CLOSER LOOK

American Diabetes Association 77th Scientific Sessions

June 9-13, 2017; San Diego, CA; Full Report - Policy and Reimbursement - Draft

Executive Highlights

This document contains our coverage of policy and reimbursement at ADA 2017. Immediately below, we enclose our themes on the category, followed by detailed discussion and commentary. Talk titles highlighted in yellow were among our favorites from ADA 2017; those highlighted in blue are new full report additions from our daily coverage.

For comprehensiveness, we have included some talks in this report that also overlap with our ADA 2017 GLP-1 Agonist, Glucose Monitoring, Treatment Algorithms and Strategies, and Epidemiology, Education, and Additional Topics reports.

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Themes

INSULIN PRICING

- **Insulin pricing continued to be a major focus at the ADA, where - for the third year in a row - a headlining symposium was dedicated to the topic at the Scientific Sessions.** The symposium was chaired by Dr. Irl Hirsch (one of the first to sound the alarm bells on the insulin pricing controversy) and featured experts from all perspectives on the topic, including former ADA Chief Medical and Scientific Officer Dr. Robert Ratner, Yale's Dr. Kasia Lipska, University of Kansas' Dr. David Robbins, and pharmacist Dr. Alan Carter. Every speaker in the session acknowledged the complexity of the healthcare and drug pricing system and emphasized that no one stakeholder is the sole driver of increased prices. That said, there were varying degrees to which the presenters highlighted the role of pharmacy benefits managers (PBMs) and pointed the finger at pharmaceutical companies. Dr. Ratner, in particular, noted that rebates to PBMs rose substantially from $67 billion in 2013 to a whopping $106 billion in 2015 - leading him to suggest that we should get rid of these "middlemen with no added value increasing expenditures." We aren't sure they add no value, but we agree that we'd like to see more transparency. On the other hand, Dr. Lipska briefly acknowledged the role of PBMs in insulin pricing during Q&A, but largely described the role of what she termed "incremental innovation" and new patents from pharmaceutical companies in increasing the price of insulin. In terms of solutions, all speakers emphasized that "it takes a village" to substantially improve the financial burden of insulin for patients. Dr. Robbins in particular highlighted several things that individual healthcare providers, patients, regulatory agencies, pharmaceutical companies, and the FDA can do to improve this issue. For the field as a whole, Dr. Robbins asked all the various stakeholders to stop oversimplifying the issue of drug pricing and to share the blame, rather than point fingers. Further, the formation of partnerships to tackle this problem are crucial. He also emphasized the need to healthy, educated, and fair critics, while recognizing that we are all subject to bias. To that end, he emphasized that "new" is not always better. And finally, he called upon attendees to always advocate for their patients. Dr. Ratner looked at specific ongoing or proposed events and policies and their potential impact on insulin costs, including the arrival of more biosimilar competition, the proliferation of direct-to-consumer discount programs, lawsuits that force pricing transparency as part of discovery, and several proposed policy and legislative changes. All in all, it's clear that the furor over insulin pricing has not abated, and we're glad to see continued discussion of concrete solutions to help patients on this front.

CLINICAL VS. COMMERCIAL ENTHUSIASM

- **As thought leaders sounded off on the latest and greatest in diabetes care at ADA 2017, we couldn't help but notice some discrepancies between what scientists/researchers are most excited about and what's being adopted by real-world patients/providers.** A glaring example of this is combination therapy. We heard an abundance of enthusiasm on this front from diabetes experts, including Dr. John Buse, who advocated for greater uptake of fixed-dose and fixed-ratio combination products, and Dr. James Gavin, who advocated for earlier intervention with multiple agents (simultaneous as opposed to sequential treatment). On the other hand, patients/ providers in the real world show a certain reluctance to combination therapy. In a separate call with our team, Dr. Sam Engel, Associate VP of clinical research in diabetes at Merck, attributed this hesitation to two factors: (i) HCPs feel obligated to up-titrate drugs to maximum dosage before trying something new, even though the majority of an agent's efficacy will show at low- to mid-range doses. (ii) HCPs fear that it'll be difficult to parse out the cause of adverse events if they start patients on more than one drug at a time, even though the side-effect profile of an agent is usually well-characterized prior to approval. Moreover, one of the distinct advantages to combo pills or injections is that each component comes at a lower dose, and the combination thus comes with a milder side-effect profile vs. either monotherapy. Guidelines are starting to evolve, and are recommending earlier co-administration of drugs for patients with A1c >9%, but it'll take dedicated, concerted effort to educate diabetes care providers far-and-wide on the benefits to combination therapy. We see great potential for pharmaceutical companies to play a leading role in this education. Merck, for example, is already positioning its SGLT-2/DPP-4 fixed-dose combination (ertugliflozin/sitagliptin) high on the priority list within the ertugliflozin franchise - oral presentations on VERTIS FACTORIAL and VERTIS SITA2 both emphasized the convenience of a single, oral tablet that combines two agents with complementary mechanisms of action. AZ is also investing strategically in Qtern (dapagliflozin/saxagliptin) and hosted a corporate symposium at this meeting with lots of discussion on combination therapy as a means to circumvent therapeutic inertia. We'd love to see additional patient/provider education efforts outside the context of scientific meetings, from these and other companies with combo products in their diabetes portfolios.
    - **Another (extremely unfortunate) clinical vs. commercial discrepancy involves sulfonylureas.** Diabetes experts acknowledge the affiliated risk for hypoglycemia, weight gain, potential for beta cell burnout, and heightened CV risk. And yet, sulfonylureas remain a major part of treatment algorithms due to their generic status and low cost. While we can't underplay the affordability factor, we also can't emphasize enough the substantial downstream costs of severe hypoglycemia and CV events (hospital visits, emergency care, productivity loss, major adverse effects on patient quality of life, etc.). The ongoing CAROLINA and GRADE studies could produce the data we need to remove sulfonylureas from their current mainstream role in diabetes management: CAROLINA is Lilly/BI's CVOT comparing DPP-4 inhibitor Tradjenta (linagliptin) vs. a sulfonylurea (glimepiride), expected to complete in March 2019 (which, suddenly, doesn't seem that far away), and the GRADE study will analyze diabetes therapies head-to-head to determine the optimal combination treatment for long-term care. As newer classes like DPP-4 inhibitors, SGLT-2 inhibitors, and GLP-1 agonists approach generic status, we hold out hope that sulfonylureas will slowly but surely fall out of practice, yielding to superior therapies that offer A1c-lowering, weight loss, and other advantages to outcomes beyond A1c without conferring CV or hypoglycemia risks.

A WELCOME INCREASED EMPHASIS ON PREVENTION

- **We noticed a greater emphasis on prevention at this year's ADA - a welcome sign of growing recognition of the importance of prevention efforts to combat diabetes on a population level.** In fact, this was the central focus of this year's Presidential Health Care & Education address in which Ms. Brenda Montgomery discussed the ADA's pursuit of "pillars of

prevention" in the form of prevention-related research and clinical trials, educational efforts, and political advocacy to establish Medicare coverage for the NDPP. To this end, we heard several notable presentations evaluating the efficacy of diabetes prevention approaches in different demographic subgroups over time. For instance, a 15-year analysis of the Diabetes Prevention Program (DPP) study reported that metformin has an enduring preventive effect for younger people, individuals with a greater BMI, and women with a prior history of gestational diabetes. Furthermore, we heard the highly-anticipated results of the PREVENT-DM study, the first comparative effectiveness trial of diabetes prevention treatments in a real world setting. In a population particularly vulnerable to type 2 diabetes (Hispanic females with low socioeconomic status), intensive lifestyle intervention delivered by community health workers produced significantly greater weight loss than metformin and standard of care, suggesting that such programs are an effective population-level strategy for diabetes prevention. Despite the growing conversation on diabetes prevention programs, the legendary Dr. Ann Albright, director of the CDC's Division of Diabetes Translation, issued a compelling call for even greater effort on this front, arguing that "we need to address prevention to a much great degree than we currently are" in order to make a dent in the diabetes epidemic. Because policy and community-level strategies for prevention take place so incrementally, Dr. Albright offered a perspective for how to promote diabetes prevention in the context of one-on-one conversations in the physician's office. She suggested tailoring conversation topics for people at different levels of diabetes risk - low (general information about healthy behaviors), medium (NDEP resources and recipe guides), and high (structured programs like the DPP, or medication like metformin).

Detailed Discussion and Commentary

Oral Presentations: Potential Implications of the Affordable Care Act on Diabetes Care

DRUG COPAY AND MEDICATION ADHERENCE IN MEDICARE PATIENTS WITH TYPE 2 DIABETES

Manjiri Pawaskar, MD (Merck, Kenilworth, NJ)

Dr. Manjiri Pawaskar (Director of the Center of Real-World and Observational Research at Merck) presented a Merck-sponsored study that found a significant correlation between high co-pays and low medication adherence for non-insulin prescription drugs. Notably, Medicare patients with type 2 diabetes (n=160,250) who faced a monthly co-pay >$60 were 71% less likely to be adherent vs. patients who faced a monthly co-pay <$10 (OR=0.29; 95% CI: 0.26-0.33). Moreover, a monthly co-pay >$60 was associated with a 1.5x risk for treatment discontinuation vs. a monthly co-pay <$10 (OR=2.49; 95% CI=2.17-2.87). Other categories of high co-paHy were also linked to significantly lower medication adherence and to a greater likelihood of discontinuation as showed in the picture below (whenever the odds ratio doesn't cross the line of unity), but adherence to generic drugs was unaffected by co-pay. Importantly, few Medicare patients in the analysis had to pay >$10/month out-of-pocket for generic agents, so we wouldn't expect the same adverse impact of co-pay on engagement.

IMPACT OF SWITCHING TO A HIGH-DEDUCTIBLE HEALTH PLAN ON DIABETES TREATMENT DISCONTINUATION

Yuexin Tang, PhD (Merck, Kenilworth, NJ)

Dr. Yuexin Tang (Associate Director at Merck's Center of Real-World and Observational Research) presented a second Merck-sponsored study to show how switching to a high-deductible health insurance plan (HDHP) increases risk for discontinuation of branded, non-generic drugs. The observational analysis compared 1,496 type 2 diabetes patients who were mandated by their employer to switch onto a HDHP between 2013 and 2014 vs. 21,623 patients who were covered by a non-HDHP for two consecutive years. In the HDHP cohort, 46% of people discontinued a prescription in 2014 vs. 33% of individuals in the non-HDHP cohort ($p<0.05$). Once again, this effect did not extend to generic drugs. Macrovascular complications were seen in 10% of the non-HDHP group vs. 11% of the HDHP cohort, which Dr. Tang

characterized as a potential unintended health consequence of an employer-mandated switch to high-deductible insurance. Helping patients access advanced therapies in diabetes is an essential goal. We're hopeful that quantifying the impact of co-pays and deductibles on patient engagement builds a compelling case for better reimbursement and patient discount programs sponsored by the manufacturer, and we're glad to see Merck investing in this area of research. We've witnessed a proliferation of high deductible health plans and an increase in patient cost-sharing measures as an unfortunate unintended consequence of the ACA (and this will likely only get worse if the ACA is repealed and patients lose health coverage altogether), and we look to pharmaceutical companies and other stakeholders to work together to hopefully relieve the patient financial burden.

Table. Odds ratio for medication adherence and discontinuation by copay categories in elderly patients with type 2 diabetes

Medication adherence (Proportion of days covered ≥ 80%)			
Patients on branded medications (n =28,656)		**Patients on generic medications (n = 131,594)**	
Drug copay categories	Odds ratio (95% confidence intervals)	Drug copay categories	Odds ratio (95% confidence intervals)
(reference: $0-10)		(reference: $0)	
$10.01-$20	0.79 (0.68- 0.91)	$0.01-$2	1.30 (1.25- 1.35)
$20.01-$30	0.61 (0.53- 0.70)	$2.01-$4	1.12 (1.08- 1.16)
$30.01-$40	0.48 (0.42- 0.54)	$4.01-$6	1.37 (1.32- 1.42)
$40.01-$50	0.44 (0.39- 0.49)	$6.01-$8	1.06 (1.01- 1.11)
$50.01-$60	0.62 (0.53- 0.74)	$8.01-$10	1.31 (1.24- 1.38)
$60+	0.29 (0.26- 0.33)	$10+	1.07 (1.03- 1.12)
Medication discontinuation (treatment gap ≥ 60 days)			
Patients on branded medications (n =28,656)		**Patients on generic medications (n = 131,594)**	
(reference: $0-10)		(reference: $0)	
$10.01-$20	1.15 (0.98- 1.34)	$0.01-$2	0.65 (0.62- 0.68)
$20.01-$30	1.46 (1.26- 1.70)	$2.01-$4	0.79 (0.76- 0.82)
$30.01-$40	1.81 (1.59- 2.07)	$4.01-$6	0.57 (0.55- 0.59)
$40.01-$50	1.67 (1.46- 1.90)	$6.01-$8	0.77 (0.74- 0.81)
$50.01-$60	1.42 (1.19- 1.70)	$8.01-$10	0.55 (0.53- 0.58)
$60+	2.49 (2.17- 2.87)	$10+	0.71 (0.68- 0.75)

Notes:
Logistic regression analyses were conducted for drug adherence (proportion of days covered ≥ 80%) and drug discontinuation (treatment gap ≥ 60 days).
All logistics regressions were adjusted for baseline patient characteristics including demographics, comorbidities, prior healthcare utilization, and geographic locations.

Oral Presentations: Translating Therapeutics into the Real World

VALUE INDEX FAVORS USING GLP-1 MORE THAN DPP-4, SAVING MEDICARE $200 MILLION

Saad Sakkal, MD (Metabolic Care Center, Mason, OH)

Dr. Saad Sakkal defined the value index in diabetes as the amount of money spent to improve A1c by 1% in three months. According to Medicare pricing, the value index for DPP-4 inhibitors was calculated at $927 vs. $750 for GLP-1 agonists. If Medicare switched the 1,197,066 patients currently on a DPP-4 inhibitor onto a GLP-1 agonist, it could save up to $211,880,682 annually. For context, the annual cost of diabetes care nationally is around $340 billion, and this is expected to rise. This analysis reflects the clinical trial data showing that GLP-1 agonists are more effective than DPP-4 inhibitors, and we now have cost-savings information to support greater use and better reimbursement prospects for products in the GLP-1 class. In light of this information, we'd also love to see future studies comparing the value index between other therapy classes beyond GLP-1 agonists and DPP-4 inhibitors.

Posters

THE DISRUPTION CONTINUES: NEGATIVE IMPACT OF MEDICARE COMPETITIVE BIDDING PROGRAM (175-LB)

G Puckrein, IB Hirsch, C Parkin, L Xu, and DG Marrero

This late-breaking poster shared new data documenting continued striking disruptions of Medicare beneficiary access to prescribed SMBG supplies following CMS's expansion of its competitive bidding program (CBP) in 2013. The results follow up on the study's original results (published in Diabetes Care) that showed an increase in mortality associated with the CBP in nine test markets in 2011. Scarily, it appears that the negative impact of the program has only worsened since 2013, when - as a reminder - CMS expanded the program nationally to both mail order and retail channels with lower reimbursement. This iteration of the study investigated changes in the acquisition of SMBG supplies by beneficiaries in those nine test markets (n=43,939) and all non-test markets (n=485,688) in the six months following the national CBP rollout and identified two major trends: (i) a significant increase in the percentage of beneficiaries who migrated from full SMBG to partial/no SMBG access in both test and non-test markets; and (ii) a significant increase in the percentage of insulin-treated beneficiaries with no record for SMBG (from 54.1% in January 2013 to 62.5% by December 2013, p<0.0001). Indeed, the authors estimate that as of January 2014, 37.5% (n=90,923) of insulin-treated beneficiaries were calculating their insulin dosage with partial/no SMBG. These results differ greatly from CMS' April 2012 report on adverse outcomes associated with competitive bidding, which suggested that there was no disruption of access to supplies and no negative healthcare consequences associated with the program. However, the continued criticism and evidence to the contrary raises red flags for what is already a heavily scrutinized program. Our biggest question now that the evidence seems overwhelming … When will CMS actually listen? What will it take to reverse this policy?

THE ECONOMIC IMPACT OF ADOPTING PROFESSIONAL CONTINUOUS GLUCOSE MONITORING WITH THE FREESTYLE LIBRE PRO SYSTEM (109-LB)

S Yu

Based on interviews at eight US endocrinology offices, Abbott's Dr. Shensheng Yu estimated that the first-year equipment cost per office of existing professional CGM technologies (Medtronic iPro2; Dexcom G4), excluding the sensor, is ~$1,170, while this cost is just ~$75 with the FreeStyle Libre Pro system. The Libre Pro's inexpensive setup - $65 for the reusable reader, $10 for cable and adapter, and $60 per 14-day sensor - allows for ~18 individuals to experience professional CGM for the same cost that it takes to simply set up clinics on one of the other systems. Wow! The hands-off design of the Libre Pro system also cuts down on time, and therefore cost: Dr. Yu estimates that Libre Pro workflow (outside of analysis/interpretation) takes 10 minutes - five minutes for consultation and application, and five minutes for download. Other reusable, more hands-on systems (requiring calibration, training, disinfection, etc.) require closer to 45 minutes - 20 minutes for CGM training, 10 minutes for cleaning and disinfecting, and 15 minutes for calibration data entry. Assuming a nurse's salary of $40/hour, the workflow cost per procedure is under $7 for the Libre Pro system, but $30 for existing technology. Per procedure, Dr. Yu also calculated the clinical economic benefit of using Libre Pro: a ~0.4% reduction in A1c yields an estimated ~$100 in savings, while a 43% reduction in severe hypoglycemia event rate yields nearly $25 in savings per procedure. Taken together, and subtracting the $60 cost per procedure (assuming high volume), this comes out to ~$65 saved per patient year on Libre. The lower equipment and staff costs from Libre Pro, along with the potential clinical benefit, make it a compelling and quite scalable at a population level. Two real-world retrospective studies of FreeStyle Libre Pro use in India each demonstrated a ~0.3% reduction in A1c - hypoglycemia was not reported, but we would love to see an economic analysis from these real-world cohorts. Did Dr. Yu's projections translate into real world use?

ONE-YEAR TIME ANALYSIS IN AN ACADEMIC DIABETES CLINIC (174-LB)

P Huynh, A Toulouse, and I Hirsch

This study found that an impressive 1,461 non-billable hours were spent per year to support one physician or advanced registered nurse practitioner (ARNP) in an academic diabetes care clinic. To conduct the analysis, clinic support staff at an academic diabetes clinic that sees 3,727 patients in 10,332 visits per year and employs 36 endocrinologist or ARNP full time employees catalogued time spent on phone calls, faxes, electronic chart messaging, and email for patient care during one month. One-month values were then extrapolated to one year. 1,945 triage interactions were recorded, lasting an average of 14.7 minutes. The main categories requiring non-billable interactions were medication issues (46% of interactions), health challenges (12%), hyperglycemia/hypoglycemia triage (8%), labs (5%) and coordination of care (5%). Overall, for every 1,264 face-to-face patient hours expended by a full-time physician or registered nurse practiioner per year, 1461 non face-to-face hours are spent by support staff. The authors conclude that this balance of incurring more non-billed than billed hours for diabetes care is not sustainable in the current healthcare landscape.

IMPACT OF CENTER FOR MEDICARE SERVICES (CMS) INSULIN PUMP POLICIES ON PATIENTS WITH T1D (1036-P)

NB Argento and AL Peters

New data from a T1D Exchange myGlu.org survey (n=124) indicates that the Center for Medicare Services' (CMS) mandated quarterly visits for pump users may be quite detrimental to patient safety. In 43% of surveyed respondents, this policy led to potentially adverse pump practices: nearly one in three respondents said they have extended pump site duration past three days, 11% had to obtain emergency supplies, 7% said they had reused supplies, and 4% said they had switched to injections. The authors note that there is no supporting evidence for this quarterly visit policy. Ugh! The result, as participant comments indicate, is that once a patient goes on Medicare, pump companies (Medtronic was specifically mentioned) will no longer send supplies without prompting and instead rely on doctor visits as a marker for when to replenish materials. In the case of patients with remote access, the requirement poses a significant inconvenience, since HCP visits might require traveling hundreds of miles. Likewise, amongst those who are well-controlled, these visits may not even be medically necessary, unduly increasing cost and administrative burden on the system. Data from the T1D Exchange cohort examining mean A1c levels vs. frequency of visits in Spatients 65 and older did not even yield a significant correlation, further adding to the lack of evidence for this policy. Given these findings, it may be time for CMS to reconsider the quarterly visit policy for pump users. With the lack of government response to the crisis caused by competitive bidding - a poster presented at ADA estimates that the program has left 90,000+ insulin-dependent patients with partial or no SMBG - we don't expect a rapid response without patient uproar. We're glad to see Drs. Argento and Peters bringing yet another antiquated CMS policy to the forefront.

COST CALCULATION AND ADHERENCE TO GUIDELINES FOR A FLASH CONTINUOUS GLUCOSE MONITORING SYSTEM FOR ADULTS WITH TYPE 1 DIABETES MELLITUS USING INTENSIVE INSULIN: A UK NHS PERSPECTIVE (1325-P)

R Hellmund

Using statistics from the IMPACT study of Abbott's FreeStyle Libre in type 1 patients and real-world data presented at ATTD, Mr. Richard Hellmund made a compelling cost-effectiveness argument for the use of FreeStyle Libre over SMBG. A FreeStyle Libre sensor costs £48.29 (~$60 USD), and Mr. Hellmund's analysis assumes that patients use 26 per year (one every two weeks), equating to £1,255.54/patient-year. In the IMPACT trial, patients also performed 0.5 SMBGs per day, which Mr. Hellmund's calculated adds an additional £60.23/patient-year for supplies, resulting in a FreeStyle Libre-wearing total of £1,315/patient-year. He then compared this cost to three different SMBG scenarios: (i) 2015 UK NICE guidelines calling for 10 SMBGs per day; (ii) 5.6 SMBGs per day seen in the run-in period of the IMPACT trial; and (iii) 16 SMBGs per day - the number of times people check their blood glucose with FreeStyle Libre in the real-world. Based

on reasonable assumptions for cost per lancet (£0.04) and strip (£0.29), Mr. Hellmund estimated the following cost differentials by scenario: (i) UK NICE guidelines: FreeStyle Libre costs £111.27 more per patient-year than SMBG; (ii) RCT testing frequency: FreeStyle Libre costs £641.25 more per patient-year than SMBG; and (iii) Real-world testing frequency: FreeStyle Libre costs £611.43 less than SMBG per patient-year (see table below). The first two scenarios are certainly more realistic than the third, and SMBG will likely be cheaper than flash glucose monitoring for the foreseeable future, but Mr. Hellmund pointed out that flash monitoring has the potential to reduce costly complications. For example, in IMPACT, Libre was associated with a 48.5% reduction in low glucose events (<45 mg/dl) - one prevented episode of severe hypoglycemia, with a single hospital admission estimated to cost approximately £1134 ($1433) at 2016 prices, would completely flip the script and rationalize the value of Libre. Additionally, implementation of flash monitoring systems may decrease occurrence of cardiovascular complications through decreased hypoglycemia and hyperglycemia, while also decreasing overall utilization of healthcare resources (as demonstrated in IMPACT). Patients test nearly three times as much with Libre vs. SMBG, potentially aiding in reduced complications long term, which are a much bigger economic drain on the system than the sensor itself. At least 13 countries, including France, Belgium, and Germany, have come to this realization and offer full or partial reimbursement for the device.

	Assumed: # of fingersticks per day	**Annual Cost of SMBG per patient (£)**	**Annual Cost of FreeStyle Libre + 0.5 SMBGs/day per patient (£)**	**Annual cost of FreeStyle Libre relative to SMBG per patient (£)**
NICE Guideline Testing Frequency	10	1204.50	1315.77	+111.27
RCT Testing Frequency (based on IMPACT trial)	5.6	674.52	1315.77	+641.25
Real-world testing frequency (based on real-world data from 55,000+ patients using Libre)	16	1927.20	1315.77	-611.43

Symposium: Dealing with the Rising Costs of Insulin - An Active Dialogue

THE RISING COSTS OF INSULIN - INTRODUCTION AND HISTORICAL PERSPECTIVE

Kasia Lipska, MD (Yale School of Medicine, New Haven, CT)

Dr. Kasia Lipska opened this highly-anticipated symposium on insulin costs with a look at the history of insulin development and pricing. Unsurprisingly, given her somewhat controversial previous commentary

on insulin pricing, Dr. Lipska took a relatively critical stance on the value of modern insulin analogs, describing what she termed "the paradox of incremental innovation." She acknowledged that substantial and important advances have been made in insulin therapy - making insulin much safer and more convenient - since its discovery in 1922, but pointed out that these improvements have occurred in a stepwise manner, with new patents accompanying each advance. Further, she noted that, with the arrival of newer insulin, older insulins often largely became obsolete and disappeared from the market in high-income countries like US in particular. She highlighted this as the "paradox," as generally older products create a market for generics, which largely has not happened in the insulin field - though this may be changing with the arrival of Lilly/BI's biosimilar insulin glargine Basaglar (and upcoming biosimilars from Merck and Mylan/Biocon). All in all, she posed the question, "Was each incremental innovation worth the price that we pay today?" While we certainly sympathize with the point that insulin pricing has gotten out of hand, it is not our sense that innovation in insulin is the main driver of increasing costs (compared to the complex PBM/rebate negotiation system, etc.) and we certainly would not term substantial benefits in hypoglycemia and ease-of-dosing an "incremental" improvement in quality of life for patients. That said, we recognize that insulin analogs may unfortunately be out of reach for some patients in the current healthcare system and, to that end, we appreciated Dr. Lipska highlighting her recent JAMA viewpoint (co-authored with Drs. Irl Hirsch and Matthew Riddle) on practical tips for physicians on human insulin therapy in patients with type 2 diabetes. We also appreciated Dr. Lipska's acknowledgement that human insulin certainly is not a solution for everyone and that modern insulins are "definitely better" than older versions from a pure clinical standpoint. Finally, Dr. Lipska concluded her presentation by acknowledging the complexity of contributors to insulin pricing and highlighted several remaining questions: (i) Who are the other players contributing to rising insulin prices?; (ii) What else can clinicians do to keep costs down?; and (iii) What are the potential policy solutions?

Questions and Answers

Q: The average wholesale price (AWP) shown in that diagram - why is there so little transparency in that?

A: Some say "AWP" also stands for "Ain't What's Paid." It's not the real price of the insulin. Pharma companies tell us that the actual net price of insulin has either stayed the same or hasn't increased as well. The gap between the two has risen, and part of that is because of rebating and discounts for insurers and PBMs in this process. You're right, we need more transparency to see if we can judge it as far as it's not clear where money changes hands in this system.

UNDERSTANDING THE PLAYERS IN THE RISING COSTS OF INSULIN

Alan Carter, PharmD (MRIGlobal, Kansas City, MO)

Pharmacist Dr. Alan Carter emphasized the complex "cast" of players in the issue of insulin pricing, including suppliers of raw materials, manufacturers pharmaceutical wholesalers, pharmacies, prescribers, and people with diabetes. Overall, however, he underscored in great detail that insulin is an extremely complex process, with safety and quality assurance standards largely in the court of individual manufacturers. As a result, trust in insulin manufacturers is paramount and quality assurance trumps price. He suggested that new policies like Medicare Part D and the ACA had the unintended consequences of increasing PBM leverage, which is one of the main drivers of increasing costs. At the same time, Dr. Carter argued that it will take all stakeholders - "a village" - to safety and effectively lower insulin costs without sacrificing safety and quality.

CLINICAL DECISION-MAKING IN A COST-CONSCIOUS ERA

David Robbins, MD (University of Kansas, Kansas City, KS)

Dr. David Robbins outlined several opportunities for healthcare providers, patients, the ADA, the government, pharmaceutical companies, and all of us to impact insulin, drug, and healthcare pricing. For the field as a whole, Dr. Robbins asked all the various stakeholders to stop oversimplifying the issue of drug pricing and to share the blame, rather than point fingers. Further, the formation of partnerships to tackle

this problem are crucial. He also emphasized the need to healthy, educated, and fair critics, while recognizing that we are all subject to bias. To that end, he emphasized that "new" is not always better. And finally, he called upon attendees to always advocate for their patients - hear hear!

- **For healthcare providers, Dr. Robbins emphasized the need to be a "tough, but fair, critic."** He suggested that conflicts of interest and bias is rampant in among prescribers. Underscoring his point, he cited a study that found every additional $13 payment or gift from a pharmaceutical company to a prescriber was associated keeping a patient on a particular drug for an additional 107 days ($p<0.001$). He emphasized that the healthcare field has a whole has to take a hard look at conflicts of interest and be honest with themselves about how this may bias clinical care. To help make better decisions on which diabetes drugs to actually prescribe, Dr. Robbins highlighted the importance of healthcare providers asking patients about their individual resources. Dr. Robbins also called upon healthcare providers to demand better guidelines and rigorous comparisons of new vs. old medications and tools. Additionally, more emphasis on the prevention and early reversal of type 2 diabetes is needed. Finally, Dr. Robbins suggested that healthcare providers have an obligation to spend time volunteering care in free clinics.
- **For patients, Dr. Robbins highlighted the benefits of being an informed consumer.** Dr. Robbins asked patients to understand the benefits of drugs and ask their providers if the branded medications are really better than lower-cost generics. Further, in cases where insurance coverage may be denied, Dr. Robbins called on patients to doggedly ask the insurance companies for the reason behind the denial, rather than just accepting it.
- **For the ADA, Dr. Robbins wished for greater transparency on the organization's funding sources and the inclusion of such disclosures on the widely-used ADA diabetes guidelines.** Dr. Robbins acknowledged that pharmaceutical funding is critical to support the wide breadth of programs that the ADA is engaged in, but he suggested that separating ADA guideline and opinion statements from such funding. He also asked the ADA to support comparative effectiveness studies of different medications - including both branded and generic options - to help providers with difficult clinical decision-making. Finally, Dr. Robbins argued that the ADA should not taking advertising from pharmaceutical companies on its website or other materials.
- **From a regulatory standpoint, Dr. Robbins argued that the FDA and other government agencies should set a higher bar for new diabetes drugs,** demonstrating improvements over standard of care rather than just demonstrating efficacy compared to placebo. As he put it, the government has dual obligations of protecting and also guiding the consumer.
- **Dr. Robbins also highlighted several opportunities for pharmaceutical companies.** In particular, he asked manufacturers to demonstrate that new drugs are cost-effective and to expand and simply safety net programs for expensive and critical drugs. He also suggested that companies stop fighting Medicare's efforts to employ competitive bidding (though, in our view, competitive bidding processes must also be accompanied by rigorous quality assurance standards). Finally, Dr. Robbins emphasized that pharmaceutical companies need to do a better job of communicating their narrative and "what they do right." For instance, he emphasized that these companies employ truly dedicated people, the USA leads the world in discovery and innovation, and these companies often return reasonable profit margins (which the exception of predatory companies like Turing and Valeant). All in all, Dr. Robbins suggested that manufacturers need to do a better job of communicating the high cost of drug R&D.

PAVING THE WAY FORWARD

Robert Ratner, MD (Georgetown University School of Medicine, Washington, DC)

Answering the question "What's the solution to high insulin prices?," former ADA Chief Scientific and Medical Officer Dr. Robert Ratner stated that there is only one real solution: "Someone has to make less money." He emphasized that the system of insulin pricing/coverage/rebating is extremely complicated and that a lack of transparency makes it difficult to understand where the bulk of the money is going. That said,

Dr. Ratner noted that rebates to pharmacy benefits managers (PBMs) rose substantially from $67 billion in 2013 to a whopping $106 billion in 2015. While acknowledging that an appropriate level of profit from insulin supports R&D and prices in the US subsidize insulin in low- and middle-income countries, Dr. Ratner stated to great applause, "The issue of middlemen with no added value increasing expenditures is something we can get rid of without having any downward pressure on insulin pricing elsewhere" - hear hear! Dr. Ratner views free market competition mechanisms as the most likely to be successful in driving insulin pricing reform. He acknowledged that the very first biosimilar insulin glargine - Lilly/BI's Basaglar - has not been discounted quite as much as some had hoped (in the US, the follow-on biologic is discounted about 15% relative to originator Lantus). On the other hand, he underscored that we typically must wait for two or more generics to see price driven down, and Dr. Ratner was fairly optimistic on the future launch of additional biosimilars given that new FDA commissioner Dr. Scott Gottlieb has publicly highlighted simplification of the biosimilar regulatory process as one of his goals. Even with the current, rather complicated process, Merck has already submitted a biosimilar insulin glargine formulation and Mylan/ Biocon are planning to submit their own formulation shortly. Dr. Ratner also sees greater proliferation of direct-to-consumer programs as promising - he highlighted Walmart's $26/vial human insulin as an excellent example of how the complex insurance/PBM/rebate system can be bypassed entirely to bring insulin directly to patients at a lower cost. We think that the Blink Health and InsideRx direct discount programs are a good example of this principle as well, though the prices for medications through these programs are admittedly still much higher than that of Walmart insulin. Most promising in Dr. Ratner's view, however, are the recent proliferation of lawsuits accusing insulin manufacturers, payers, and PBMs of price-fixing in insulin. While he reserved judgement on whether any of these lawsuits had merit, he pointed out that they will force transparency in this opaque field by forcing various stakeholders to disclose their contractual agreements as part of discovery. We think it's highly unlikely that any actual price-fixing is occurring and, while we wholeheartedly agree with the need for transparency, we wish it wouldn't take several high-profile lawsuits to encourage companies to disclose their financial agreements. We certainly believe voluntary disclosures would generate more goodwill, while these lawsuits that only further exacerbating the public furor over drug pricing. The "story" has spun out of control in many ways and we continue to hope that manufacturers and other stakeholders will take the initiative to address these concerns head-on - without being pushed by external forces. Some progress has been made in recent months, but there is still much more room to help relieve the financial burden of diabetes care for patients.

- **On the other hand, Dr. Ratner was less optimistic about the potential for legislative or regulatory controls to offer near-term relief on insulin pricing.** He noted that there has been significant discussion among politicians and in legislature (both at the state and the national level) on potential policy solutions to the issue of high drug costs. He highlighted proposals to allow Medicare Part D to negotiate with manufacturers, government-imposed price controls, and challenges to "pay for delay" tactics, but ultimately emphasized that the legislative process can be incredibly slow. On the regulatory front, he suggested that some of the proposals floating around could have unintended, negative consequences from a global perspective. For instance, he noted that calls to allow the importation of drugs from other counties have become popular in some circles and that this would actually be possible within the current purview of the FDA, without need for legislative change. That said, Dr. Ratner pointed out that the last four FDA commissioners (including Dr. Gottlieb) has come out "categorically against" this idea. Further, Dr. Ratner suggested that cross-border importation of insulin would actually incentivize companies to only sell insulin in companies that can command a higher price, like the US, and potentially create insulin shortages in other countries.

Symposium: Population Health, Affordable Care Act (ACA), and New Approaches for Dissemination/Implementation of the Diabetes Prevention Program (DPP)

POLICY UPDATE - IMPACT OF ACA AND MEDICARE ON DISSEMINATION AND IMPLEMENTATION OF THE DPP

Nina Brown-Ashford, MPH (CMS, Baltimore, MD)

In an engaging presentation, Ms. Brown-Ashford of CMS shared an inside perspective on the Medicare DPP program expansion. She first addressed how social determinants of health have a huge impact on diabetes outcomes, especially type 2 diabetes, and emphasized the importance of approaching diabetes at the level of population health. In the context of Medicare, 25% of Americans age 65 or older have type 2 diabetes, and diabetes care for this older population costs $104 billion annually and keeps growing. To address this problem, the CDC National Diabetes Prevention Program and Y-USA implemented a DPP model test with 7,800 beneficiaries from February 2013-January 2015, and found that 83% of participants who attended four or more sessions experienced an average weight loss of nine lbs. Each of these participants saved Medicare >$2,000, on average. In 2016, the Medicare Diabetes Prevention Program (MDPP) expansion was announced and it will go live in 2018. Ms. Brown-Ashford described the many logistical and bureaucratic issues that needed to be addressed for the MDPP model expansion to succeed, such as working to implement a quality-based model in a fee-based system. The MDPP benefit will include the CDC-approved DPP curriculum, a 12-month core benefit that includes 16 core sessions over the first six months, monthly sessions for the next six months, and maintenance sessions if the participant achieves and maintains a minimum weight loss of 5%. Any Medicare Part B beneficiary with a BMI >25 kg/m² (>23 kg/m² for Asians), lab tests that demonstrate high blood glucose levels, and no history of type 1 or type 2 diabetes will be eligible, and coverage will be once per lifetime per beneficiary with no referral required. Organizations must obtain CDC recognition and enroll in Medicare as MDPP suppliers. Ms. Brown-Ashford suggested that organizations interested in participating should work toward becoming CDC-recognized and should gain more familiarity with all requirements. Policies still need to address how payment will be structured, how to ensure quality, and how to accommodate virtual DPP suppliers. We were impressed with Ms. Brown-Ashford's dedication to the MDPP benefit, and we look forward to having diabetes prevention programs become more widely-accessible.

Questions and Answers

Q: Is the funding for the MDPP tied to the ACA, and will it survive?

A: Reimbursement for these services come from the Medicare Part B trust fund and not from 3021 funds from the Affordable Care Act statute. Right now, the ACA is the law of the land and I can't speak too much on the current state of affairs.

Q: Will Medicaid support a version of the DPP?

A: We modeled these outcomes on the original pilot, and are limited because of that. There are a number of DPP demonstrations happening in Medicaid, and whatever Medicaid puts forward is what others tend to follow. They are waiting for what happens with Medicare, but I agree with your comment 100% in terms of the need for Medicaid to start working on this.

Symposium: The Fate of the Affordable Care Act

PAST, PRESENT, FUTURE - THE AFFORDABLE CARE ACT AND DIABETES

Alvin Powers, MD (Vanderbilt University, Nashville, TN)

Dr. Alvin Powers opened the symposium with an overview of how the Affordable Care Act (ACA) has impacted people with diabetes, walking attendees through the policy's history. He shared how before the policy was implemented, people with diabetes were denied coverage or charged with very high premiums and necessary diabetes treatments were often not covered. Praising the ACA, Dr. Powers discussed the positive impacts of Medicaid expansion and the financial help for low/moderate income populations, presenting data on the progress made in low-income populations and the prevalence of uninsured

individuals. Specifically for diabetes, he noted that the ACA was monumental in bringing about access to essential health benefits, developing consumer protections (guaranteed issue/renewability, protection against higher premiums due to diabetes, and protection against coverage exclusion for pre-existing conditions), and bringing a greater focus on preventative services such as diabetes screening. Turning to the current landscape, Dr. Powers expressed disappointment of ongoing legislative threats to the ACA, as he emphasized that such policies threaten the gains in access, affordability, and adequacy of healthcare coverage. As the ADA's President of Medicine and Science, Dr. Powers closed by emphasizing the ADA's principles on the current political environment: the ADA is not for or against any specific bill but believes that any attempts to modify or replace the ACA must provide coverage for at least the same number of people under the ACA, ensure continuous availability of health insurance coverage regardless of the person's circumstances, and ensure access to adequate and affordable health insurance. With these principles, Dr. Powers initiated a passionate call to advocacy, inviting attendees to join the ADA in its efforts - a sentiment that was echoed and strengthened throughout the rest of the symposium.

IMPLICATIONS FOR PEOPLE WITH DIABETES AND OTHER CHRONIC CONDITIONS

Marc Boutin, JD (National Health Council, Washington, DC)

National Health Council CEO Mr. Marc Boutin led an energized call to advocacy, as he shared insights on the most recent happenings and impending future of the Affordable Care Act (ACA). Mr. Boutin first described the new balance of power at the level of the federal government, where the focus has centered on capping federal healthcare spending and cost growth and offering greater flexibility to the private sector and states. Discussing how to address these issues, he outlined the "three-pronged approach" of executive and regulatory action, reconciliation, and piecemeal legislation. As he reviewed the recent events surrounding the repeal of the ACA, Mr. Boutin stressed that the National Health Council remains "very concerned" with the federal government's focus to "repeal and replace," as he sees the new American Health Care Act as dangerous to many of the key principles held in the patient advocacy community. Specifically, he expressed significant concern over the bill's proposed reductions in Medicaid coverage, elimination of subsidies, implementation of premium rating for age and health status, and states' ability to opt out of essential health benefits. Mr. Boutin stressed the need to build greater momentum in patient advocacy (which was further emphasized during the Q&A), as he noted that he believes Congress is moving quickly and may make significant progress by July 4, 2017. Explaining the National Health Council's role in this work, he shared that the Council is working hard to: (i) identify the universe of policy proposals; (ii) create a patient-centered framework;(iii) prioritize proposals; and (iv) assess policy proposals. With these in mind, Mr. Boutin expressed that their final policy recommendations include: expediting generic and biosimilar approvals, promoting transparency, encouraging outcomes-based contracting, and facilitating value-based insurance design. In conclusion, Mr. Boutin heavily emphasized that "the voice of the patient must be carried forward," stressing that the field must genuinely embrace the patient-centered model in order to make the desired progress.

Questions and Answers

Comment: Thank you for your presentations, but we need even more passion, like we saw in Des Schatz's talk last year. We need to get energized and get strong advocates. We really need to get fired up. We can have a very, very strong voice if we get everyone together here.

Q: I'd like you to comment on the very skewed media that portrays Obamacare as a miracle and as Trumpcare as horrible. How can we get more balanced information out there on mainstream media?

Dr. Powers: On behalf of the ADA, I think we're not in favor of law x, y, z. We have core principles that are targeted for people with diabetes.

Mr. Boutin: The media portrayal has been oversimplified and has bought into partisanship. The irony of the ACA is that much of the framework was bought from several Republican proposals from the past. It has now become very partisan. We've had difficulty with focusing in on what's best for people. We had trouble with that for the ACA and we have trouble with that now. We have not done a good job of explaining this to people.

A lot of people still don't understand that if we take this away, a lot of people will get hurt. We're putting out a video on this in lay terms next week. This has been complicated, as our own President has said. But it's been grossly partisan. We have to figure out how to do a better job of providing high-quality, low-cost care. And as a country, we're not doing a good job.

Dr. Elbert Huang (University of Chicago, IL): I worked on the implementation of the ACA. If you're a scientist or clinician, we adhere to evidence-based medicine. And well, policymaking is crazy - there's essentially very little evidence-based policymaking. A lot of ideas in the law aren't proven. I know that a lot of us are not natural advocates. Expansion of healthcare coverage was not palpable to people and it's questionable if the people who would be most impacted voted. We need to look at the behavioral side of this, as well. With repeal of the ACA and with loss of coverage, losses loom larger than gains. I'm a big advocate of evidence-based policymaking and we need to evaluate this of the ACA. Also, I'd like to note that there is no intersection of the HCA and ADA principles. The press is definitely marginalized and we have problems with segregated populations. The ADA and patient communities need to speak louder.

Q: I have lots of colleagues who are not interested in advocacy. They think it's political or just hurts feelings. What can we do to make things issue-based rather than based on politics or personalities?

Mr. Boutin: Being issue-based is tough with complex social issues like these. It's a bit easier with something tangible like diabetes and cancer. But when elevated to the system level, it's hard to create that same emotion. Partisanship has been very cyclical - we have at least four more years until we have a chance to change that.

Dr. Powers: We have to get outside of our comfort zone. We can't just be an educator, clinician, or scientist. With the technology we have now, you can engage with and alert your congress members. We need to inspire our colleagues. If you care about people with diabetes, you will do this. [Applause]

Comment: I just want to share that I am completely utterly perplexed as to why there is so much opposition for preventative care by the Republicans when their focus is on fiscal responsibility. [Applause]

-- by Melissa An, Adam Brown, Abigail Dove, Helen Gao, Brian Levine, Nancy Liu, Payal Marathe, Maeve Serino, Pearl Subramanian, Lisa Vance, and Kelly Close