acute care sectors (e.g., SNFs and IRFs), as well as between acute care and long-term care hospitals.[6] However, LLS urges HHS to consider the incentives that any such polices would create around site of care. While it is necessary that providers not be incentivized to provide care in a more expensive setting than necessary, it is also crucial that these policies do not result in incentives for providers to push patients towards clinically inappropriate sites of care.

Implementation of a Medicare Part B Competitive Acquisition Program (CAP)

LLS agrees with the intention of a Medicare Part B CAP; however, the extent to which it translates to a meaningful impact on patient out-of-pocket cost will depend on its design and implementation. In the past, efforts to implement a CAP were unsuccessful, in part due to limited participation. The American Society of Clinical Oncology (ASCO) has also pointed to additional shortcomings of the previous CAP, such as requirements that patient copayments be completed prior to drug delivery, limited flexibility for changes in chemotherapy scheduling, and restrictions on the use of drugs in multiple practice

[4] GAO. December 2015. Increasing Hospital-Physician Consolidation Highlights Need for Payment Reform. https://www.gao.gov/assets/680/674348.pdf.

[5] Milliman. April 2016. Cost Drivers of Cancer Care: A Retrospective Analysis of Medicare and Commercially Insured Population Claim Data 2004-2014. http://www.siteneutral.org/wp-content/uploads/2016/06/1_COA-Study.-Cost-Drivers-of-Cancer-Care.pdf.

[6] MedPAC. March 2015. Report to Congress: Medicare Payment Policy. http://www.medpac.gov/docs/default-source/reports/mar2015_entirereport_revised.pdf?sfvrsn=0.

locations.[7] To maximize the impact of this type of program in the future, the Administration would need to address these potential structural issues and encourage participation from many providers to ensure leverage in negotiations with manufacturers.

If the Administration moves forward with this policy, LLS urges CMS to carefully design a CAP and closely monitor its implementation to ensure that it does not have the unintended effect of limiting patients' access to the appropriate treatment as determined by their providers. LLS also recommends that a CAP program be designed in such a way that patients can share in any potential savings.

REFORMING MEDICARE PART D

LLS is concerned about unsustainable rising drug and patient out-of-pocket costs in the Medicare Part D program. The combination of escalating list prices and the Part D benefit design lead patients who rely on costly medications to face enormous cost-sharing in the first month or two of each plan year, requiring the beneficiary to pay thousands of dollars for their first prescription of the year. Increasingly, patients continue to experience high cost-sharing throughout the year, since the five percent cost-sharing required under the catastrophic phase of the benefit can still require hundreds of dollars each month.

These costs have a real and dangerous impact on treatment adherence. The 1986 RAND Health Insurance Experiment (HIE) first demonstrated the basic behavioral trend that as costs go up, patients are less likely to seek or adhere to treatment. More recently, a 2018 study published in the *Journal of Clinical Oncology* found that high out-of-pocket costs may limit access to novel oral cancer medications. Specifically, the study found that nearly one third of patients whose out-of-pocket costs were between $100 to $500 and nearly half of patients whose out-of-pocket costs were more than $2,000 failed to pick up their new prescription for an oral cancer medication. By comparison, only 10 percent of patient who were required to pay less that $10 at the time of purchase did not pick up their mediations. Delays in picking up prescriptions were also more frequent among patients facing higher out-of-pocket costs.[8]

To help address this crisis in out-of-pocket costs, LLS recommends the Administration adopt a number of complementary reforms, including an extension of existing cost-sharing exceptions to specialty tier products, an annual cap on out-of-pocket expenses, manufacturer rebate pass-through at the point of sale, and meaningful drug price

[7] ASCO. February 22, 2013. ASCO in Action Brief: Physician Administered Drugs — The Evolution of Buy & Bill. https://www.asco.org/advocacy-policy/asco-in-action/asco-action-brief-physician-administered-drugs-%E2%80%94-evolution-buy-bill.

[8] Journal of Clinical Oncology. December 20, 2017. Association of Patient Out-of-Pocket Costs with Prescription Abandonment and Delay in Fills of Novel Oral Anticancer Agents. https://ldi.upenn.edu/brief/association-patient-out-pocket-costs-prescription-abandonment-and-delay-fills-novel-oral.

transparency. We appreciate the Administration's efforts to identify reforms to the Part D program, including the annual out-of-pocket cap outlined in the President's FY2019 Budget. We encourage CMS to work with all stakeholders to continue to develop specific reforms to reduce out-of-pocket costs for patients who rely on Part D to access life-saving therapies.

First, the Administration also should allow for cost-sharing exceptions for medications on plans' specialty tiers allowing them, based on clinical need, to access their prescription at a lower cost-sharing level. As we have mentioned in previous comments, if a patient requires a drug on the specialty tier—where plans place many cancer treatments—CMS rules prohibit his or her access to an important Part D patient protection, called a 'tiering exception'. This type of exception allows a beneficiary to pay a lower amount out-of-pocket for their 'non-preferred tier' medication, when the beneficiary has no clinically-appropriate option available on their plan's 'preferred tier.' Without access to this protection, many cancer patients face cost-sharing often as high as 33 percent of the drug's list price. For cancer patients who are likely taking multiple drugs, including multiple specialty drugs, the lack of an appropriate tiering exception can result in extremely burdensome costs each year. No other policy change under discussion in Congress or by the Administration would make as significant an impact on lowering the amount Medicare beneficiaries pay out-of-pocket for their drugs, and HHS has the statutory authority to implement this reform without new legislation.

Second, an annual cap on out-of-pocket expenses in Medicare Part D would provide an important financial protection to Part D beneficiaries, especially those with serious medical conditions like cancer. Cancer patients in employer health plans, individual health plans, Medicaid, and Medicare Advantage plans often depend on their annual out-of-pocket cap to provide some limit to the amount they must pay for life-saving care. Yet, patients who access their treatment through Medicare Part D do not have this key protection. Creating an annual out-of-pocket spending cap in Part D plans would dramatically lower seniors' cost-sharing for costly and often lifesaving drugs. Today, more than one million Part D beneficiaries enter the catastrophic phase of the Part D benefit, and many are forced to spend $10,000 or more per year to maintain access to their cancer treatment. An out-of-pocket cap in Part D would save these seniors hundreds—and often thousands—of dollars each year. LLS appreciates the Administration's endorsement of a Part D out-of-pocket cap, and we look forward to seeing the Administration work with Congress to enact this important reform.

Third, a rebate pass-through policy could also help stem rising patient out-of-pocket costs by requiring a portion of the rebates that manufacturers already pay to plans—or plans' pharmacy benefit managers (PBMs)—to be passed on to beneficiaries, reducing cost sharing at the point-of-sale (POS). As we noted in our comments on the Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the

PACE Program proposed rule, rebates are currently used to benefit all other parties except the patient. We understand that savings from manufacturer rebates may be applied to plans' or PBMs' operational activities or used to help lower premiums for all enrollees. However, premiums are not beneficiaries' only financial responsibility. As we have previously mentioned, patients who are most in need, like those undergoing cancer treatment, are disproportionately burdened with other cost-sharing responsibilities, including high drug coinsurance costs.

We believe that establishing an appropriate rebate amount required to be passed onto consumers at the point of sale will balance cost-sharing responsibilities in a way that is sustainable for beneficiaries, plans, and manufacturers. We again encourage the Administration to work with all stakeholders to develop a specific, data-driven approach to determining average rebate amounts and specified minimum percentages to reduce negotiated prices for Part D covered drugs at the point of sale.

Fourth, LLS believes that patient-centered reforms that improve transparency around drug costs, price increases, and drug value have the potential to help stem the tide of rising drug prices and the out-of-pocket costs that rise with them. However, to have an impact on costs and to empower patients to make informed decisions, transparency must be meaningful. It is not enough that data on price increases and other cost be available; it must be accompanied by plain-language communication, consumer tools, and support services that enable beneficiaries to understand the information and incorporate it into their plan choices. Importantly, transparency into cost is of limited value to patients if they do not have lower cost options from which to choose—which is the experience of many cancer patients who have only one optimal therapeutic option.

Importantly, reforms that lower out-of-pocket costs for Part D beneficiaries have the potential to benefit both patients and taxpayers, lowering spending on hospitalization and other serious medical interventions reimbursed under Medicare Parts A and B. In fact, a 2013 MedPAC report showed that Part D beneficiaries with lower medication adherence levels have more hospitalizations and emergency room visits and higher mortality rates.[9] A later MedPAC report suggested that improved adherence among the least adherent beneficiaries with congestive heart failure could result in lower medical spending, ranging from nearly $860 to $2,500 per beneficiary per year.[10] Adherence to prescription cancer therapies can often lead to similar savings by avoiding very costly medical-benefit interventions.

[9] MedPac Report. June 14, 2013. Measuring the Effects of Medication Adherence for the Medicare Population.
[10] MedPAC. December 23, 2019. Medication Nonadherence and the Risks of Hospitalization, Emergency Department Visits, and Death Among Medicare Part D Enrollees with Diabetes. Drug Benefit Trends.

Increasing Part D Plan Flexibility

Existing regulation and guidance around coverage, access, and non-discrimination have been developed over many years, and plans are largely familiar with the current set of rules. Before protections like the six protected classes were established early in the implementation of Part D, barriers to access were greater and there were greater disparities between plans, which increased the likelihood that patients would select plans that did not meet their needs. Removing or loosening these protections could have a significant negative impact on patients and make it more likely that some patients will struggle to access their medications.

At the same time, LLS is concerned that, without appropriate guardrails, efforts to allow Part D plans more flexibility will result in decreased access for patients. HHS noted that, as an immediate step, it may provide full formulary flexibility for Part D plans to manage high-cost drugs, including in protected classes. LLS is concerned that giving plans greater flexibility to manage high-cost drugs and/or drugs with certain price increases in Part D would result in barriers to access for patients, particularly in protected classes. LLS believes that access to treatment need not be limitless but should be appropriate to the patient's needs and avoid unnecessary or unreasonable barriers.

RESTRICTING THE USE OF REBATES IN PART D

LLS agrees with the Administration that current rebate incentives are driving up patient out-of-pocket costs and federal taxpayer spending on Medicare Part D. However, LLS is also concerned that making rapid, large-scale changes to the program will not inevitably result in better incentives. If HHS moves forward with proposals to curtail rebates to PBMs, a new system of incentives, both "good" and "bad," would be created. For example, plans may be incentivized to provide less generous benefits or increase utilization management, which would negatively impact patients. LLS believes that targeted reforms are necessary to better align rebating incentives with the goals of treatment adherence and taxpayer savings. Yet, HHS should also carefully evaluate potential patient impacts before moving forward with a specific approach.

In addition, HHS should note that a suite of complementary policy changes will be necessary to change the underlying rebate system incentives; these reforms should be structured in such a way that patients directly benefit from savings.

IMPLEMENTING VALUE-DRIVEN / INNOVATIVE PAYMENT MODELS

LLS believes that innovative, value-driven payment models can have the potential to lower both systemic and out-of-pocket costs as well as incentivize improving health outcomes and developing new treatments. As LLS stated in its Cost of Care Recommendations, to incentivize patient-centered innovation, prescription drugs that significantly improve important patient outcomes should be rewarded generously, in comparison to new

therapies that bring limited or no benefit over existing options. For example, a new, curative therapy should be deemed "higher value" than a new brand drug that's clinical value is comparable to that of existing drugs.

LLS welcomes the Administration's focus on developing value-based models. However, it is imperative that value-based models and creative financing arrangements remove existing barriers to access for patients, not create new ones. Patients and patient groups should play a role in determining how "value" will be defined as HHS considers value-based purchasing arrangements, indication-based pricing models, and long-term financing models.

Value-Based Purchasing (VBP) Arrangements

VBP demonstrations must take into account the patient perspective and should ideally be structured to directly benefit patients or, at a minimum, to ensure no decrease in access to or quality of care. In particular, the outcomes metrics for evaluating success under the VBP arrangement should measure outcomes that are meaningful for patients. Further, these arrangements should be structured to share any accrued savings under the contract directly with the patients who use the products (e.g., rebate pass through, refunds shared with patients). Whenever possible, VBP arrangements should reduce barriers to patient access, such as high out-of-pocket costs.

LLS agrees with the Administration that there are barriers to developing VBP arrangements; however, we reiterate the previous recommendations we made for modernizing regulations to facilitate innovative models: 1) reforming the Medicaid best-price regulations and anti-kickback protections to allow contracting arrangements that include financial adjustments based on patient outcomes, and 2) providing sufficient latitude in communications between drug makers and PBMs/insurers in advance of a product's approval in order to allow the sharing of information necessary to develop innovative payment models. LLS commends the FDA for recently finalizing two long-awaited guidances as part of its efforts to advance medical product communications to support drug competition and value-based care. By allowing manufacturers to share accurate information about their products with payers, the FDA has signaled that prices should be able to adjust to reflect the value of the outcomes they deliver. LLS believes patient groups can and should play an important role in partnering with other stakeholders to ensure that patient data is appropriately collected and leveraged in these demonstrations.

Development of an Indication-Based Pricing Model

LLS believes that indication-based pricing models have the potential to help incentivize higher quality and lower-cost care by reducing prices for some indications. Indication-specific pricing may offer a new mechanism to facilitate patient access to medications within a model that seeks to balance payer needs for affordability. However, HHS should monitor the implementation of these policies carefully to ensure that there is not an

unexpected negative impact on patient access, including the fact that they work differently for various conditions and may not lower out-of-pocket costs uniformly. For example, relative to uniform pricing, indication-based pricing may result in higher prices for patients who benefit the most, higher utilization by patients who benefit least, higher overall spending, and higher manufacturer profits. In addition, any Administration proposals seeking to incorporate an indication-based pricing model should account for the fact that off-label use is common in oncology, representing the typical treatment regimen for many types or stages of particular cancers. In this environment of common off-label use, indication-based pricing models incorporating clinical and economic value must consider such value for the approved indications and other off-label uses.

In addition, it is essential that coding and reimbursement for new treatments be appropriate so that providers are not disincentivized from providing access to these treatments. Ultimately, the Administration should be mindful of the trade-offs between patients with higher and lower utilization when designing indication-based pricing policies.

Long-Term Financial Models

Long-term financing models can potentially have a positive impact in promoting patient access to new, innovative treatments. They can reduce the upfront burden on the healthcare system, which has the potential to improve access to high-cost, potentially curative treatments for patients. However, these models must be structured in a way that protects patients from undo cost burdens. For example, curative and/or breakthrough treatments are typically associated with major upfront costs, but, over time, can result in significant savings and improve patient outcomes. LLS believes that innovative, long-term financing mechanisms can potentially make it easier for payers to cover high-cost drugs, which could lead to fewer barriers to access for patients.

These potential benefits notwithstanding, proper guardrails must be established and contracted to ensure long-term financial responsibility from manufacturers and payers and protection for patients. For example, a patient who receives an expensive treatment may want to change insurers before that treatment is fully “paid for” – the Administration should consider how these models can be structured so that patients do not experience challenges moving to a new insurer in such cases.

INCREASING COMPETITION: REMS REFORMS AND BIOSIMILAR DEVELOPMENT

LLS believes that generic and biosimilar products have the potential to reduce costs for patients and the healthcare system. At the same time, recent pricing examples prove that biosimilar and generic markets with limited competitors do not produce the level of savings expected by payers and patients. LLS supports the Administration’s goal of increasing competition and agrees that inappropriate use of Risk Evaluation and Mitigation Strategies (REMS) to deter generic entry has been one barrier to competition.

Further, LLS believes that taking steps to streamline biosimilar development and accelerate adoption of these products can be important for increasing competition.

First, as FDA Commissioner Scott Gottlieb has stated, "branded companies may be using regulatory strategies or commercial techniques to deliberately try to block a generic company from getting access to testing samples."[11] LLS believes that measures to prevent companies from either restricting product distribution to generic or biosimilar companies or misusing patent rules around REMS have the potential to improve generic and biosimilar competition and reduce patient out-of-pocket costs for patients. Accordingly, LLS supports the FDA's recent guidances aimed at streamlining the generic drug development and approval processes while maintaining the safety controls achieved by REMS, by encouraging the development of shared-system REMS or waiving the requirement altogether.

Despite the FDA's indicated willingness to waive the single, shared REMS requirement when appropriate, REMS patents continue to threaten generic competition. Even if granted a waiver, a generic manufacturer is unlikely to avoid infringement when the brand manufacturer has patented its REMS program. Accordingly, LLS encourages both the Administration and Congress to pursue patent reforms that will reduce the risk of infringement that generics confronts from REMS patents. For example, FDA should issue guidance that clearly states that REMS process patents will not be listed in the FDA's Orange Book, and FDA should consider delisting the REMS-related patents currently listed in the Orange Book. In addition to these administrative actions, Congress should consider deeming REMS methods or systems patents as within the "prior art," thereby limiting patent claims that branded companies have used to delay generic competition on REMS products. Taken together, these actions would certainly speed patient access to generic alternatives to costly branded medications, while maintaining the public safety protections that have proven so beneficial to patients who rely on drugs that would not receive FDA approval except under a REMS program.

Second, as a recent NIH study concluded, the expansion of biosimilar products advancing through the developmental pipeline could result in additional cost savings to the health care system.[12] Similarly, the RAND Corporation estimates that biosimilars could reduce direct spending on biologic drugs, which make up much of the oncology market, by $54 billion from 2017 to 2026, or about 3 percent of total estimated biologic spending over the same period, with a range of $24 to $150 billion.[13] Realizing these cost-savings, of

[11] FDA. Commissioner Scott Gottlieb. June 21, 2017. FDA Working to Lift Barriers to Generic Drug Competition. https://blogs.fda.gov/fdavoice/index.php/2017/06/fda-working-to-lift-barriers-to-generic-drug-competition/.
[12] NIH. Dana, Kaitlyn N., Hertig, John B., and Weber, Robert. February 2017. Drug Pricing Transparency: The New Retail Revolution. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5345916/.
[13] RAND Corporation. Mulcahy, Andrew, Hlavka, Jakub, and Case, Spencer. 2017. Biosimilar Cost Savings in the United States: Initial Experience and Future Potential. https://www.rand.org/pubs/perspectives/PE264.html.

course, relies on the efficient development and approval of these products, and sufficient uptake in the market. As such, LLS supports FDA efforts to improve the efficiency of the biosimilar and interchangeable product development and approval process, as well as continuing its education initiative[14] aimed at providers and patients to increase confidence in these products.

LLS believes that increasing competition is not necessarily a goal in and of itself for patients. Indeed, increased competition is only meaningful if it results in lower out-of-pocket costs for patients and incentivizes the development of innovative new treatments. With that in mind, the Administration should advance policies that will leverage generic and biosimilar options to help lower costs to the system and to patients.

PROMOTING TRANSPARENCY

As previously stated, LLS commends the Administration on its intent to increase transparency and agrees that having accurate and complete data around national spending is important. It is not enough that data be available, however. To have an impact on costs and to empower patients to make informed decisions, transparency must be meaningful and actionable. As a recent TransUnion survey demonstrated, transparency is a major factor in patient's choice of providers and health plans during open enrollment. Lack of price transparency can lead to confusion and fear over how much medical treatment can cost.[15]

In addition, a 2017 Brookings report demonstrated the potential positive effects of greater transparency aimed at improving patient decision making. Specifically, the report outlined a proposed policy, which would make actual average generic drug price information selectively available to third-party payers and would analyze the likely effects of limited price disclosure on competition and efficiency. The authors estimate that additional information would cut health spending by $4 billion for every $1 reduction in the average reimbursement to retail and mail-order pharmacies for a generic prescription.[16]

Developing Tools and Technology around Out-of-Pocket Costs in Medicare

HHS should work closely with stakeholders to improve the tools used to communicate with beneficiaries, especially around costs. In particular, patients should be able to easily

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[14] FDA's website: Biosimilars, available at: https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/

[15] TransUnion. November 20, 2013. TransUnion Survey: Healthcare Cost Transparency Major Factor in Patients' Choice of Providers, Health Plans During Open Enrollment. https://newsroom.transunion.com/transunion-survey-healthcare-cost-transparency-major-factor-in-patients-choice-of-providers-health-plans-during-open-enrollment

[16] The Brookings Institution. June 2017. Would Price Transparency for Generic Drugs Lower Costs for Payers and Patients? https://www.brookings.edu/wp-content/uploads/2017/06/es_20170613_genericdrugpricing.pdf.

compare plan options and understand how their out-of-pocket costs for drugs and medical expenses may vary throughout the year, compare Medicare fee-for-service (FFS) to Medicare Advantage (MA) plans, and determine the effects of adding on Medigap.

Ultimately, the intent of greater transparency is to improve patient's ability to make better coverage decisions using unbiased information. HHS should also devote adequate resources so that improvements are meaningful for patients, including increased funds State Health Insurance and Assistance Programs (SHIPs) and 1-800-Medicare, as well as modernizing the medicare.gov website to have better e-commerce tools for people needing minimal assistance. Specifically, CMS must ensure its tools to help beneficiaries find plans that best meets their needs offer details of the benefits offered by all plans. Moreover, CMS' Plan Finder and the Medicare and You handbook should allow beneficiaries to filter and/or sort plans by benefit features. For CMS to ensure that beneficiaries can make the most of the innovative options potentially being offered, plan selection tools must reflect the ways in which plans might be distinguished from one another.

Requiring Plans to Provide Certain Cost Information in the Explanation of Benefits
LLS believes that providing additional cost information to patients can help empower them to make decisions about their care. Again, LLS recommends that HHS require that communications from plans be designed in a way that makes it easy for patients to understand any changes in cost and make informed decisions. While some beneficiaries may be able to choose which drugs to take, many patients do not have multiple options. For these patients, knowing that the price of drug is increasing, without corresponding information about any increase in rebates that plans are receiving, will not empower them to make better, more informed choices. Information about cost and cost increases should not be limited to drugs – it should also reflect medical costs and cost to MA plans. Further, this information should be displayed on Plan Finder as well as included in the Explanation of Benefits.

In addition, if it moves forward with policies in this area, HHS should increase its oversight and survey patients and pharmacists to monitor the extent to which plans are complying and to better understand what steps can be taken to increase beneficiary awareness and understanding.

Prohibiting Part D Plans from Limiting Disclosure of Cost Information by Pharmacists
LLS agrees that Part D plans should be prohibited from preventing pharmacists from discussing lower out-of-pocket cost options with beneficiaries, given that a host of studies have concurred that higher out-of-pocket costs lead to greater abandonment of treatment. If pharmacists are not able to communicate freely with patients about different options and their impact on out-of-pocket costs, patients may be at risk of making decisions that, in the long term, causes them to pay higher costs out-of-pocket.

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REFORMING THE 340B PROGRAM

LLS agrees that the 340B program should be the subject of extensive scrutiny to better determine whether it has achieved and continues to achieve its goals of promoting patient access to necessary treatments. LLS urges the Administration to consider 340B program reforms that would improve transparency around how covered entities utilize the significant discounts they receive under the program, in order to promote the sharing of these discounts with patients served by these facilities. At the same time, given the breadth of the 340B program and the number of patients served by covered entities, the Administration should carefully investigate the potential patient impact of reducing the program's size or limiting its growth. Many patients depend on 340B covered entities to access their medication, and it is imperative that potential policy proposals do not unduly disrupt access to care or increase out-of-pocket costs.

ABOUT LLS

LLS is the world's largest voluntary health agency dedicated to the needs of blood cancer patients. Each year, over 150,000 Americans are newly diagnosed with blood cancers, accounting for nearly 10 percent of all newly diagnosed cancers in the United States. The mission of LLS is to find cures for leukemia, lymphoma, Hodgkin's disease, and multiple myeloma and to ensure that blood cancer patients have sustainable access to quality, affordable, coordinated healthcare. LLS funds lifesaving blood cancer research, provides free information and support services, and advocates for public policies that address the needs of patients with blood cancer. Since our founding nearly 70 years ago, LLS has invested more than $1 billon into research for cures and LLS-funded research has been part of nearly all of the FDA-approved therapies for blood cancer.

LLS appreciates the Administration's focus on the cost of care and patient out-of-pocket costs, as well as the opportunity to offer its comments. LLS welcomes the opportunity to engage with the Administration further on these important issues. Should you have any questions about our comments, our organization, or the patient community we serve, please do not hesitate to contact Bernadette O'Donoghue by email at bernadette.odonoghue@lls.org or by phone at 202-989-1810, or Brian Connell at brian.connell@lls.org or by phone at 202-989-1805.

Sincerely,

Bernadette O'Donoghue

Bernadette O'Donoghue
Vice President, Public Policy

Office of Public Policy
10 G Street NE, Suite 400
Washington, DC 20002
www.LLS.org

BEATING CANCER IS IN OUR BLOOD.