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July 16, 2014

The Honorable Joseph Pitts
Chairman, Subcommittee on Health
U.S. House Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Pitts:

Thank you for the opportunity to testify before the Subcommittee on Health at the hearing entitled, "21st Century Cures: Examining the Role of Incentives in Advancing Treatments and Cures for Patients." Getting incentives "right" will be crucial if the United States wants to continue to foster innovation while controlling health care costs.

I am pleased to respond to the three questions posed by Representative Ed Whitfield.

1. The data correlating patient choice to improved adherence and compliance is a national issue of huge importance. Patients who fail to take their medication as prescribed have higher healthcare costs. They often suffer from unnecessary complications, including heart attacks, strokes, heart failure, amputations, end-stage renal disease and vision loss. Express Scripts estimates that failure to take medications as prescribed costs the U.S. approximately \$317 billion annually^{i,ii,iii}. Several studies document the association between adherence and positive clinical outcomes (e.g., high blood pressure, glucose levels for diabetes) for several medical conditions.^{iv,v,vi,vii,viii} Express Scripts research demonstrates that switching a patients' diabetes medication from a 30-day retail fill to a 90-day mail order pharmacy fill improves adherence, leading to lower all-cause and diabetes-related healthcare costs.^{ix} Previous studies have also indicated that medication adherence is associated with reducing disease morbidity,^x reducing healthcare resource utilization,^{xi} and decreasing hospitalization.^{xii} The Centers for Medicaid and Medicare Services (CMS) has understandably adopted goals to increase adherence as part of their Medicare Star Ratings clinical metrics. This new metric reinforces that better outcomes and cost containment can be achieved through improved medication adherence.
2. We do view the opportunities to improve health outcomes and lower costs being driven by taking a more holistic approach across the entire medical community. PBMs can and do play a critical role in this process. The pharmacy benefit is the most frequently utilized health care benefit. Pharmacy data is real time and powerful. Appropriate use of pharmacy represents the sharp end of the spear when it comes to improving patients' outcomes and reducing costs. If we can use every touch point with a patient to both educate and activate their good intentions, we are more likely to have a good outcome.

At Express Scripts, we have designed a system in which we use behavioral approaches combined with our clinical specialization to engage patients, activate good intentions, close gaps in care and share data with the other provider partners. This holistic approach has the potential to truly move the health of our country in a new direction.

3. The GAIN Act as enacted by Congress provides incentives to promote the development of novel antibiotics to treat unmet medical needs. In addition to this law, science continues to evolve and prior investments in basic research like the human genome project are now making a difference. It is our belief that investment in basic research via the NIH is still the best approach to spurring innovation and developing treatments for unmet medical needs. As we stated in our testimony, incentives can often have perverse effects and actually stifle innovation as seen with periods of exclusivity for pharmaceuticals. If incentives are to be utilized, they should be very narrowly defined, time limited and treated as pilots. Otherwise, they could potentially add substantially to long term health care costs.

Again, thank you for the opportunity to testify before the Committee. I appreciate the Committee's attention to this important topic.

Sincerely,



Steven B. Miller
Senior Vice President and Chief Medical Officer
Express Scripts Holding Company

ⁱ Nasseh K, et al. Cost of Medication Nonadherence Associated with Diabetes, Hypertension, and Dyslipidemia. *Amer Journal of Pharmacy Benefits*. 2012;4(2):e41-e47.

ⁱⁱ New England Healthcare Institute (NEHI). Thinking outside the pillbox: a system-wide approach to improving patient medication adherence for chronic disease. Available at:

http://www.nehi.net/publications/44/thinking_outside_the_pillbox_a_systemwide_approach_to_improving_patient_medication_adherence_for_chronic_disease. Accessed January 19, 2012.

ⁱⁱⁱ Balkrishnan R. The importance of medication adherence in improving chronic disease-related outcomes: what we know and what we need to know further. *Med Care*. 2005;43(5):517-520.

⁵ Bramley TJ, Gerbino PR, Nightengale BS, Frech-tamas F. "Relationship of Blood Pressure Control to Adherence With Antihypertensive Monotherapy in 13 Managed Care Organizations" (*J Manag Care Pharm*. 2006;12(3):239-45)

⁶ Caro JJ, Ishak KJ, Huybrechts KF, Raggio G, Naujoks C. The Impact of Adherence with osteoporosis therapy on fracture rates in actual practice (*Osteoporosis Int* (2004) 15:1003-1008)

^{vi} Ho MP, Sperrus JA, Masoudi FA, Reid KJ, Peterson ED, Magid DJ, Krumholz HM, Rumsfeld JS. "Impact of Medication Therapy Discontinuation on Mortality After Myocardial Infarction" (*Arch Intern Med* 2006;166;1842-1847)

^{vii} Pladevall M, Williams LK, Potta LA, Divine G, Xi H, Lafata J Diabetes Care "Clinical Outcomes and Adherence to Medication Measured by Claims Data in Patients with Diabetes" 2004 (*Diabetes Care* 27:2800-2805)

^{viii} Williams LK, Pladevall M, Xi H, Peterson EL, Joseph C, Lafata J, Ownby DR, Johnson CC. "Relationship between adherence to inhaled corticosteroids and poor outcomes among adults with asthma." (*J Allergy Clin Immunol*. 2004 Dec;114(6):1288-93)

^{ix} Devine, S., Vlahiotis, A., & Sundar, H. (2010). A comparison of diabetes medication adherence and healthcare costs in patients using mail order pharmacy and retail pharmacy. *Journal of Medical Economics*,13(2), 203-11.

^x Albert NM. Improving medication adherence in chronic cardiovascular disease. *Crit Care Nurse*. 2008;28(5):54-64.

^{xi} Sokol MC, McGuigan KA, Verbrugge RR, Epstein RS. Impact of medication adherence on hospitalization risk and health care cost. *Med Care*. 2005;43(6):521-530.

^{xii} Stuart BC, Simoni-Wastila L, Zhao L, Lloyd JT, Doshi JA. Increased persistency in medication use by U.S. Medicare beneficiaries with diabetes is associated with lower hospitalization rates and cost savings. *Diabetes Care*. 2009;32(4):647-649.

FRED UPTON, MICHIGAN
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HENRY A. WAXMAN, CALIFORNIA
RANKING MEMBER

ONE HUNDRED THIRTEENTH CONGRESS
Congress of the United States
House of Representatives

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July 1, 2014

Dr. Steven B. Miller
Senior Vice President and
Chief Medical Officer
Express Scripts Holding Company
One Express Way
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Dear Dr. Miller:

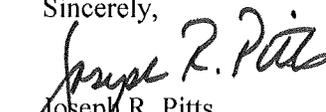
Thank you for appearing before the Subcommittee on Health on Wednesday, June 11, 2014, to testify at the hearing entitled "21st Century Cures: Examining the Role of Incentives in Advancing Treatments and Cures for Patients."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

To facilitate the printing of the hearing record, please respond to these questions with a transmittal letter by the close of business on Wednesday, July 16, 2014. Your responses should be mailed to Sydne Harwick, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, D.C. 20515 and e-mailed in Word format to Sydne.Harwick@mail.house.gov.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,


Joseph R. Pitts
Chairman
Subcommittee on Health

cc: The Honorable Frank Pallone, Jr., Ranking Member, Subcommittee on Health

Attachment

Attachment—Additional Questions for the Record

The Honorable Ed Whitfield

1. The Centers for Disease Control and Prevention (CDC) recently released alarming new data on diabetes: 29 million Americans are living with diabetes, close to 10% of the population. Over 85 million people are living with pre-diabetes. The trajectory is only getting worse with no end in sight. Yet, we know that proper care and treatment of diabetes can prevent many of the costly complications of diabetes like blindness, amputation, and stroke. What is the data correlation to patient choice and improved adherence and compliance—something so important to help prevent these horrible complications of diabetes?
2. Chronic illnesses are a burden to our federal budget. Reducing overall medical costs involves a multitude of approaches including lifestyle management, appropriate early diagnosis and treatment, and medication adherence. As the CMO of the largest PBM in the U.S., how do you see the medical community, PBMs, and pharmaceutical industry working together to address this issue?
3. Congress can help drug development by providing incentives such as we did with the Generating Antibiotic Incentives Act (GAIN Act). But we have also heard that there are changes to the regulatory process that can act as an incentive as well. For example, if FDA had the clear authority to approve antibiotics for limited populations for whom there were few or no treatments the agency may be more willing to tolerate a higher level of risk or uncertainty in approving these drugs. We have heard from companies that this could also act as an incentive by making clinical trials more feasible than they would be if FDA had to consider the risk/benefit of a drug for a much broader population, some of whom may have other options. In your view, would a limited population pathway be a useful incentive to get drug developers engaged in addressing the dwindling pipeline and making antibiotics to treat unmet needs?