Drug Pricing Investigation

Teva—*Copaxone*

Selected Investigation Documents

Staff Report
Committee on Oversight and Reform
U.S. House of Representatives
September 2020
oversight.house.gov

Teva Selected Documents

Document #*	Citation	Short Description
Teva 31	TEVA_HCO_IC_005008955	February 2017 Emails
Teva 32	TEVA_HCO_IC_005040409, at Slide 32	September 2016 Presentation Excerpt
Teva 33	TEVA_HCO_IC_005199492, at Slide 12	February 2017 Presentation Excerpt
Teva 34	TEVA_HCO_IC_005001166	August 2016 Emails
Teva 35	TEVA_HCO_IC_005007009	April 2017 Emails
Teva 36	TEVA_HCO_IC_005142081, at Slide 27	August 2011 Presentation Excerpt
Teva 37	TEVA_HCO_IC_005141925, at Slides 46, 50	August 2008 Presentation Excerpt
Teva 38	TEVA_HCO_IC_005095970	March 2017 Emails
Teva 39	TEVA_HCO_IC_005293411	January 2016 Email
Teva 40	TEVA_HCO_IC_005036573, at Slide 28	October 2016 Presentation Excerpt
Teva 41	TEVA_HCO_IC_005001347, at Slide 1	2018 Presentation Excerpt
Teva 42	TEVA_HCO_IC_005001345	August 2017 Emails
Teva 43	TEVA_HCO_IC_005028530, at Slide 5	January 2018 Presentation Excerpt
Teva 44	TEVA_HCO_IC_005021634, at Slide 4	October 2017 Presentation Excerpt
Teva 45	TEVA_HCO_IC_005235121, at Slide 6	July 2008 Presentation Excerpt
Teva 46	TEVA_HCO_IC_005132452	August 2008 Emails
Teva 47	TEVA_HCO_IC_005233185	December 2008 Emails
Teva 48	TEVA_HCO_IC_005159378, at Slide 2	June 2009 Presentation Excerpt
Teva 49	TEVA_HCO_IC_005159378, at Slide 5	June 2009 Presentation Excerpt
Teva 50	TEVA_HCO_IC_05239258, at Slide 4	April 2011 Presentation Excerpt
Teva 51	TEVA_HCO_IC_005141157, at Slide 41	November 2014 Presentation Excerpt
Teva 52	TEVA_HCO_IC_005045517, at Slide 2	October 2017 Presentation Excerpt
Teva 53	TEVA_HCO_IC_005035591, at Slide 11	January 2017 Presentation Excerpt
Teva 54	TEVA_HCO_IC_005002063	January 2018 Emails
Teva 55	TEVA_HCO_IC_005007799, at Slide 4	April 2015 Presentation Excerpt
Teva 56	TEVA_HCO_IC_005178747, at Slide 3	November 2015 Presentation Excerpt
Teva 57	TEVA_HCO_IC_005000887	October 2016 Talking Points
Teva 58	TEVA_HCO_IC_005147355	July 2014 Emails

*The document numbers for Teva begin at 31 to avoid confusion with documents for another company.

From: [redacted]
Sent: Saturday, February 18, 2017 8:46 AM
Subject: Fwd: generic Copaxone 40 mg delayed because of fill/finish issues
Attachments: image001.png; ATT00001.htm; image001.png; ATT00002.htm; MYL, TEVA - Quick Take Teva, Mylan - Another Hanukkah miracle; but will it last (Bernstein Research) 7 Pages - 17-Feb-17.pdf; ATT00003.htm

Best regards
[redacted]
Sent from my iPhone

Begin forwarded message:

From: [redacted]
Date: February 18, 2017 at 7:23:58 AM EST
Subject: Fwd: generic Copaxone 40 mg delayed because of fill/finish issues

Might be good for cash flow and debt pay down and some of your bonuses :)

Best regards
[redacted]
Sent from my iPhone

Begin forwarded message:

Subject: Fwd: generic Copaxone 40 mg delayed because of fill/finish issues

Begin forwarded message:

From: TevaInvestorRelations [redacted]
Date: February 17, 2017 at 10:33:54 PM EST
Subject: generic Copaxone 40 mg delayed because of fill/finish issues

Below is Evercore' s note, and attached is a Bernstein report on the matter.

In a press release filed by MNTA just now, it seems that Copaxone generic is delayed

As a reminder, at least 5 generics are in development for Copaxone. However, only MNTA/Sandoz was approved for 20 mg generic (where patent expired already).

Teva Document 31

Street has widely expecting an approval of 40 mg generic - at least from MNTA/Sandoz (mostly because their 20 mg is already approved). In fact, i was hearing investor feedback that a generic 40 mg from MNTA/Sandoz is likely launching in 1Q17 (and Novartis' Sandoz had actually put up a slide on this on recent earnings call).

As per press release just now, here's what MNTA is saying:

1. **MNTA's contract manufacturer (Pfizer) got a warning letter**

2. The warning letter does NOT restrict the 20 mg generic

3. **However, the approval of 40 mg generic depends on successful resolution of this warning letter. Thus MNTA/Sandoz generic is delayed**

We also touched base with Momenta who aren't giving additional details until Tuesday's press conference

This is very good news for Teva - for now. At the very least, it delays MNTA/Sandoz for few months (am waiting to hear back from MNTA).

In some ways, it explains why MNTA did not get approved when 30-month stay on Copaxone 40 mg expired last week.

In light of Teva/MNTA news just now (generic Copaxone 40 mg delayed because of fill/finish issues), we thought it would be helpful to look at precedents.

Here's what we just did:

1. Look at all warning letters in last 20 yrs
2. Zoom in specifically on warning letters relating to CGMP issues on finished pharmaceuticals

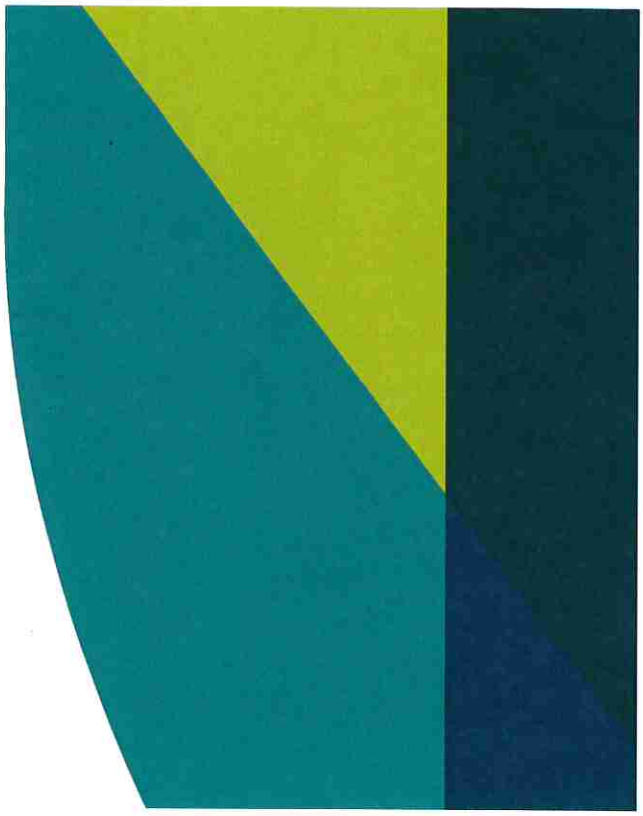
- The implied sample size was 31 cases

Here's what we're seeing: ~13-17 months for resolution (median/avg) ... and minimum of 5 months

GSP & GHE Kick-Off

Sheraton Valley Forge Hotel

13th & 14th September, 2016



Teva Document 32

What does Teva do well in Pricing? (Overall GSM & GGM)

- Pricing negotiation strategy and able to increase prices successfully
  - Influenced heavily by US being allowed to hike prices p.a
- We have dedicated pricing negotiation packages & strategy for all key accounts and tenders
- We apply more frequent price changes
  - Once, twice a year and many on a continuous basis - adaptive
- Teva pricing organization set-up in the right place
  - Pricing established as a business partner
  - Reporting directory to CEO, Marketing or Business Unit
  - Organized by Pricing activity or Business Unit
- Timely, reliable and actionable market intelligence data in place, feeding into pricing strategy and models

Teva Document 32

Teva Document 33

Multiple Sclerosis Franchise Strategy

"MS Disease Area Strategy"—Confidential Working Draft

February, 2017

Teva Document 33

Teva Document 33

Pricing Trends

DRAFT

Generitization of multiple classes on the 5 year horizon potential to change the pricing paradigm

	US dynamic	EU dynamic
Current pricing dynamic	• Premium prices are available – current list prices average $80k per patient per year • But payers demand competitive discounting – highest discounts for older DMTs, lower for newer DMTs - but averaging ~25% in GTN w/ COP 40 at 40% GTN • HEOR is a key lever for preferred plan coverage • Payers do not generally dictate prescribing despite high cost	• Health technology assessment is the firmly established P&R gatekeeper • Current list price (average $13k per patient per year) much lower than US price • With discounts averaging ~10 to 15% • H2H comparisons against SoC are expected, but do not guarantee success (if no H2H comparator – DMT is relegated to lowest priced DMT or reference pricing) • Country-specific eligibility guidelines and prescribing restrictions may be narrower then EMA labeling
Future pricing dynamic	• Generitization of oral (small molecule) DMTs could potentially drive pricing erosion of ~85% within two years[1] • Biosimilars expected to drive pricing erosion of only ~35% within two years[1] • Rebate range for biosimilars are not expected to be significantly different from the originator rebate; biosimilars are hampered by volume-based contracts and longer originator contracts • Payers are interested in piloting outcomes-based contracts • Potential HHS negotiation power for Medicare and Medicaid	• (Compared to the US,) generic or follow on products drive significantly less price and sales erosion happening over a significantly longer period of time • Possible move to rejection of placebo-controlled studies for reimbursement consideration (e.g., Italy) • More focus on cost-effectiveness analysis; budget impact management • To reduce spending, focus on simpler contracts (e.g., straight discounts) over risk-sharing and outcome-based contracts (where administrative cost and compliance decrease effectiveness)

Sources: Evidera Policy Change presentation, Feb 2017; Decision Resources Disease Landscape & Forecast, November 2016 BY2015
1. Decision Resources Market Forecast Assumptions, November 2016 BY2015

teva

Teva Document 33

From: John Hassler
Sent: Friday, August 19, 2016 9:20 AM
To: Dalton Tomlinson; [redacted]
Subject: FW: Financial Assistance
Attachments: Patient Assistance Spending Trends_081816.pptx

FYI, I had asked [redacted] for an update on patient assistance spend and she provided the attached information on Copaxone.

Best regards,

John

John Hassler
Senior Vice President and General Manager, Teva CNS
Highly Confidential

[redacted]
Sent: Thursday, August 18, 2016 4:56 PM
To: John Hassler
Subject: RE: Financial Assistance

Hi John,

Please see the attached summary of the activity that we have been seeing on Copaxone over the past few years. There definitely have been increases in out of pocket costs to patients. As you look at the first graph, please take note that the 'patient cost' reflects the amount that Teva incurs on behalf of the patient and in 2014 to 2015 is when we introduced the $0 program. Some of the increased costs during this time period relates to the additional $35 that we were picking up for transition or new 40mg patients, not all of this is attributable to plan designs. However, you can definitely see a trend in the increase in OOP costs that the payers are shifting to patients and some of this may be our price increases as well. Please let me know if you have any questions.

[redacted]

From: John Hassler
Sent: Friday, August 12, 2016 7:46 AM
[redacted]
Subject: Financial Assistance

[redacted]

Teva Document 34

What changes have we seen over the past couple of years in overall patient assistance spending? I am interested in understanding what you are seeing in terms of shifts in patient volumes in the various channels and how out of pocket exposure for the patients are changing. We have experienced rapid growth in patient assistance while prices were rising rapidly. Now price increases have moderated and I'd like to see whether the cost increase in assistance is still increasing at the same rate or whether it has changed.

Best regards,

John

CNS
John Hassler
Senior Vice President and General Manager, Teva CNS
Highly Confidential

From: Katie Hiett
Sent: Friday, April 7, 2017 11:56 AM
To: [redacted]
Subject: RE: Question

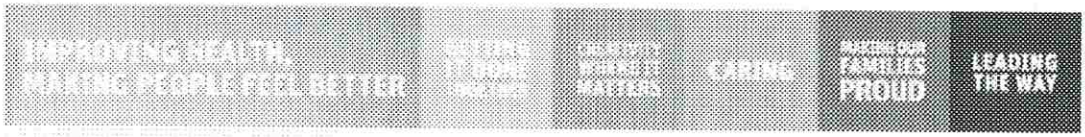
[redacted]

[redacted] is probably not aware that I am raising the issue but he is aware of the issue itself. We get hammered by prior period corrections from Medicaid going back years and we are getting hammered with duplicate claims between Medicare and Medicaid and I know I am not finding all of it. Looking forward to doing something other than just taking it.

Best regards,

Katie Hiett, CPA Vice President - US Market Access Pricing and Contracting

Highly Confidential



OUR PURPOSE & VALUES

From: [redacted]
Sent: Friday, April 07, 2017 8:58 AM
To: Katie Hiett
Cc: [redacted]
Subject: RE: Question

Good Morning Katie,
Thank you for the outreach—you've come to the right place. I am going to ask [redacted] to set you and I up with a call to discuss this a bit further. We are also in the process right now of developing proactive policy strategy for Teva and these may fit well into that effort. I have a meeting with [redacted] a week from Monday where we will be discussion some of the policy options we are considering including—is he well aware of this pain point?

Look forward to speaking soon.

[redacted] please find at least 30 minute for Katie and I as soon as possible (Katie I am on vacation next week).

Teva Document 35

[redacted]

Highly Confidential

From: Katie Hiett
Sent: Thursday, April 06, 2017 4:21 PM
To: [redacted]
Subject: Question

[redacted]

I am looking for some direction on who can help me with some policy changes I would like to see Pharma start pushing for when it comes to the Medicaid program and Medicaid Expansion.

There are two issues I would like to see Pharma start lobbying for.

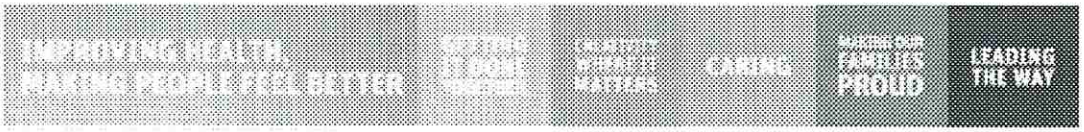
- There is no statute of limitation on the states on when they can submit Medicaid. They can go back forever and we have no way of knowing about these liabilities. We continue to get hit with surprises and if Medicaid continues to expand this will only get worse. This is millions of dollars for Teva and I know all other pharma gets hit with the same amounts. It has been referenced on some earnings calls when they miss earnings.
- Medicaid currently collects 100% of the rebate even if they only pay a penny against the claim. We are seeing more and more of this with the aging population. They have dual coverage so we get hit with the rebate from the payer claim and then we get hit with the full rebate from Medicaid even though Medicaid was the secondary payer. Currently Teva has several products that have 100% rebate in Medicaid due to best price and a long history of price increases or just being on the market for a long time. Copaxone 20, [Redacted - Other Product Information] are all at 100% WAC rebate in Medicaid meaning we don't ever cover our COGS or other GTN discounts.

I think we need to start advancing some of these changes given the massive increase in this program since ACA and our voice needs to be heard. Don't know where to start.

Best regards,

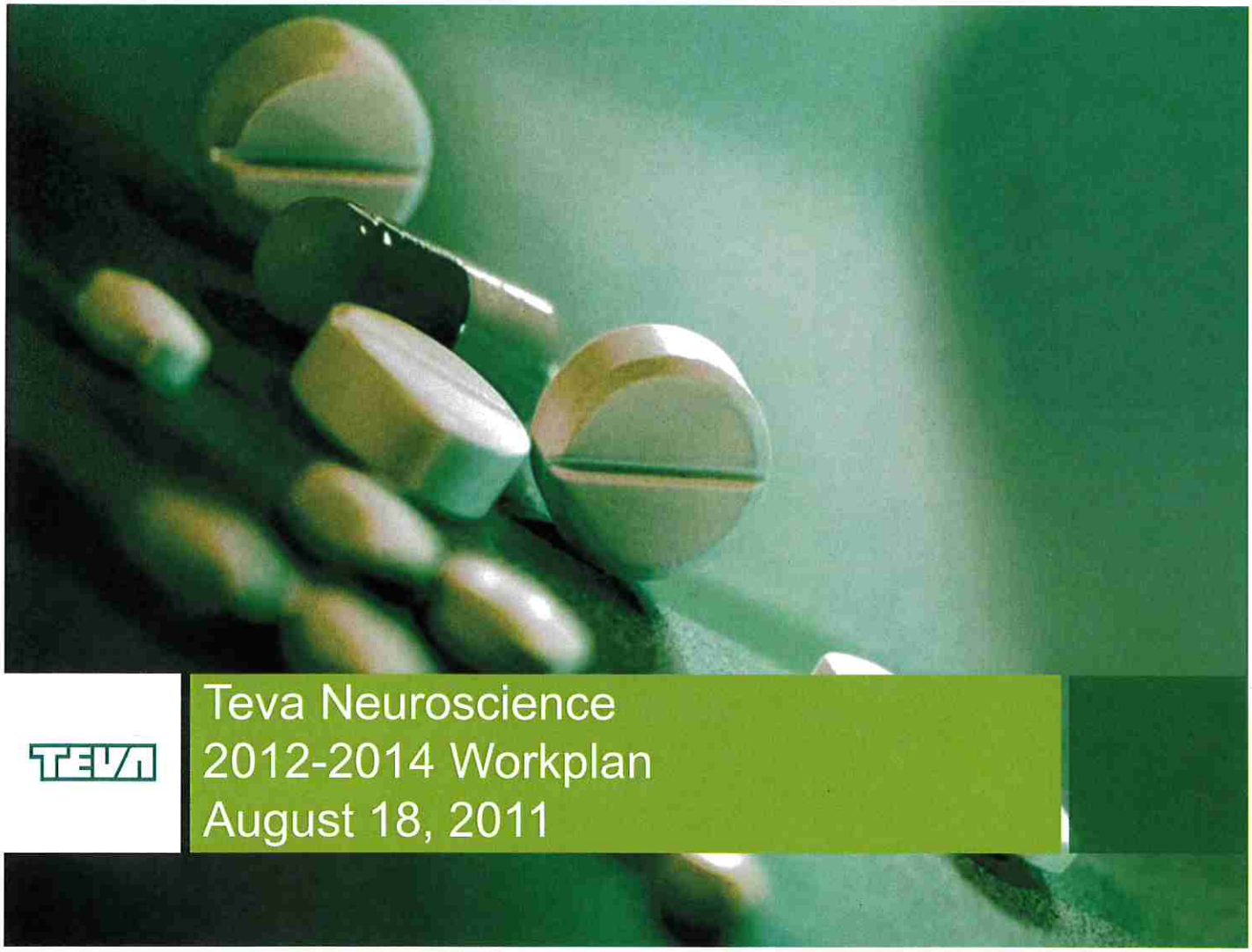
[redacted]
Katie Hiett, CPA Vice President - US Market Access Pricing and Contracting

Highly Confidential



OUR PURPOSE & VALUES

Teva Document 35


Teva Neuroscience
2012-2014 Workplan
August 18, 2011

COPAXONE Expense Drivers

Expense Driver	Budget	ROI (>0 is considered positive)
Patient Assistance	$81M direct	▪ Returns for commercial patients average 451% with a range of 205% to 761% ▪ Medicare D grants are not included in the assessment
Sales Force	$41M people related	▪ 178% short term ROI ▪ 95% carryover at 6 months
Patient Services	$14M direct $17M people related	▪ 29M invested in 2011 generated $363M with a ROI of 1152% ▪ PAP is not included in this ROI
Opportunity and Educational Funds	$17M direct	▪ Not tracked, but assumed similar to Peer to Peer
Peer to Peer	$10M direct	▪ AHM is the surrogate metric ▪ Average ROI for AHM programs is 701%
Scientific Communications	$7M	▪ Not Tracked

COPAXONE®

2009-2011 WP Review

USMT and LT
2008.08.06

+/- 10 M Impact V1

Tactic	Investment	2009 Impact
Medicare Part D Grants	- 4.3 M	- 11.4 M
MOP	- 5.7 M	No ST impact
CNE program	+ 2 M	Est @ 3.0 M
MCO rebates	+ 7 M	unknown
DTC	+ 1 M	Est @ 1.5 M

Downside to Plan V1

Probable Net Sales	1,742	1,957	2,150
Downside Events:	2009	2010	2011
No Pricing Action	(144)	(324)	(517)
Discount Rx - No Impact on Compliance	(53)	(74)	(75)
Eliminate Medicare PAP investment	(16)	(33)	(45)
[redacted]			
Private PAP Programs does not increase Patients	(14)	(26)	(35)

Probable Contribution	894	1,390	1,671
Downside Events:	2009	2010	2011
No Pricing Action	(94)	(272)	(468)
Discount Rx - No Impact on Compliance	(34)	(63)	(68)
Eliminate Medicare PAP investment	(11)	(28)	(41)
[redacted]			
Private PAP Programs does not increase Patients	(9)	(22)	(31)

From: Larry Downey
Sent: Thursday, March 30, 2017 11:21 AM
To: David Loughery
Subject: RE: Urgent: 2017 Copaxone Donation-- Medicare Donations Process

I approve, but I have not seen the Oracle notice...

From: David Loughery
Sent: Thursday, March 30, 2017 9:52 AM
To: Larry Downey
Subject: Fwd: Urgent: 2017 Copaxone Donation-- Medicare Donations Process

FYI

Sent from my iPad

Begin forwarded message:

From: [redacted] Highly Confidential
Date: March 30, 2017 at 10:45:00 AM EDT
To: David Loughery Highly Confidential, [redacted]
Highly Confidential
Cc: [redacted] Highly Confidential, [redacted]
Highly Confidential, [redacted] Highly Confidential
Subject: RE: Urgent: 2017 Copaxone Donation-- Medicare Donations Process

David
Thank you for your approval, however, the request is pending Larry's approval through Oracle. Please have him approve so payment can be initiated once Global Treasury provides their approval.

Thank you

[redacted]
Highly Confidential

From: David Loughery
Sent: Thursday, March 30, 2017 10:29 AM

To: [redacted]
Cc: [redacted]
Subject: Re: Urgent: 2017 Copaxone Donation-- Medicare Donations Process

I'm not sure if there is anything I need to do system wise but both Larry and I approve this payment.

Sent from my iPad

On Mar 29, 2017, at 4:16 PM, [redacted] Highly Confidential wrote:

> Hi,
> Hope you are well. Please know that I have completed the check request in Oracle [redacted] and have also attached the wire transfer instructions from PAN with the check request. Per [redacted] would request that this be taken care of and processed early next week?
> Thanks!
>
> <image001.png> Donna Faix Corporate & Social Responsibility Program Manager
> **Highly Confidential**
>
> **From:** [redacted]
> **Sent:** Wednesday, March 29, 2017 9:46 AM
> **To:** [redacted]
> **Subject:** Urgent: 2017 Copaxone Donation-- Medicare Donations Process
>
> [redacted]
> See below and attached details from laurie on exactly the process she followed for the donation. I'm copying Alejandro here so he's aware we're attempting to do this urgently (if possible to accrue against Q1). Because it's only a $5M donation we're intending to make this quarter, I don't think you need to seek approval from Mike M, I think you only need approval from Dave Loughery. I'm sure you do need to connect with [redacted] sap to ensure we have the funds we could send immediately. The attached email notes the 3 funds we donated to this year; the first fund, the assistance fund, was the one we donated to in the previous year.
>
> I am also attaching the couple of emails Laurie sent which contain the paperwork and other files needed for the donation to occur as a reference.
> [redacted]
>
> **From:** [redacted]
> **Sent:** Friday, January 13, 2017 5:23 PM
> **To:** [redacted]
> **Subject:** RE: Medicare Donations Process
>
> Will do. I had already reached out to [redacted] see attached email) because he is the Treasury person we worked with last year but I will reach out to [redacted] and [redacted] and make sure we are all set. Just so I am clear, who is seeking approval from Larry, Rob etc. and if it is me do they know this request is coming? Thank you!

From: [redacted]
Sent: Friday, January 13, 2017 6:14 PM
To: [redacted]
Subject: RE: Medicare Donations Process

Based on the grant of authority levels, I think that's exactly who needs to approve, and likely who approved. [redacted] I think if you can do the part below that notes connecting with AP and Treasury that will also help us with next steps.

From: [redacted]
Sent: Friday, January 13, 2017 5:03 PM
To: [redacted]
Subject: RE: Medicare Donations Process

I just reached out to Dave L and asked him if we would be asking Mike Mc, Larry D, and Rob K (amount needs TEC member approval) for their approvals.

Best regards,

<image001.png> [redacted] Dir Business Finance

Highly Confidential

From: [redacted]
Sent: Friday, January 13, 2017 4:53 PM
To: [redacted]
Cc: [redacted]
Subject: Re: Medicare Donations Process

Hi! Thank you for sending this. However, this is not how the process actually worked. We requested the funds by completing the wire transfer, but we were not involved in securing the appropriate levels of approval. I am happy to do this, but need to know who has the authority to approve these payments. Please let me know and we will move it forward ASAP. Thank you!

Sent from my iPhone

On Jan 13, 2017, at 4:51 PM, [redacted] **Highly Confidential** wrote:

> Per your process noted below,
>
> **Completed Actions:**
>
> - [redacted] to receive a request for Copaxone donations from The Assistance Fund – done, received from 3 funds
> - [redacted] to request the perspective of the Copaxone Marketing team [redacted] and determine the Marketing budget available—done, [redacted] confirms $38M available in Copaxone 2017 budget for donations

To Be Completed:

? [redacted] to work with Dave Loughery (NASM CFO) and Mike McClellan (GSM CFO) to determine the timing of payment. For example, Teva may pay a portion of the 2016 budgeted donations in the last few days of 2015.—In progress- [redacted] Copied here, see attached documents for 3 donations

? [redacted] to give [redacted] and [redacted] Treasury) a heads up of the payment about a week prior to payment. [redacted] will ensure Teva has the cash available to make the payment, and [redacted] will ensure the proper attention is given to making a timely wire transfer. [redacted] can also advise to the last possible time you will need to notify her and achieve a same day wire transfer. She will need a completed wire transfer form and written documentation of approval at the appropriate approval authority level.

? [redacted] to request approval of donation payment.

? [redacted] to communicate to A/P and Treasury with copies of the wire transfer form and written documentation of the appropriate approval authority.

From: [redacted]
Sent: Friday, January 13, 2017 3:27 PM
To: [redacted] David Loughery
Subject: FW: Medicare Donations Process

Regarding the process to take place when making a donation, I found this e-mail from 2015 when the process changed to move ownership of the donation to Corporate Giving.

Best regards,

<< OLE Object: Picture (Device Independent Bitmap) >>

[redacted] Dir Business Finance

Highly Confidential

From: [redacted]
Sent: Wednesday, September 23, 2015 5:05 PM
To: David Loughery; [redacted]
Subject: FW: Medicare Donations Process

The Copaxone donation payment process has changed. Changes in Teva's policy have moved the ownership of the donation to Corporate Giving. I asked [redacted] to schedule time with the Corporate Giving team ([redacted]) to make sure they understood what this meant. Since both of you are fairly new to this process, they are definitely new to it, and I'm leaving the group, I thought it would be best to document this process to ensure everyone knows what to do. ☺

See my email to [redacted] below for the details. Let me know if you have any questions.

From: [redacted]
Sent: Wednesday, September 23, 2015 4:59 PM
To: [redacted]
Cc: [redacted]
Subject: RE: Medicare Donations Process

Hi Laurie,

Thanks for meeting today to discuss the process to pay Copaxone donations. We didn't talk about it, but the Reslizumab team has budgeted for donations in their 2016 AOP as well. There will likely be activity related to both products; however, the Reslizumab donations are less than $1M.

A question for you - Is it possible to code the donation to the Copaxone Marketing department? Or does the donation have to be coded to Corporate Responsibility?

To recap the Copaxone donation wire transfer process...

? [redacted] to receive a request for Copaxone donations from The Assistance Fund
? [redacted] to request the perspective of the Copaxone Marketing team [redacted] and determine the Marketing budget available
? [redacted] to work with Dave Loughery (NASM CFO) and Mike McClellan (GSM CFO) to determine the timing of payment. For example, Teva may pay a portion of the 2016 budgeted donations in the last few days of 2015.
? Laurie/Donna to give [redacted] Accounts Payable) and [redacted] (Treasury) a heads up of the payment about a week prior to payment. [redacted] will ensure Teva has the cash available to make the payment, and [redacted] will ensure the proper attention is given to making a timely wire transfer. [redacted] can also advise to the last

Teva Document 38

possible time you will need to notify her and achieve a same day wire transfer. She will need a completed wire transfer form and written documentation of approval at the appropriate approval authority level.

? [redacted] to request approval of donation payment.

? [redacted] to communicate to A/P and Treasury with copies of the wire transfer form and written documentation of the appropriate approval authority.

The rest of this email is reference information only...

Approval Authority Levels
$0.5M Sr. Director
$1M VP
$5M SVP (Larry Downey in the past)
$15M TEC members (Rob Koremans)
$25M CFO (Eyal Desheh)
>$25M CEO (Erez Vigodman)
*** I'm not sure if there is a point in which Board of Directors approval is necessary. A[redacted] can advise.

Wire Form:
The financial coding in this form will need to change.
<< File: Copaxone Donation wire transfer.xls >>

Sample approval escalation email:
<< Message: FW: Response requested: Approval for Copaxone donation payment >>

Sample A/P and Treasury heads up email:
<< Message: FW: Copaxone April Donation >>

Thanks,
[redacted]

[redacted] Associate Director, Finance

<< OLE Object: Picture (Device Independent Bitmap) >>

Highly Confidential

-----Original Appointment-----
From: [redacted]
Sent: Monday, September 21, 2015 12:31 PM
To: [redacted]
Subject: Medicare Donations Process
When: Wednesday, September 23, 2015 3:30 PM-4:00 PM (UTC-06:00) Central Time (US & Canada).
Where: **Highly Confidential**

[X]

[X]

Sorry, I meant to add a Global Meet to this meeting!!!

Hello everyone,
With the Medicare donations (related to Copaxone and Cinqair) moving out of Patient Solutions and into the Brand Marketing Budgets in 2016, we just wanted to have a quick discussion around the process for getting payments approved/processed.

Thanks!
[redacted]

You're Invited.

You've been invited to a GlobalMeet® web meeting.

Have the

<mime-attachment>
<mime-attachment>
<mime-attachment>
<mime-attachment>

Teva Document 38

From: David Loughery
Sent: Thursday, January 28, 2016 11:26 AM
To: Larry Downey; Michael McClellan
Cc: [redacted]
Subject: Copaxone Donation wire transfer -$10M January 2016-.xlsx
Attachments: Copaxone Donation wire transfer -$10M January 2016-.xlsx

Larry/Mike,

Attached is a request to pay another $10M for Copaxone donations. Mike Sheehy has approved. As this is a common payment we make each year, I'm not clear on what further approvals we need beyond the 2 of you. This amount is included in the 2016 AOP.

DL

Teva Document 39

Go To Market Action Plan (GTMAP)

COPAXONE

Launched
Relapsing Forms of Multiple Sclerosis

Teva Document 40

Marketing: Supporting Activities and Spend

KBQ: What supporting activities are needed to successfully execute key tactics?

$ million

SI	CSF	Key Tactics	Supporting Activities	Owner	Start Month	End Month	Budget
1	a.	HCP Personal HCP Promotion	*Field Sales and Materials*	*US Sales*	Jan	Dec	2
			Speaker Programs	*US Marketing / US Sales*	Jan	Dec	7
			Conventions	*US Marketing*	Jan	Dec	1
1	a	HCP Non Personal Promotion	*COPAXONEHCP.com*	*US Marketing*	Jan	Dec	4
			MSKnowledgeSeries.com (unbranded)				
			Email and other Digital Media				
2	a	Medicare Donation	-	*US Marketing*	Jan	Dec	40
1	a	*Advocacy*	*Charitable Donations and Sponsorships*	*US Marketing*	Jan	Dec	2

Continued on next slide

COPAXONE Highlights - Changes on August 3 from June Submission and Subsequent August 21st Changes

Summary of Changes	Total 2018 expense reduction of $71M (31%), $159M vs. original submission of $229M
Key Areas of Change	• Sales Force reduced by $[redacted] *- Assumes Sales Force COPAXONE weighting reduced from 60% to 50%* • Marketing Direct Tactical reduced by $2M • Medicare Donation reduced by $22M– *Donation reduced a further $21M to $0M* • Commercial Operations reduced by $3M • Patient Solutions reduced by $11M *- Anticipate 75% reduction in call center capacity* • *Market Access reduced by $3M* • *Marketing other reduced $1M*
Risk to Topline (Net Sales) By Areas of Change	• Sales Force: [redacted] • Marketing Direct Tactical: $5 - $14M • Medicare Donation: $0 - $128M– *revised impact $0M-$261M* • Patient Solutions: $50 - $80M
Overall Risk to Topline	• *$75M - $413M (revised total impact)*

Teva Document 41

From: John Hassler
Sent: Wednesday, August 30, 2017 6:24 PM
To: David Loughery
Subject: RE: LRP Expense Reduction
Attachments: 8-17-17 2018 LRP August 21st COPAXONE Submission Changes and Impacts 2017.08.17 530pm.pptx

Dave,

The first slide in the attached deck is what is in the memo and it is editable.

Best regards,

John

CNS
John Hassler
Senior Vice President and General Manager, Teva CNS
Highly Confidential

From: David Loughery
Sent: Wednesday, August 30, 2017 3:49 PM
To: John Hassler
Subject: FW: LRP Expense Reduction

John,

Larry forwarded this to me and I then asked Mark to prepare something similar for Respiratory that I could then consolidate and allow Larry to provide to Rob. I am not comfortable including the sales impact of the reduced donations. Since the table is attached as a picture, could you have someone send this to me with the 0-$128M range line excluded. I will however, add a comment that we believe that reducing the level of donations could mean that a significant number of patients will not be able to remain on Copaxone due to financial constraints.

Thanks,

DL

From: Larry Downey
Sent: Friday, August 18, 2017 9:16 AM
To: John Hassler
Cc: David Loughery
Subject: FW: LRP Expense Reduction

John:
I appreciate your very good summary and quantification of the situation. I agree we are getting to the point that we are making it impossible to achieve the top line.

If you do not mind, I would like to forward your document to Rob and Asaph to give them a feel of the situation and to get their direction as to how they want us to proceed. They may want to get on the phone with us if they have any questions.

Dave:
Any other thoughts on how to proceed?
Thanks, Larry

From: John Hassler
Sent: Friday, August 18, 2017 7:29 AM
To: Larry Downey
Subject: LRP Expense Reduction

Larry,

We have completed the expense reductions that have been requested. I want to communicate the impact of these changes and have tried to objectively capture what we have done and the anticipated impact. I'd like to get your thoughts on the assessment and if appropriate, how to ensure that those who ultimately make these budget allocation decisions are aware of the expected impact.

Best regards,

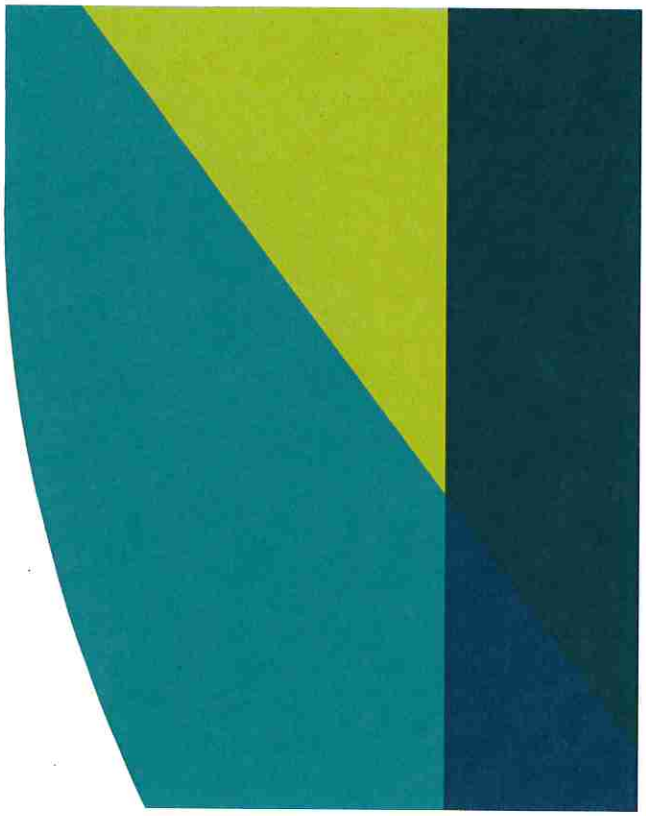
John

John Hassler
Senior Vice President and General Manager, Teva CNS
Highly Confidential

AOP Review

Teva NA Specialty Marketing

Tuesday January 9, 2018



Teva Document 43

COPAXONE Executive Summary

COPAXONE: Upside and Downside

- Compared to current AOP (1st Gx Oct 2017, 2nd Gx April 2018); less than anticipated erosion of COPAXONE 40mg post generic introduction has led to a Q4 2017 upside and an anticipated Q1 2018 upside of approximately $174M.
  - Current COPAXONE brand AOP net sales: $1.054B
  - Potential revised AOP net sales with Q1 adjustment: $1.228B
- Additionally, competitive intelligence suggests a delay in introduction of 2nd generic to the market, which may lead to further upside in 2018.
  - Potential revised AOP net sales with Q1 adjustment and 2nd Gx in Dec: $1.562B

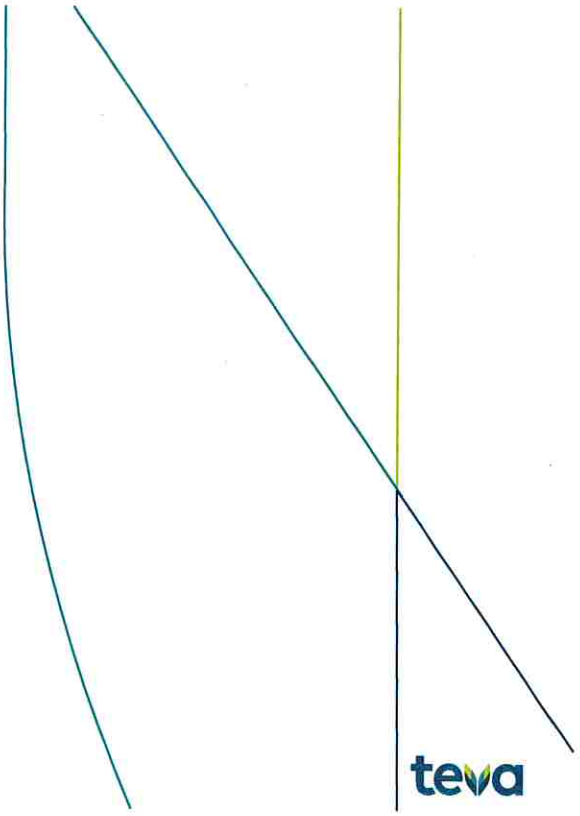
- Forecast Risk: 27% of patients on COPAXONE 40mg are Medicare Part D. Patients who are unable to meet the donut hole deductible in Q1 may not fill Rx and go off therapy, which would result in a negative impact to the brand of $210-280M.
- Holding the execution of high priority tactics during ongoing budget reviews may place additional risk in the topline forecast.
- Current AOP investment: $65.6M (minus labor e.g. sales force and ShS).
  - [redacted] direct marketing investment planned for 2018 [redacted] tactical marketing, [redacted] shared services direct marketing) + [redacted] indirect marketing costs (driven by MR, MCM and HSM)
  - Need to confirm we are covering expenses beyond labor that are included with indirect expense [redacted]

Teva Document 43

Generic COPAXONE 40mg Update*

Board, October 2017

*first preliminary analysis – for internal use only



Teva Document 44

Key Activities to Defend Against Generic Erosion

Brand over Generic (House Brand) Contracting Strategy

- Contracting with major payors, PBMs and pharmacies
- Contracts range from Brand over Generic terms (all 40mg Rx will be switched to Brand), to loyalty allowing access to COPAXONE 40mg alongside generic

Sales force DAW messaging and activities

- Sales force proactively messages to HCP customers the need for "Dispense as Written" on all new Rx and refills
- Working with office accounts to ensure they have the capabilities and resources need to communicate DAW through verbal, written and electronic means

Outbound efforts to 40mg patients through Shared Solutions

- Call center outbound effort to contact all current 40mg patients with active marketing authorization
- Emails to all patients with DAW messaging
- Ability to produce current 40mg patient lists for HCP offices to proactively DAW scripts

Legal pathways also being explored

Teva Document 44

GA Life Cycle Management

Presentation to the BOD
July 23, 2008

Teva Pharmaceutical Industries Ltd.
Global Innovative Resources
November 21, 2006
CONFIDENTIAL

Teva Document 45

Teva Document 45

GA Life Cycle Initiatives
Lower frequency of injections

No formal dose ranging or frequency humans studies (PK/PD) have been performed to link with clinical outcomes

- **40 mg every other day**
  - Based upon "sameness" of 40mg to 20mg in the FORTE trial
  - **Issue**: existing data from every other day with Copaxone may prompt patients using generic COPAXONE every other day
- **Higher doses in less frequent dose regimen (i.e once weekly)**
  - How do we justify the use of higher doses after Forte?
  - Solubility of a higher dose, increased injection site reactions
  - Once weekly injections of 15 and 30 mg TV-5010 in MS patients provided equivocal MRI results, anti TV5010 antibodies profile looks different from that induced by daily GA
- **Issue for consideration : costs of yearly treatment of the lower frequency regimen compared with COPAXONE daily**

Teva Document 45

From: [redacted]
Sent: Tuesday, August 26, 2008 8:26 PM
To: [redacted]
Cc: [redacted]
Subject: Re: brief update from GIR meeting on GA LCM

Thanks for the update. A few points:

1. The limiting step with GA is the density of the solution. I assume that [redacted] has the information for the 60mg back from the days we have worked on the 80mg.
2. Please consider the ISR we saw in the rats with the 80mg (so we may not want to go to high).
3. In addition, we have currently a 5 fold safety ration based on monkeys only and excluding the ISRs - we should consider whether this should guide us when choosing the next dose.
4. What is the TPP - efficacy as 20mg?
5. Can we patent the frequency?
6. This is also a long term plan, assuming Phase II and Phase III bringing us to 2016 - still relevant?

[redacted]

[redacted]
26/08/2008 18:55

To [redacted]
cc
Subject brief update from GIR meeting on GA LCM

Dear all,
In the Gir meeting today the following decisions were made:
1. 0.5 ml GA 20 mg - Go decision. However it was decided that TN will run the clinical trial in parallel to the 6 M stability to see if indeed we get better /same injection side reaction and not worse.

2. Gir accepted the LCM recommendation not to pursue the 40 mg every other day. Instead of that it is requested that we prepare a development plan with GA 50 mg or even higher if feasible for once or twice weekly injections. My input was that the highest feasible dose is 60 mg and therefore the 50 mg was accepted. A CDP for this product should be developed as well.

3. New formulations/pumps etc.. - the concept of looking on new GA products of such kind was accepted. we need to work with [redacted] nd TN, map the relevant options and make a recommendation for these products developments. Vera, it will be very helpful to organize a CMC meeting asap.

Thank you all,

[redacted]

Senior Director,

Special Innovative Projects
Innovative R&D
Tel: Highly Confidential
Fax: Highly Confidential
Mobile: Highly Confidential

CONFIDENTIAL ATTORNEY CLIENT PRIVILEGE

Teva Document 46

From: Ronit Weiss
Sent: Monday, December 29, 2008 3:41 AM
To: Yifat Shorer
Cc: Ety Klinger; Yossi Gilgun
Subject: Re: GA Infrequent injection proposed study

Totals added. Yossi and I will compere the numbers between projects tomorrow as soon as Vera will give as the allocation for the CMC FTEs.

Yifat Shorer Highly Confidential
28/12/2008 21:50

To Ronit Weiss Highly Confidential
cc Yossi Gilgun Highly Confidential
Klinger Highly Confidential
Subject

DocLink1.ndl

Re: GA Infrequent injection proposed study

Thanks, Ronit.

Could you please add the 'total FTEs' for each stage?

Thanks,
Yifat

Ronit Weiss Highly Confidential
28/12/2008 13:56

To Yifat Shorer Highly Confidential
cc Yossi Gilgun Highly Confidential
Subject

DocLink2.ndl

Re: GA Infrequent injection proposed study

Hi

Here are the number of FTEs per department from the Copaxone 40mg development per stage:
1. From G/NG to FPI (2-9/2006):

2. From FPI to LPO (10/2006-5/2008):

3. From LPO to Results - (6-7/2008):

Teva Document 47

Yossi - as you can see the CMC allocation is far from zero and this needs to get attention here as well. I think we need to sit on this together.

Regards,
Ronit

Yifat Shorer Highly Confidential
24/12/2008 22:38

To Yossi Gilgun Highly Confidential
cc Ronit Weiss Highly Confidential
Subject


DocLink3.ndl

Re: GA Infrequent injection proposed study

Ronit,
Can you please check how many FTEs were invested in 40mg for MS (+ in which department, globally)? do you think it might be used as a benchmark?
Best regards,
Yifat

Yossi Gilgun Highly Confidential
24/12/2008 12:13

To Ronit Weiss Highly Confidential
Shorer Highly Confidential
cc
Subject GA Infrequent injection proposed study

Teva Document 47

Dear both,

Please find below the presentation prepared for the discussion in the GA LCM meeting one month ago (the relevant study design can be found in slides 7-9- Option 2- Superiority study GA 32 mg thrice a week vs, placebo, and the appropriate FTE slide can be found in slide 14).

I would like to make it clear that the IR&D management, led by [redacted] are **strongly against the study** since it has no scientific rationale/ value. The IR&D decision was conveyed to the GA LCM team; however, the GA LCM members, though agree with IR&D decision, think that such a study has its business value.

I know from [redacted] that a GIR meeting is planned for 08-09 Jan 09, so I assume that a final decision will be taken then by [redacted]

Please contact me if you need any further clarifications.

All the best

[redacted]

[attachment "GA infrequent injection- Optional scenarios- 19 Nov 08.ppt" deleted by Yifat Shorer/NTA/TEVA/IL]

Yossi Gilgun-Sherki, Ph.D.
Global Clinical Leader
Clinical Development Section
Global Innovative R&D
Teva Pharmaceutical Industries, Ltd.
Netanya, Israel

Highly Confidential

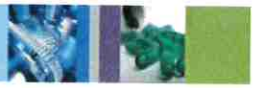
Teva Document 48

Development of High dose/ low frequency formulation of GA

- **Situation**
  - There is a need to develop a low frequency formulation of GA to:
    - Ensure the competitiveness of Copaxone in the future and to address the market unmet need for less frequent injections
    - Prepare a mid-term solution as an insurance policy in case [redacted] fail and our next launch is not before 2016 / 17
- **Complications**
  - No supporting clinical data for the selected dose or dosing regimen
  - Regulatory authorities may request a dose range finding study and comparison of the new formulation to daily GA and placebo
  - The new formulation must be approved no later than 2014
- **Possible Resolution**
  - To conduct a 2 -arm PC study, using the 40mg/ml configuration e.g. 32-40 mg GA 2-3 times a week
  - Do not consult with regulatory authorities before study initiation – they will most probably not accept this design
- **Risks**
  - The cost of the study is $52 M
  - Regulatory authorities may not approve the new formulation based on a single study results
  - Recruitment to a PC study will be slow and the TTM may be later than 2014

Teva Document 49

High dose /low frequency formulation Challenges



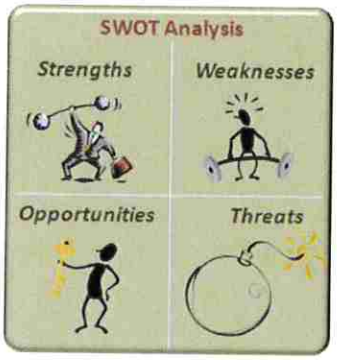
- No supporting data for the selected dose or dosing regimen
  - There is no supportive clinical data - no POC study
  - Less frequent injections may delay the onset of action
  - Overall, the data available to date do not support going to higher doses
  - Immunogenicity - twice weekly injections may induce a different antibody response – it is not clear how it would affect the clinical efficacy since the correlation was never proven
- In the absence of rationale for dose selection, the regulatory authorities may not approve the product based on a single study exploring only one dosing regimen
- No market exclusivity in Europe

Teva Document 49

GA 40mg SWOT

Marketing Team

GSM, 2011



Teva Document 50

GA 40mg– Opportunities & Threats

Opportunities

- Barrier to Generic entrance – Suggest the opportunity is extension of Life Cycle and new IP vs. your proposed statement – we don't want to been seen as "creating" barriers to generics as this is Teva's core business
- Capture IFN patients that switch because of Tolerability (no flu-like syndrome, same convenience)
- Capture GA 20mg aiming at less injection / more convenience
- Reinforce the "franchise in MS" of Teva.

Threats

- Crowded & competitive market, physicians not ready to accept additional "minor" innovation/benefit
  - Peg-avonex
  - Orals (Gilenya, [redacted], TeriF, BG12)
  - [redacted]
- GA 20mg
  - CIS Indication
  - Owns positioning territory
- Challenging Teva MS franchise Strategy [20mg, 40mg, [redacted], *0.5 ml at the horizon*]
- We are putting patients in play for a switch who might have been otherwise satisfied
- GA market share is declining overtime due to fragmentation of the market
- Generic or biosimilar GA

Teva Document 50

Gx GA Readiness Work Team

November 18, 2014

COPAXONE
(glatiramer acetate injection)

Teva Document 51

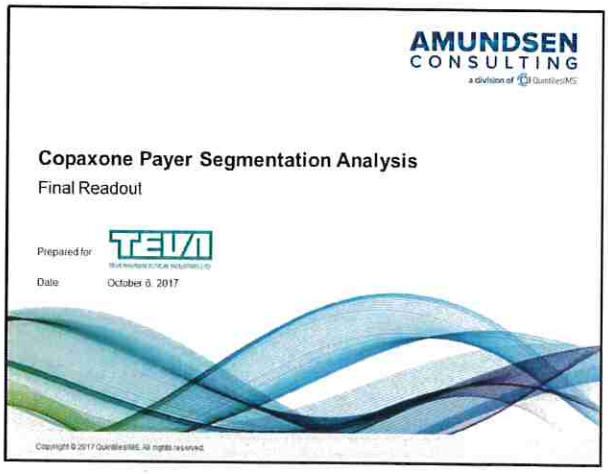
Marketing: Deliverables

Deliverables	Status	Responsible Party	Start Date	Completion Date
Pre-Gx Launch				
Gx Strategy	Complete	Jeff	8/14	9/14
Tactical Plan	In Development	Jeff / Marcy	8/14	10/14
Field Communications / TPs	Complete	Scott / Karen	2/14	4/14
Discontinue 20mg Financial Programs (Patient Services)	In Process	Karen / DeAnne	8/14	12/14
Post-Gx Launch				
Tactical Plan	In Development	Jeff / Marcy	8/14	10/14
Field Communications / TPs	In Development	Marcy / Karen	9/14	12/14

Teva Document 51

QuintilesIMS™

9/27/2020

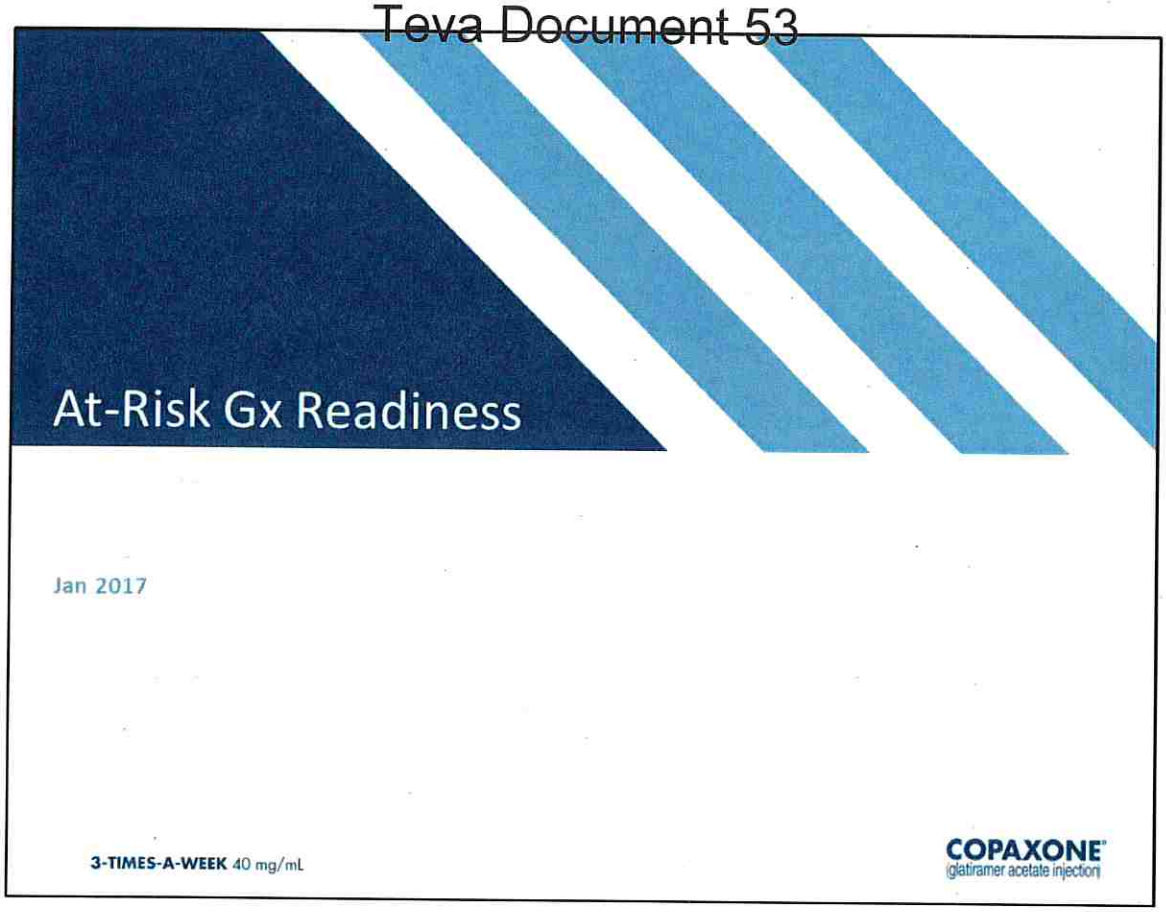


Teva is interested in understanding payer control in MS, anticipating a potential entry of generic Copaxone 40mg

Market and Project Background	▪ Teva's Copaxone franchise is a mature MS brand and long time market leader ▪ Copaxone currently has two formulations – 20MG and 40MG, and the 20MG formulation's branded generic Glatopa was launched in 2015 by Sandoz ▪ Prior to Glatopa's launch, Teva released and promoted a long-acting Copaxone 40MG, effectively pushing existing and new patients to the branded 40MG and minimizing generic substitution ▪ As part of Copaxone's life-cycle management and preparing for its LoE, Teva is interested in contracting strategy optimization
Project Objectives	▪ The primary objective for the project is to assist Teva in understanding payer control across therapeutic areas – namely Multiple Sclerosis (MS), Rheumatoid Arthritis (RA), and Type II Diabetes (GLP-1s) ▪ Our segmentation analysis examines a payer's willingness to control vs. its ability to control utilization, using analog markets to assess risk of increased controls

AMUNDSEN CONSULTING
a division of [illegible]

Teva Document 52


At-Risk Gx Readiness
Jan 2017
3-TIMES-A-WEEK 40 mg/mL
COPAXONE
(glatiramer acetate injection)

Market Access Update

- House Brand Accounts:
  - Contracting Strategy for Brand over Generic. Discussions have taken place with these designated accounts.
    - — 2 of the House Brand target accounts will be executed at the formulary level. Blocking the generic via formulary restriction.
    - — 2 of the House Brand target accounts will be executed at the specialty pharmacy level. Pharmacy will fill brand regardless if prescribed as generic.

- Loyalty Accounts:
  - Contracting for continued formulary access, without any step edits through Gx. These plans may decide to add Gx to their formulary. Assume modest increases in rebate for this strategy (1-5 points)
    - — HCP loyalty and DAW strategy will help retain many of these branded units.
    - — Assumed retention of 50% of 40mg units

Teva Document 53

From: Brendan O'Grady
Sent: Wednesday, January 31, 2018 4:05 PM
To: [redacted]
Subject: RE: CONFIDENTIAL: ***FORMULARY UPDATE*** Insurer Commercial/MPD & COPAXONE 40mg

I have to get up in 2.5 hours to fly to Switzerland. I may just stay up and work on email.

Best regards,

Brendan P. O'Grady EVP and Head of North America

Highly Confidential

IMPROVING HEALTH. MAKING PEOPLE FEEL BETTER | CARING | LEADING THE WAY

OUR PURPOSE & VALUES

From: [redacted]
Sent: Wednesday, January 31, 2018 3:05 PM
To: Brendan O'Grady
Subject: Re: CONFIDENTIAL: ***FORMULARY UPDATE*** Insurer Commercial/MPD & COPAXONE 40mg

I know that! I guess I am missing my pint in texting. We will talk live someday. Safe travels

Sent from my iPhone

On Jan 31, 2018, at 4:02 PM, Brendan O'Grady Highly Confidential wrote:

> No as last I understood, Specialty Pharmacy only ships brand Copaxone no matter how it is written or what the formulary states. That is why this has little impact. Then again, my knowledge may be dated.
>
> Best regards,
>
> <image001.png> Brendan P. O'Grady EVP and Head of North America
>
> **Highly Confidential**
>
> <image002.png>

From: [redacted]
Sent: Wednesday, January 31, 2018 3:01 PM

To: Brendan O'Grady
Subject: Re: CONFIDENTIAL: ***FORMULARY UPDATE*** Insurer Commercial/MPD & COPAXONE 40mg

Ok- thanks. I thought they only received that for non- mail order and since 95% of Insurer is mail order through Specialty Pharmacy it doesn't sound so great, so I obviously need to understand it better

Sent from my iPhone

On Jan 31, 2018, at 3:56 PM, Brendan O'Grady Highly Confidential wrote:

> Because PBM is getting an additional rebate to fill all "glatiramer" or Copaxone scripts with Copaxone...if a doctor orders generic glatiramer or the pharmacy benefit mandates it be filled as a generic, it will come in a plain box with Copaxone inside. Win-win for all...
>
> Best regards,
>
> <image001.png> Brendan P. O'Grady EVP and Head of North America
> **Highly Confidential**
>
> <image002.png>

From: [redacted]
Sent: Wednesday, January 31, 2018 2:54 PM
To: Brendan O'Grady
Subject: RE: CONFIDENTIAL: ***FORMULARY UPDATE*** Insurer Commercial/MPD & COPAXONE 40mg

Sorry for the question – I worked it out in my piddly little mind today, and kind of understand it better. Just don't know how PBM benefits from this, as they are the PBM for Insurer I get how Specialty Pharmacy and Insurer would benefit .....oh well – another learning curve will possibly keep my mind young.

Warm Regards,

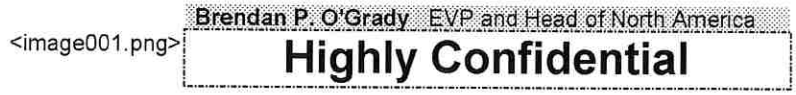
<image001.png> [redacted]
Highly Confidential

<image002.png>

From: Brendan O'Grady
Sent: Wednesday, January 31, 2018 3:52 PM
To: [redacted]
Subject: RE: CONFIDENTIAL: ***FORMULARY UPDATE*** Insurer Commercial/MPD & COPAXONE 40mg

Because they are looking at the future...this has almost zero impact on actual prescriptions – I will explain later. Also, the NP status means little as we buy the patients copay down to zero anyway. Unless they NDC block Copaxone 40mg, we are fine. That is why they did not inform the reps because the actual impact is very low and it would just confuse them.

Best regards,



<image002.png>

From: [redacted]
Sent: Wednesday, January 31, 2018 1:02 PM
To: Brendan O'Grady
Subject: FW: CONFIDENTIAL: ***FORMULARY UPDATE*** Insurer Commercial/MPD & COPAXONE 40mg

Hi,

I thought I would take you down five million levels and let your brain totally veg out on things so below your pay grade.

I realize we have the Specialty Pharmacy House Brand Strategy that will lessen the blow on this Insurer decision, but – do why would a plan of this size make this type of move if they were being offered a rebate that made a brand drug more economical than a generi? (at least I am assuming that is the case, but haven't spoken to [redacted] about it yet, as it is not official that this is my account.)
Wish you weren't so important and busy with higher level decisions and control – I need you as my mentor! Ahahahha!

Warm Regards,

<image002.png>

From: [redacted]
Sent: Thursday, January 18, 2018 6:37 PM
To: USKAN_DIST_MANAGED_MARKETS_FIELD
Subject: CONFIDENTIAL: ***FORMULARY UPDATE*** Insurer Commercial/MPD & COPAXONE 40mg

Greetings,

In follow-up to our discussion on this topic from last Friday's call, [redacted] the COPAXONE brand team, [redacted] and I agreed that **the house brand strategy with** Specialty Pharmacy **that impacts this formulary change should not be formally shared with the sales team**. We did agree, however, to communicate this detail with [redacted] and the ASDs personally - which I completed yesterday. I also confirmed with the COPAXONE IC team that representatives WILL get credit for scripts getting filled with the brand at Specialty Pharmacy through **Insurer**

When supporting the TN sales force on this coverage change, please align to the confidential nature of the Specialty Pharmacy House Brand strategy and encourage representatives to use DAW as their reactive response in the field.
Don't hesitate to reach out to [redacted] or me if you would like to discuss further.

Best regards,

<image003.png> [redacted] **Highly Confidential**

<image004.jpg>

From: [redacted]
Sent: Thursday, January 18, 2018 3:33 PM
To: TevaUS_TNS_Sales_Regional_Managers
Cc: USKAN_DIST_MANAGED_MARKETS_FIELD
Subject: ***FORMULARY UPDATE*** **Insurer** Commercial/MPD & COPAXONE 40mg

Greetings TN Sales Leadership,
See below for a COPAXONE 40mg coverage update. Effective immediately, **Insurer** Commercial and Medicare Part D will move COPAXONE 40mg to *non-preferred* status. This change impacts new starts immediately, and current COPAXONE patients will be grandfathered until annual PA re-submission. Providers should document DAW on the PSR to ensure highest probability of a branded fill.

Please don't hesitate to contact me if you have any questions about this coverage change.
Best regards,

<image003.png> [redacted] **Highly Confidential**

<image004.jpg>

Effective 1/1/17, COPAXONE 40mg is Non-Preferred on Insurer Commercial & Medicare Part D

Effective immediately, COPAXONE 40mg is Non-Preferred on **Insurer** Commercial & Medicare Part D (representing ~15 million and ~1 million lives respectively).

- This formulary change impacts new patients where HCPs should request DAW on the PSR
- Current COPAXONE 40mg patients will be grandfathered until their annual PA submission, then will also be subject to restrictions listed below

Restrictions:

- Requests for Brand Copaxone 20mg/ml or Brand Copaxone 40 mg/ml must meet the following criteria:
    - Individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response or intolerance to one of the following:
        - One preferred beta interferon agent (Avonex, Betaseron Plegridy) or
        - Tecfidera or
        - Glatiramer 20mg/ml, glatiramer 40mg/ml, or Glatopa 20mg/ml
- Current COPAXONE patients will be grandfathered until their annual PA submission, then will also be subject to the step edit through generic GA
- Providers should document DAW on the PSR to ensure highest probability of a branded fill

Effective Date: January 1, 2018

Plan Details:

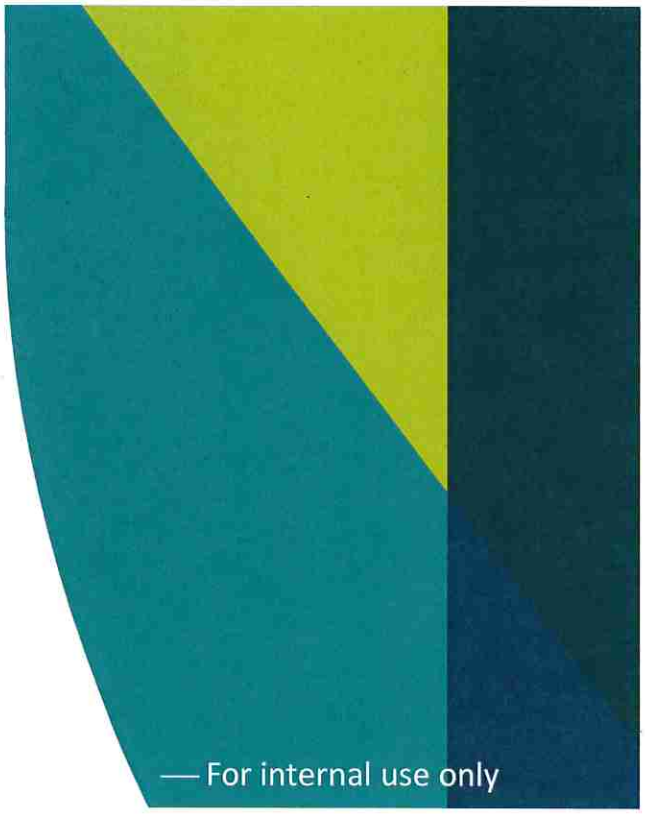
- **Insurer** Commercial Pharmacy Benefit represents ~15 million lives (includes health exchange)
- **Insurer** Medicare Part D represents ~1 million lives
- This announcement does not impact **Insurer** Managed Medicaid (~5 million lives) as branded COPAXONE 40mg is non-formulary
- **Insurer** formulary decisions impact the following health plans:

Health Plans

Contact your manager if you have any questions about this formulary change.

Copaxone House Brand Review

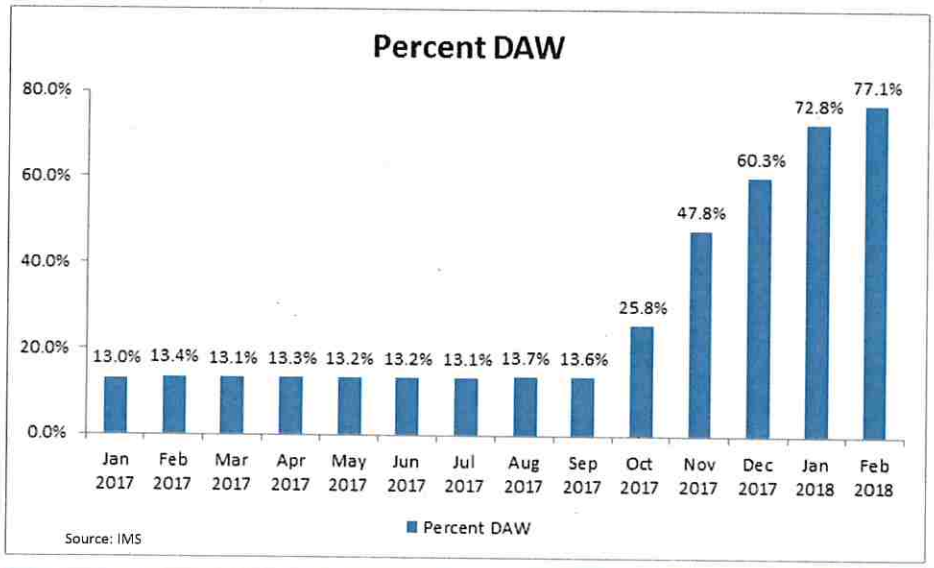
April 5th, 2018



Teva Document 55

Teva Document 55

Copaxone 40mg National DAW



Teva Document 55

2016 AOP budget and priorities

Asaph Naaman | Board STC | November 30th, 2015

Teva Document 56

Benchmarking our budget and multiples

	R&D Budget (Est. 2015 $M)	R&D Budget (2015 % of Rev)	EPS (Est. 2015)	Multiples (Est. 2015) ↓
UCB	1,116	26.6%	1.9	48.4
Novo Nordisk	2,214	13.5%	2	28.4
Celgene	2,394	25.9%	4.1	28.3
Eli Lilly	4,821	24.0%	3.3	24.6
Roche	8,380 (2014)	21.5%	15	19.1
Biogen	2,093	19.4%	16	18.5
GSK	4,802	12.8%	1.2	18.3
Bayer	2,283 (2014)	15.6%	7.9	17.4
Novartis	7,331 (2014)	22.4%	5.3	16.9
J&J	6,213 (2014)	19.2%	6.3	16.3
Pfizer	7,510	15.8%	2.1	16
Sanofi	5,864 (2014)	14.3%	6.3	15.4
Merck	6,744	16.7%	3.6	15.2
Abbvie	3,630	15.8%	4.3	15
Teva (specialty)	897	10.0%	5.4	11.2
AstraZeneca	5,211	22.5%	4.1	7.8

Source: EvaluatePharma (where indicated, 2014 data was used due to lack of separate forecast for pharma segment)

Teva Document 56

Healthcare Costs in the U.S. Talking Points

Intended for use by Corporate Communications,

IR and Teva Leadership with media and analyst audiences only (Oct 18, 2016)

Background

Recent events have placed an increased focus and request for commentary on healthcare costs in the U.S., including:

- Mylan Inc. has come under sharp criticism from a variety of stakeholders, including political candidates and patients, for the recent dramatic price increase of EpiPen, as well as the salary increases for top executives, especially CEO Heather Bresch
    - In September 2016, Heather Bresch testified before the House Oversight and Government Reform Committee, justifying that the profits the company has collected compared to the price is not what people assume
    - The Committee called for a Justice Department investigation to determine if the company acted illegally when it classified EpiPen as a generic drug and qualified for lower rebate payments to states
    - In response to the criticism, Mylan announced a series of measures to mitigate the cost to consumers, including the release of their own generic version and a direct-ship option, which allows consumers to buy the product directly from the company instead of through pharmacies
        - While positioned as a positive from Mylan's perspective, there is still a focus on the extremely high price of the branded EpiPen, as well as scrutiny surrounding the company making a generic version of its own branded product and ultimately, still profiting
- Shortly following the Mylan issues, Allergan CEO Brent Saunders posted commentary on the company's position on drug pricing on his executive blog
    - Resulting response has been factual and mostly positive
- In May 2016, Valeant issued a press release announcing the formation of a committee to oversee drug pricing following their pricing scandal and subsequent Senate hearings in October 2015
- In addition to highly critical media response to these events, several Federal and State legislative proposals are currently being floated whose professed aim is lowering prescription drug spending, and there is increasingly negative election rhetoric surrounding the upcoming U.S. Presidential election.

Key Messages – Teva Overall:

- Teva is a diversified, world-leading pharmaceutical company dedicated to the development of safe, effective and quality medicines. Upholding our commitment to maintaining a fundamental focus on patients and improving their treatment experiences has been, and remains, at the core of Teva's heritage.

- Teva acknowledges that the pharmaceutical industry as a whole needs to be mindful and responsible as to what the healthcare system can tolerate when pricing medications and each company's role in keeping down healthcare costs.

- Teva is committed to the development and production of high-quality, affordable generic medicines and innovative specialty medicines for doctors, pharmacists, and most importantly, patients.
    - With nearly 600 generic medicines available, Teva has the largest portfolio of FDA-approved generic products on the market.

- Teva is disciplined in our R&D and branded commercial strategies and our approach has resulted in research treatments and technologies that have fundamentally changed the way diseases are understood and treated.

- The pharmaceutical industry as a whole provides tremendous overall value to the healthcare system.

- Recent attention on the cost of medications in the U.S. stemming from both the political arena and specific actions by select companies raises an important issue to the forefront of today's conversation– but also paint a narrow view of industry practices and undermines the important strides Teva and other companies are making through investment in research and drug discovery to prevent and treat complex life altering disorders.

- Industry pricing decisions are largely reflective of investments made to research, develop and commercialize high quality, safe and effective products, the health benefits of products and the invaluable patient services companies provide.

Generics-Specific Messages:

- Generics, specifically, create tremendous additional savings.
- As the largest generic drug manufacturer in the U.S. market, Teva is responsible for 12.7 percent of the total savings accruing from generic drugs. This amounts to approximately $214 billion in savings in the last decade attributable to Teva. Of the $214 billion in generic healthcare savings attributable to Teva, $82 billion accrued to the federal government, $62 billion to Medicare, and $20 billion to Medicaid (state and federal)..[i]
- It is a misconception that the overall cost of generic drugs is increasing.
  - Recent data shows that the generic cost trend continues to decline. In fact, drug costs are a small portion (approximately 10%) of overall health system costs and generic drugs are an even smaller fraction of that expenditure.
  - To date, we continue to see depreciation of our generic product prices year over year.
- Like all commodity markets, the generic drug market is dynamic and prices fluctuate based on external factors.
  - The number of competitors in the market.
  - The cost of ingredients can fluctuate based on supply and demand (i.e., fewer suppliers in the market, the cost of ingredients increases).
  - The cost of production can change due to requirements by the FDA.
- Generic drug manufacturers can proudly point to a legacy of savings and access that brings expensive treatments within reach for millions of people:
  - The IMS Institute for Health Informatics found that generic drugs were responsible for $254 billion in health system savings in 2014, bringing the total savings over the last 10 years to $1.68 trillion. A May 2015 report from AARP notes that retail prices for generic drugs dropped an average of 4% in 2013, marking nearly a decade of consecutive years of decreasing generic drug costs. The report also notes that 73% of generic drugs in the study experienced price decreases.
  - An August 2015 Drug Channels blog noted that in the second quarter of 2015 almost half (44%) of generic drugs experienced a decline in cost.

Key Messages - Specialty:

- We will continue to make calculated investments to research, develop and commercialize safe and effective treatments in areas of true unmet need and innovation aimed at improving the treatment experience for patients. For example:
    - Teva has invested in numerous development programs in CNS focused on complex high unmet need areas such as neurodegeneration and movement disorders which include orphan diseases like Huntington's disease, as well as Tourette syndrome, Parkinson's disease, multiple sclerosis, and tardive dyskinesia. Teva is currently developing [redacted] pridopidine, [redacted] and other undisclosed assets in the neurodegenerative category.
    - Further, Teva works to ensure proven safe and effective treatments, such as a COPAXONE® (glatiramer acetate injection), are available to patients. Through continued innovation to the product to enhance the patient experience, three-times-a-week COPAXONE® 40 mg/mL now offers the same proven COPAXONE® that patients and physicians know and trust with 60 percent fewer injections compared to the daily injection regimen with COPAXONE® 20 mg/mL.

Copaxone Specific Pricing-Related Messages (*reactive only*):

- The current wholesale acquisition cost (WAC) for COPAXONE® (glatiramer acetate injection) is competitive relative to other therapies in the category. COPAXONE® 40 mg/mL offers a strong value proposition when compared to Glatopa™.
- Teva continually evaluates the needs of MS patients to ensure our supportive services, like Shared Solutions®, appropriately meet patient needs. We believe that patients should not have to choose, interrupt or discontinue their MS therapy because of financial reasons. As a part of Shared Solutions®, COPAXONE Co-Pay Solutions® is one of several financial assistance offerings that help people living with a relapsing form of MS start and/or stay on COPAXONE®.

- For more than 30 years, Teva has pursued its MS research with the goal of providing effective, safe and tolerable therapies for MS patients. This ongoing commitment to patients was evidenced by the development of three-times-a-week COPAXONE® 40 mg/mL, thereby expanding the suite of COPAXONE® formulations and services to benefit patients with relapsing forms of MS.

Questions & Answers/Generics:

Q1: Why is Teva pricing its generic drugs higher, when generics are supposed to be affordable alternatives to branded therapeutic options?
A1: It is a misconception that the overall costs of generic drugs are increasing. Like all commodity markets, the generic drug market is dynamic and prices fluctuate based on external factors. Generic medicines continue to be an affordable alternative to brand therapies.

Q2. What are the circumstances that cause Teva to increase price on a generic drug?
A2: As a commodity market, the generic drug market is dynamic and prices fluctuate based on external factors. A generic drug price is adjusted (either up or down) because the market demands a change.

Q3: What percentage are prices usually increased?
A3: It is a misconception that the overall cost of generic drugs is increasing.

- Express Scripts Prescription Price index shows that generic drug prices have been cut in half since 2008. Compared to generic drug prices in December 2012, in December 2013 generic drug prices were15.9% lower.
- According to a recent survey of insurance plan benefit designs, the average copay for generic drugs is generally one-third the copay for preferred brand drugs and one-fifth the copay for non-preferred brand drugs. Similarly, research from the Department of Labor's Bureau of Labor Statistics shows that the median copay for generic drugs in 2012 was $10 and for brand drugs, $30. Despite price fluctuations that could affect pharmacy costs, median generic drug copays have remained constant in recent years.
- To date, we continue to see depreciation of our generic product prices year over year.

Q4: What impact does a generic price increase have on patients?
A4: For patients with insurance, there is no impact based on the pre-determined copay with the insurance provider. For patients that pay out-of-pocket for medicines, they pay the price that each pharmacy sets for a product, and not a price set by Teva.

Question & Answers/Copaxone (Specialty):

Q1: What is the current price of COPAXONE®?

A1: The current wholesale acquisition cost (WAC) for COPAXONE® (glatiramer acetate injection) is competitive relative to other therapies in the category. COPAXONE® 40 mg/mL offers a strong value proposition when compared to Glatopa™.

Q2: Will you take further pricing actions?

A2: We do not comment on future pricing actions.

Q3: Can you explain the COPAXONE® gross profit margin in relation to the cost of the therapy?

A3: The profit margin associated with COPAXONE® (glatiramer acetate injection) is similar to other branded molecules in this category, and is largely reflective of investments made to research, develop and commercialize a safe and effective relapsing MS product. We plan to continue to focus on innovation aimed at improving the treatment experience for patients.

Q4: Why is COPAXONE® 40 mg/mL priced lower than COPAXONE® 20 mg/mL?

A4: COPAXONE® (glatiramer acetate injection) remains competitively priced within the category, particularly considering it is the market leading product. Three-times-a-week COPAXONE® 40 mg/mL offers an outstanding value proposition and a co-pay assistance program that will allow eligible commercial patients to access the product with no out-of-pocket cost. Certain terms and conditions apply.

Q5: What was the most recent price increase for COPAXONE® and when did it happen?

A5:

The current wholesale acquisition cost (WAC) for COPAXONE® (glatiramer acetate injection) is competitive relative to other therapies in the category. COPAXONE® 40 mg/mL offers a strong value proposition when compared to Glatopa™, as there is only a XX% difference on annual wholesale acquisition cost of therapy.

- ***IF PRESSED*:** As of January 1, 2016, the WAC for a 30 day package of COPAXONE® (glatiramer acetate injection) 20 mg is $6,593.23 and a 28 day package of COPAXONE® 40 mg/mL is $5,403.00.

Q6: Why did Teva increase the price of COPAXONE®?

A6: The decision to increase pricing is determined by a number of factors as we constantly evaluate the marketplace and needs of our patients. We work hard to ensure the price of COPAXONE® - the global market-leading treatment for patients with relapsing forms of MS - reflects the clinical utility of the drug, while maintaining our commitment to ongoing clinical research.

- ***If pressed:*** We do not comment on specifics of our pricing strategy.

Q7: What are the factors that determined this price increase?

A7: We do not comment on specifics of our pricing strategy. We remain committed to ensuring the price of COPAXONE® reflects the clinical utility of the drug, while maintaining our commitment to ongoing clinical research.

Q8: Why is there a difference in the out-of-pocket costs for daily COPAXONE® 20 mg/mL and three-times-a-week COPAXONE® 40 mg/mL?

A8: The co-pay assistance for COPAXONE® 40 mg/mL was enhanced to help patients maintain financial access to the therapy.

Q9: How can you justify the price escalation of COPAXONE® over the last decade?

A9: COPAXONE® remains competitively priced within the category, particularly considering it is the market leading product. While COPAXONE® was approved for relapsing forms of MS in 1996, Teva's investment in the MS category spans three decades. Teva works to ensure we meet patient's needs and we continue to invest in researching new developments that directly translate to increased options for COPAXONE® patients. This is evidenced by:

- A robust ongoing clinical trial program designed to continue innovation that has included studying alternative dosing options such as the FORTE (double dose) and 0.5 mL studies, investment in the GALA study to bring three-times-a-week COPAXONE® 40 mg to market, plus continued investment in our overall MS program with 4 major trials for Redacted - Other Product Information
- Research has also led to an evolution in the way COPAXONE® in administrated with advances taking COPAXONE® from a frozen product to a pre-filled syringe and now the availability of the **auto***ject*®*2 for glass syringe*
- We have also invested in the Shared Solutions® network of personalized support, education, and training with free tools to help patients stay on track of their therapy with the goal of enhancing compliance and a co-pay assistance program allow eligible commercial patients to access the product with no out-of-pocket cost.

If pressed: Three-times-a-week COPAXONE® 40 mg/mL offers an outstanding value proposition based on the efficacy, safety, and tolerability that the medicine offers patients and physicians. Further, COPAXONE® 40 mg/mL offers a strong value proposition when compared to the one available generic, as there is only a 2-3% difference on annual wholesale acquisition cost of therapy, but an enhanced patient experience with three-times-a-week COPAXONE® 40 mg/mL with 208 fewer injections per year as compared to daily COPAXONE® 20 mg/mL.

Q10: What is Teva doing to help patients who cannot afford COPAXONE®?

A10: Teva continually evaluates the needs of MS patients to ensure our services, like Shared Solutions®, appropriately meet patient needs. We believe that patients should not have to choose, interrupt or discontinue their RMS therapy because of financial reasons. As part of Shared Solutions®, COPAXONE Co-Pay Solutions® is one of several financial assistance offerings that help people living with a relapsing form of MS start and/or stay on COPAXONE®. These efforts contribute to helping patients maintain financial access to COPAXONE®.

Patients who require financial assistance are invited to call the Shared Solutions® team at 1-800-887-8100. Shared Solutions® has assisted thousands of patients for more than a decade and has completed more than two million patient calls.

###

[i] Matrix, "Teva Pharmaceuticals: Providing Critical Health and Economic Benefits in the United States." June 2016.

From: Katie Hiett
Sent: Tuesday, July 1, 2014 7:56 PM
To: Brendan O'Grady
Subject: Re: APPROVAL REQUIRED: COPAXONE 20MG JULY 2nd, 2014 PROPOSED PRICE INCREASE

Maybe we still have time to convince them to sit on the CP until FDA accepts or separate it from the price increase.

Sent from my iPhone

On Jul 1, 2014, at 6:10 PM, "Brendan O'Grady" Highly Confidential wrote:

> Just for clarity...an important part of our generic defense strategy is creating price separation between 20mg and 40mg. We can do that via increased discounts on 40mg or raising the price on 20mg. I prefer the latter. Delaying a pricing action to mid-August, or later, impedes our ability to gain access for 40mg with resistant payers, makes a generic more appealing to payers, and could dampen further conversion strategies.
>
> Sent from my iPhone
>
> On Jul 1, 2014, at 5:50 PM, [redacted] Highly Confidential wrote:
>
> [redacted]
>
> I just spoke to [redacted]nd, although this may be approved by the pricing committee via this email, please do NOT take any action with customers, pricing compendia, contracts or the system until there is a final confirmation from Rob Koremans relative to the proposed increase. We will have a decision one way or another from Rob tomorrow.
>
> Thank you.
>
> [redacted]
> Teva Pharmaceuticals
> Director, Trade Operations
> **Highly Confidential**
>
> Sent from my iPhone.
>
> On Jul 1, 2014, at 6:42 PM, [redacted] Highly Confidential wrote:
>
> Good afternoon,
>
> Attached is the July 2nd, 2014 Proposed Price Increase documentation and supporting analysis for Copaxone 20mg. Your approval is required to move forward.

For your reference, following are the actions taken thus far:

- The proposed price increase was submitted by the BU.
- The Pricing Group prepared the financial evaluation. Please see attached.
- A final confirmation was received by the BU regarding this proposed price increase, to be effective July 2nd, 2014 at 3:01p (ET). Based on discussions with [redacted] the July 2nd timing was suggested as there could be issues with customers who have closed for the holiday. This will allow them enough time to implement the new price in their systems.
- Proposed price increase provides a 10% disparity on a daily cost of therapy basis between Copaxone 20mg and Copaxone 40mg.

ACTION REQUIRED: Due to the urgency of this request, please review the attached support and respond via email with your approval so we may execute the pricing action. I will circulate the formal documentation for signature in the next few days.

DUE BY: Please respond via email by noon, June 2nd. We typically like to provide more lead time for you, but with the sensitivity of this pricing action and resulting tight timeframe, we appreciate your help and quick response.

Please let me or Katie know if you have any questions.

Thank you in advance for your help!

[redacted]

<image001.png> [redacted] Senior Pricing Analyst, US Market Access

Highly Confidential

<COPAXONE 20MG Price Increase_07.02.2014.pdf>