MEMORANDUM

Abbott 4Q14 - Global, US Diabetes Care see double-digit declines; early sales of FreeStyle Libre "exceed expectations" - January 29, 2015

Executive Highlights

- Global Diabetes Care sales totaled $313 million in 4Q14, down 10% as reported and 6% operationally year-over-year (YOY). Full year global sales of $1.2 billion were down 8% operationally and marked the lowest fiscal-year revenue total since 2006.
- The launch of the FreeStyle Libre ("a great innovation, a great product") is generating big-time, enthusiasm at Abbott and in the patient community. Management has seen a "really good customer response" even without reimbursement at this stage.
- Commentary during Q&A hinted at ongoing struggles with US regulatory path for Libre - "I'm frustrated with the pace of regulatory approval in the US." Abbott has begun its pivotal trial of the FreeStyle Libre at six sites in the US.

Early this morning, Abbott CEO Mr. Miles White led the company's 4Q14 and full year 2014 financial update. The clear highlight of the call was again CEO Mr. Miles White's commentary on FreeStyle Libre. We heard clear enthusiasm over the launch of "a great innovation, a great product" and strong confidence in the investment. Notably, demand has exceeded Abbott's manufacturing capabilities. Below, we bring you the top financial and pipeline highlights from the call, followed by Q&A.

Financial Highlights

1. Global Diabetes Care sales totaled $313 million in 4Q14, down 10% as reported and 6% operationally year-over-year (YOY); full year sales reached only $1.2 billion, declining 9% as reported and 8% operationally YOY and marking the lowest fiscal-year revenue total since 2006. Management shared positive guidance for both 1Q15 and FY2015 - low-single-digit operational growth driven by sales of FreeStyle Libre in the EU.

2. US Diabetes Care sales of $108 million in 4Q14 declined 16% YOY on an especially easy comparison (down 14% in 4Q13). The company has not seen positive YOY growth in the US business in the past eight quarters (since 4Q12), though management remained optimistic, commenting on the more "moderate" drop vs. the 27% declines in the first two quarters of 2014.

3. Internationally, Diabetes Care revenue totaled $205 million, falling 5% as reported but growing 1% operationally YOY. The comparison was moderately challenging to sales of 2% in 4Q13.

4. Combined global revenue for J&J, Roche, and Abbott fell 8% relative to pooled revenue in 4Q13 (pooled revenue declined 7%). Abbott had the weakest 4Q14 performance (down 10% YOY) compared to J&J (down 9%) and Roche (down 1%). J&J's US business has been the hardest hit in the past few years, while Roche and Abbott have seen more moderate declines.

Pipeline Highlights

5. The launch of FreeStyle Libre is generating big-time, internal enthusiasm at Abbott. The device was characterized as an example of a "really good [product that] really will make a difference and really will drive share gain and growth."

6. Management is seeing a "really good customer response" despite no reimbursement at this time. The company has two six-month outcomes studies ongoing that will support EU reimbursement.

7. On the US timeline, commentary during Q&A hinted at ongoing struggles with regulatory path for Libre - "I'm frustrated with the pace of regulatory approval in the US." However, Abbott has begun its pivotal trial of the FreeStyle Libre at six sites in the US; this is expected to wrap up in March

8. On the pipeline front, there were no additional updates on the FreeStyle Precision/Optium Neo BGM, FreeStyle InsuLinx, or FreeStyle Precision Pro.

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Financial Highlights

1. Global Diabetes Care totaled $313 million in 4Q14, down 10% as reported and 6% operationally year-over-year (YOY). Performance was in-line with management guidance from 3Q14, which anticipated mid-single-digit operational decline. However, it is still disappointing considering the easy comparison to 4Q13, when sales fell 4% as reported and operationally. This also marks 4Q14 as the fifth consecutive quarter of global decline and a third quarter of double-digit decline in 2014 alone (3Q14 was the exception when sales fell 6%); this business has experienced significant challenge in the recent past with only two quarters of Diabetes Care growth in the past 13 quarters (since 1Q12). Still, a third consecutive quarter of sequential growth (4% vs. sales in 3Q14) suggests that at a high level the business may be trending in a positive direction - indeed, this is a pattern we have not seen since 2009 (2Q - 4Q). The business has historically tended to tick up in 4Q (positive sequential growth vs. 3Q in five of the past six years), so we'll have to wait until 1Q15 to see if the business is recovering YOY.

- **For the full year, global Diabetes Care sales were $1.2 billion, declining 9% as reported and 8% operationally YOY**; this marks the lowest fiscal-year revenue total since 2006 (when sales totaled $1.1 billion). The performance came against an easy comparison as sales declined 2% as reported for the full year 2013. For perspective, the business peaked in 2011 when sales reached $1.4 billion on the strength of international sales.
- **Despite recent financial challenges, management shared positive guidance for both 1Q15 and FY2015 - low-single-digit operational growth driven by sales of FreeStyle Libre in the EU.** It is great to see this optimism, and it speaks to great internal confidence in the new product.

Figure 1: Abbott Full Year Worldwide, US, OUS Sales (2003-2014)

- **The US business has driven global sales declines over the past three years.** OUS sales have remained relatively steady since 2008. We'd note that two-thirds of Abbott's business comes from outside the US, which has helped buoy the pooled global number.

2. US Diabetes Care sales declined 16% YOY, totaling just $108 million in 4Q14. This came on an especially easy comparison to a sales decline of 14% in 4Q13. The US continues to be a challenging region for Abbott as the company has not seen positive growth in the business in the past eight quarters (since 4Q12), including double-digit declines every quarter since 4Q13. It was good, at least, to see sales remain above $100 million, and we suspect that milestone was a real goal ($100 million or higher) after sales fell below that mark for the first time ever in over a decade in 1Q14. Management referred to the quarter's performance as a more "moderate" rate of decline - this is not readily apparent, though it is a significant improvement from the 27% YOY declines the company saw in the US in the first two quarters of 2014. Sequentially, US sales grew 6% - again, it's tough to read too far into the growth considering the very low base in 3Q14 ($102 million).

- **For the full year, US Diabetes Care sales reached just $405 million, falling a staggering 22% YOY against a sales decline of 9% in 2013.** This marks, by far, the lowest full year total in the past decade, as sales have not dipped below $500 million since 2009 ($497 million) [and way back to 2004 ($378 million) before that]. Additionally, the four quarters of revenue this year represent the four lowest totals ever recorded for Abbott's US business in our financial modal (which stretches back over a decade). Management did not attempt to forecast the US business in its prepared remarks or Q&A, and we can understand the desire to keep a conservative and cautious outlook.
- **As in 3Q14, management preached patience regarding the performance of the US business - "I look at the markets long term, and I think the US is a healthy market."** Management was speaking broadly to the overall business (Nutrition + Established Pharmaceuticals

+ Diagnostics + Medical Devices), so its hard to know if the positive outlook applies to Diabetes Care as well. As a reminder, management pointed out in 2Q14 that the US business still had a healthy gross margin, remained profitable, and was cash generating. Management did not speak to the transition of the US business in this quarter's call, though we assume the move to run the business for cash continues.

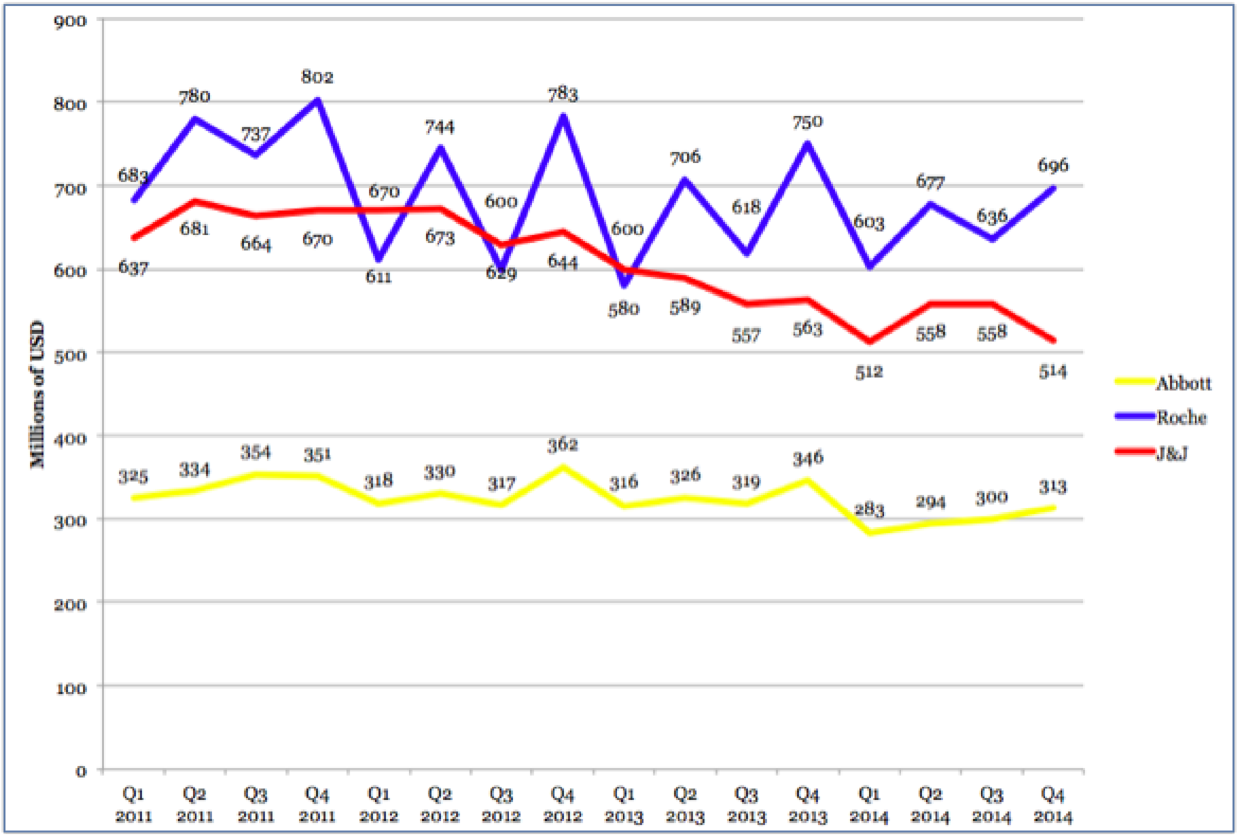
3. Internationally, Diabetes Care revenue totaled $205 million, falling 5% as reported but growing 1% operationally YOY; the comparison was moderately challenging (especially in this BGM environment) with revenue in 4Q13 growing 2% as reported and 4% operationally. This marks 4Q14 as the first quarter of reported YOY decline since 4Q12, though it seems fairly clear that the financials reflect the significant strengthening of the US dollar (negative 6% currency impact) as opposed to underlying weakness in the business' fundamentals. Indeed, management anticipates strong growth moving forward, driven by sales of the FreeStyle Libre. After all, if Abbott is to meet its low-single-digit Worldwide growth guidance for 1Q15, we would forecast at least mid-single-digit growth internationally to offset likely US weakness.

- **For the full year, international Diabetes Care revenues totaled $785 million, remaining flat as reported and growing 2% operationally YOY**; this came against another challenging comparison as sales grew 4% as reported and 5% operationally for the full year 2013. With the launch of Libre, we would say that the company is trending in a positive direction especially considering that the yearly revenue represents the fourth-highest total ever recorded.

4. Combined global revenue for J&J, Roche, and Abbott totaled ~$1.5 billion, falling 8% relative to pooled revenue in 4Q13 (~$1.7 billion). This comes against an easy comparison as combined revenue declined 7% a year ago. Abbott had the weakest growth (down 10% YOY) for the third consecutive quarter vs. J&J (down 9%) and Roche (down 1%). As a note, it is difficult to make direct comparisons between J&J, Abbott, and Roche, given that each company's Diabetes Care business includes a fraction of non-BGM revenue (J&J and Roche have global insulin delivery and Abbott has CGM outside of the US). We look forward to adding the last of the Big Four - Bayer - to this comparison when the company reports on February 26.

- **Unsurprisingly, pooled declines were driven largely by US weakness where combined sales of ~$440 million fell 11% YOY - and this is after a staggering 23% pooled decline in 4Q13.** Clearly, the US continues to be a challenging region for growth despite the fact that we are well past the annualization of competitive bidding -depressed revenues seem to be the new normal, and the big question is when the market will bottom out (or if it already has).
- **Roche's global revenues accounted for the majority (46%) of the three companies' pooled revenues**; this held steady relative to Roche's share in 4Q13 (45%). Abbott and J&J revenues also held constant at 21% and 34%, respectively. (We note that the numbers do not add to 100% due to rounding.) Regionally, J&J holds the greatest percentage of revenue in the US at 47% (vs. 44% in 4Q13), while Roche holds the greatest share of international revenue at 53% (vs. 52% in 4Q13). Overall, we are impressed with how steady market share has been.

Figure 2: Abbott/J&J/Roche Quarterly Global Revenue Comparison (1Q11 - 4Q14)



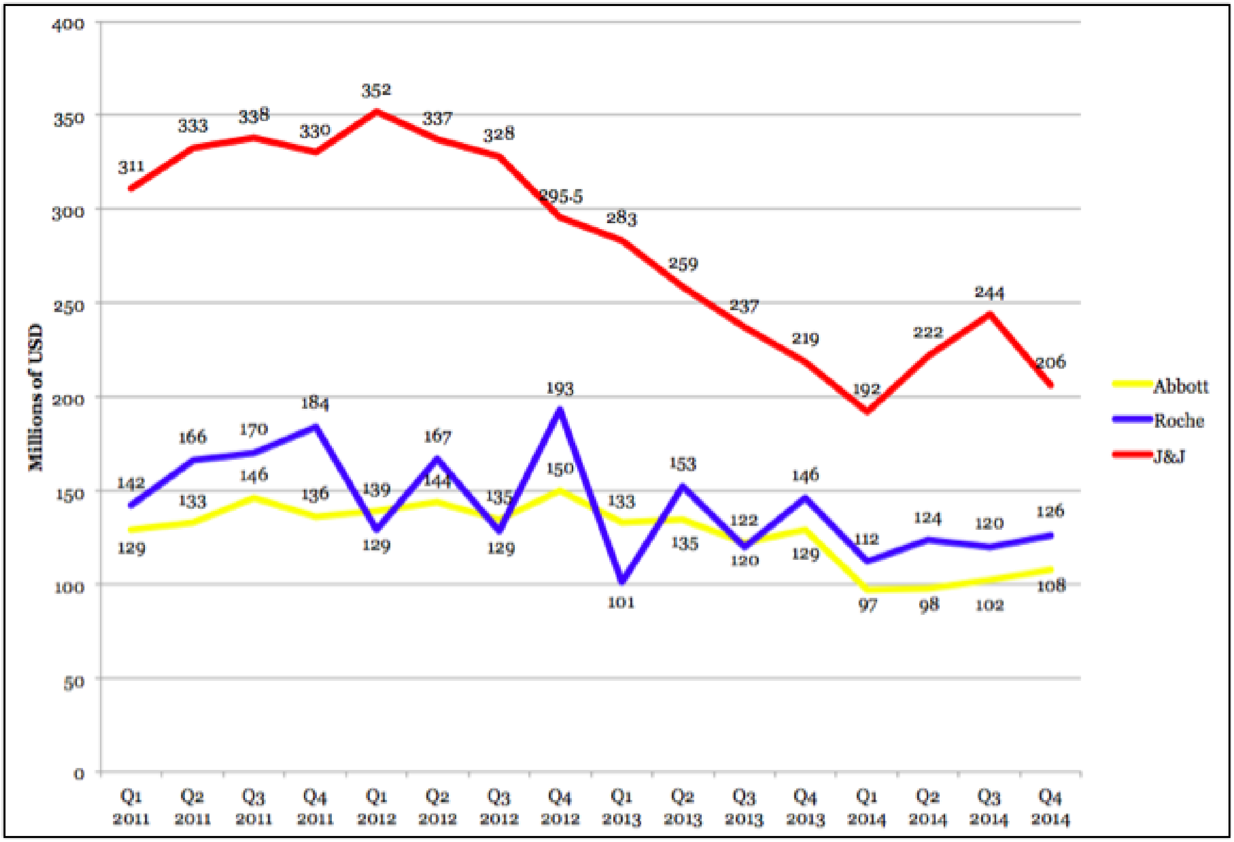
- **A comparison of Abbott/J&J/Roche quarterly global sales illustrates unique revenue trends for each company.** Roche is the most cyclical of the three with sales that vary distinctly with quarters (high in 2Q and 4Q; low in 1Q and 3Q). J&J revenue has declined substantial since 2011 (more of its business is from the US, and its stateside business has been harder hit), while Abbott sales have been surprisingly steady (two-thirds of its sales are OUS).

Table 1: J&J, Roche, and Abbott Worldwide Quarterly Performance (YOY)

	1Q13	2Q13	3Q13	4Q13	1Q14	2Q14	3Q14	4Q14
J&J	-10%	-13%	-11%	-13%	-15%	-5%	0%	-9%
Roche	-4%	-4%	0%	-7%	0%	-7%	1%	-1%
Abbott	-1%	-1%	1%	4%	-10%	-10%	-6%	-10%

- **We would note that Abbott outperformed J&J and Roche in each quarter of *2013*, but has experienced much weaker growth in 2014.**

Figure 3: Abbott/J&J/Roche Quarterly US Revenue Comparison (1Q11 - 4Q14)



- **A comparison of Abbott/J&J/Roche quarterly US sales illustrates how significantly J&J's US business has suffered in the past four years**; we would note that declines began even before the implementation of competitive bidding. Abbott and Roche have suffered more modest declines.

Pipeline Highlights

5. The clear highlight of the call was CEO Mr. Miles White's commentary on FreeStyle Libre. We heard clear enthusiasm over the launch of "a great innovation, a great product" and strong confidence in the investment. We did not get specifics on revenue/trajectory, but early sales have come "quicker, faster, and sooner than expected." This was outstanding to hear. Apparently, the company's current challenge is actually meeting this demand, and Abbott has "the blowtorch going" to facilitate capacity expansion.

- **Libre was also characterized as an example of a "really good [product that] really will make a difference and really will drive share gain and growth."** The commentary was even more notable in that it came during a question related to the overall US business, not even Medical Devices specifically. The product is clearly on management's radar in a big way, and we hope to hear more specifics on the uptake at 1Q15.
- **Click here to read the diaTribe test drive of FreeStyle Libre.**

6. Abbott continues to work to secure broader reimbursement for Libre. As a reminder, the product has still not received EU reimbursement (no specific update on this front), so it is impressive to see such fast uptake given the cash pay status. Indeed, management noted that they have seen a "really good customer response," and our scouring of social media sites has confirmed this sentiment. As we noted at 3Q14, patients have been overwhelmingly wowed by the simplicity and form factor of the device, the discretion, the ease of a ~1 second reading (without really having to stop what they are doing), and the convenience of unlimited readings. The design has led these individuals to test far more often than they would have on BGM alone. Ultimately, increased adherence and enhanced self-management (via access to overnight trends, etc.) could be the greatest testament to this novel category of monitoring.

- **Abbott is still in the process of conducting two six-month outcomes studies to support reimbursement** - REPLACE (n=210 type 2s on MDI, A1c>7.5%) and IMPACT (n=225 type 1s on MDI or pumps, A1c <7.5%). The goal of the type 2 study (ClinicalTrials.gov Identifier: NCT02082184) is to show a change in A1c at six months, while the type 1 study (ClinicalTrials.gov Identifier: NCT02232698) seeks to improve time spent in hypoglycemia at six months. Both trials will compare FreeStyle Libre to standard SMBG and both have an estimated completion date of June 2015. IMPACT is actively recruiting participants, while REPLACE ongoing but not currently recruiting participants. As a note, the A1c inclusion criterion is very smart in our view, and it's good to see that both studies are quite large, especially for a CGM trial.
- **Abbott came out with an impressive, consumer-focused approach to marketing at launch -** online ordering without a prescription, accessible pricing relative to CGM at 59.90 euros for the reader and 59.90 euros for each 14-day sensor - but we imagine that reimbursement (should it come through) will be a huge step forward in terms of accessibility. Patients have evidently come to terms with the value proposition, but ~120 euros/month out-of-pocket - while still cheaper than CGM - is still more than BGM, particularly when many European patients are not used to paying out-of-pocket for devices.

7. On the US timeline, commentary during Q&A hinted at ongoing struggles with the FDA regulatory path - "I'm frustrated with the pace of regulatory approval in the US." It is unclear whether Abbott's internal timeline (management has not publically discussed a formal timeline) has been delayed. We imagine the biggest gating factor to approval is obtaining a replacement claim to dose insulin; Dexcom also continues to work on this front.

- **Abbott has begun its pivotal trial (ClinicalTrials.gov Identifier: NCT02283411) of the FreeStyle Libre at six sites in the US.** The purpose of the study (n= 164) is to evaluate the point and rate accuracy of the system against YSI and to characterize the safety through Adverse Device Effects and Serious Adverse Device Effects experience by participants. The trial is currently recruiting (notably, in both type 1 and type 2 patients) and has an estimated completion date of March 2015. Assuming a prompt PMA submission and a 12-month review, we assume Abbott could launch FreeStyle Libre in the US in late 2016 at the earliest.

8. There were no additional updates on the pipeline front. As a reminder, Abbott's FreeStyle Precision/Optium Neo BGM received FDA 510(k) clearance in September, reflecting a seven-month FDA review. Management did not comment on this development in 3Q14 nor did it mention it today, and we are curious to see whether Abbott pushes this launch forward or will focus its effort on bringing the Libre to the US. Management was similarly silent on Abbott's FreeStyle InsuLinx or FreeStyle Precision Pro. We have not heard an update on either product since a company presentation in August 2013 when management characterized these devices as "near-term" drivers. We continue to await an update on either front.

Questions and Answers

Q: Could you talk about your excitement for the FreeStyle Libre? How big do you think it could be?

A: I am excited about the product. I think it's a great innovation, a great product. I think we've had a really good customer response, and I guess our challenge right now is capacity expansion. And I'd say that's a limiting factor for us; quicker, faster, sooner than we expected. And so, the organization has got the blowtorch going to expand capacity because I think that product - particularly as word of mouth spreads among patients - is going to be very strong. I'm frustrated with the pace of regulatory approval in the US, but nevertheless, right now, we need the capacity anyway. It's open to really good reception in Europe, and I expect it's going to be a real positive product for us and for patients in that sector.

Q: Could you talk a little bit broadly about your US franchises, particularly in the context of what looks to have been a better operating environment domestically? How do you sort of think about the evolution of your franchises in 2015 and beyond?

A: The US - first of all - it's a very important market to us. It's a big market to us. It's our largest market and three of our major businesses are large and important here. And one, the Established Pharmaceutical business, is not here at all in the US. I'd say it's interesting to me - most shareholders and analysts that I listen to today or hear from will tell me the US is better. I think better relative to what? I don't think that the healthcare environment for healthcare products companies in the US is that much better, to be honest. I don't think it's a robust market. I think it's a reaction to the kind of sudden volatility that a lot of companies have experienced outside of the US and we tend to like predictability in this country, and we tend to like our predictability in quarterly doses. But I look at the markets long term, and the US is a healthy market. It's important for products, but I don't consider it in our businesses a particularly robust growth market. And that means that as we look at the US, our expectations are to be in the good single-digit range and remain profitable and healthy here, but the real growth, even in this volatile market, worldwide, is outside of the US.

I think for healthcare products, for pharmaceuticals, for devices, for the products that we're in, I think the growth rates are much better outside of the US. We just have to navigate the volatility of what that means. And in that case, there's probably 15 countries around the world, maybe 20 countries, depending on what company you are, that are important at varying degrees as growth opportunities, market development opportunities, etc., and as those economies are developing or recovering as the case may be, I think the underlying fundamentals of growth in those markets exceed the US. That doesn't mean the US is bad. I think the US is better than it's been, but it hasn't been particularly good. So better is easy. It's a low hurdle. And while we say the US is more solid today, I think the US today isn't necessarily a better growth market. It's just a lot more stable and predictable than a lot of markets around the world. You guys want to add to that?

I'd just say even as we look at 2015, putting currency aside again, we're looking at growth rates 2X, 3X, 4X what the US is, and it underscores Miles' point that that's where the growth is. But we do see improvements in some of our US businesses in 2015. Diagnostics has continued to be a pretty good performer there relative to the lower growth market, and ADC is now moving into better territory and we do have some new product activity in Vascular, which can help you outgrow a slow-growth market. And things like MitraClip and Supera and XIENCE Alpine are going to help us do a little bit better in that business in 2015. But the relative growth rates, I'd just back what Miles says, there's no comparison and that's why we've pursued and invested more in these higher growth markets.

In the US - and frankly, this is good for any company around the world in any country - but here in the US, you're not going to get a lot of tailwind of growth, and so you better be prepared to innovate and slug it out for share. And you got to look at it that way that you've got to win. You've got to beat a competitor. You can't just take a tailwind. And we've got to keep improving our products and got to keep putting out better products and gain our share that way. The thing I'm heartened by is that when I look across all of our businesses and divisions and their R&D pipelines and the products they're bringing, whether they are incremental innovation or maybe substantial innovation like Libre in our Diabetes Care business, they're really good products and they really will make a difference and they really will drive share gain and growth.

I'm look forward to this as a real positive here - over the next, let's call it two years to five years, as we keep bringing out more and more new products. It keeps us and makes us more competitive in markets like the US. Frankly, the reverse side of that is in markets where you've got a great tailwind of growth, you tend not to be as sharp in terms of competitiveness because you are getting that tailwind of growth. So I think it's actually healthy for us to be both ways, and we'll get the benefit of our new products and new innovations in all markets.

-- by Varun Iyengar, Adam Brown, and Kelly Close