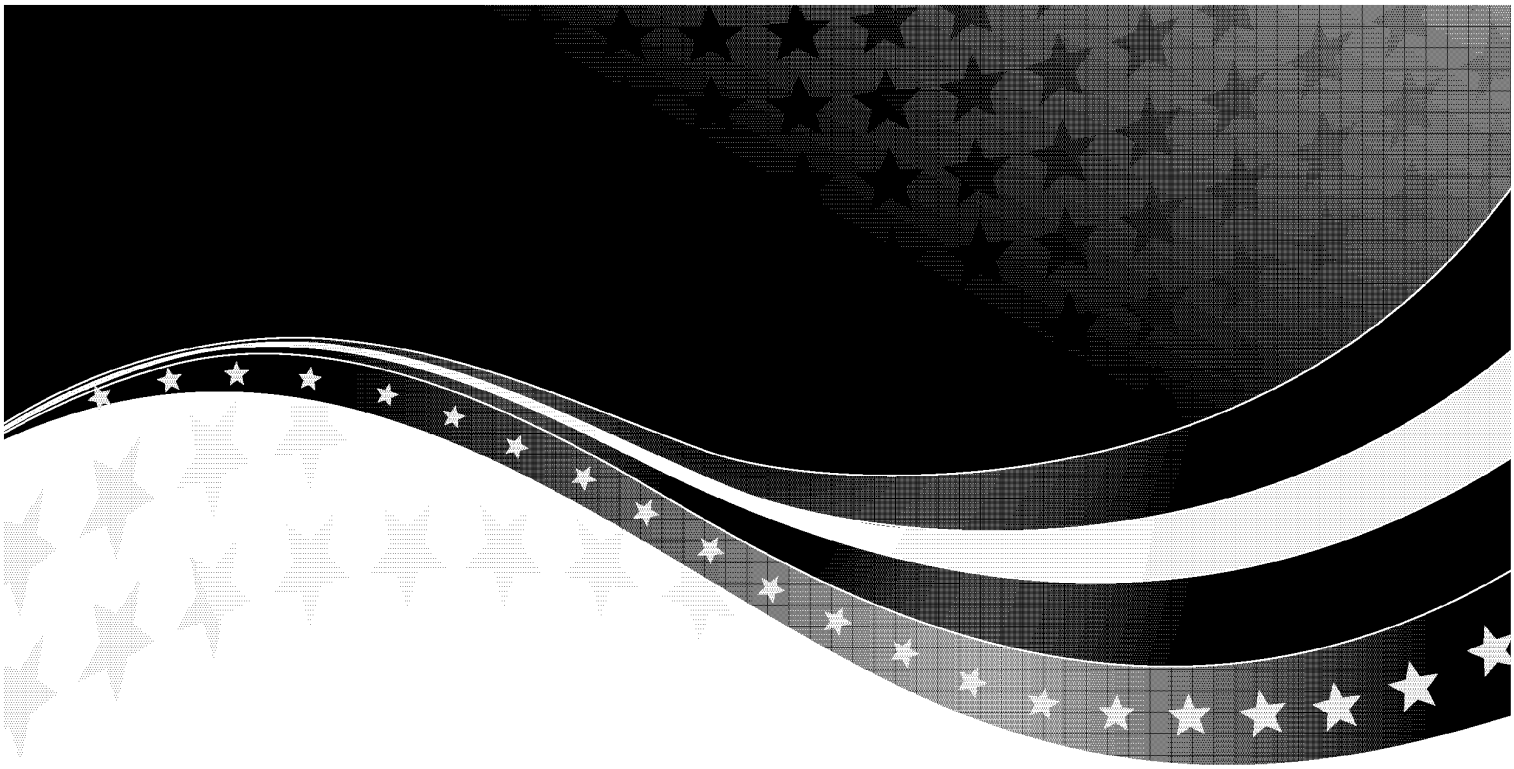


TEVA EXECUTIVE FLY-IN

September 2013

BRIEFING BOOK

PLAINTIFFS TRIAL EXHIBIT
P-23265_00001

AGENDA

Sunday, September 22, 2013

3:00 pm	Dr. Levin departs NY Penn Station for DC (Train # 2253)
5:53 pm	Dr. Levin arrives Union Station Met by Frederic Transportation in black sedan. Proceeds to Hotel George.
6:45 pm	Frederic Transportation mini-van pickup from Hotel George front. Proceeds to the Capitol Grille. Passengers: Debra Barrett, Dr. Levin, Larry Downey, Allan Oberman, Fran Zipp, Jim Ottinger
7:00 pm	Dinner with Teva/FDA meeting participants Capitol Grille, Fabric Room (contact is Vina Moore, cell: 202-255-6604) Location: 601 PA Avenue, NW (6th & PA) (202-737-6200) Attendees: Dr. Levin, Larry Downey, Allan Oberman, Fran Zipp, Debra Barrett, Grant Erdel, Terri Stewart, Jim Ottinger
10:23 pm	Dr. Hayden arrives Washington Reagan airport (Air Canada 7360) Met by Frederic Transportation at Air Canada front curbside. Proceeds to Hotel George.
11:00 pm	Debra Barrett & Dr. Hayden meet in Hotel George lobby.

Monday, September 23, 2013

6:30 am	Pickup of FDA meeting attendees from Hotel George front by Frederic Transportation mini-van. *Note: Hotel doesn't start serving breakfast until 7:30 am, so everyone will go to the Teva DC office for a light meal. Dr. Hayden will bring his luggage with him and it will be transferred to the car that picks him up from PhRMA at 4:30pm* Proceeds to Teva DC office. Location: 25 Massachusetts Avenue, NW, Suite 440, 202-639-3800

AGENDA

Monday, September 23, 2013

	Passengers: Dr. Levin, Larry Downey, Allan Oberman, Fran Zipp, Debra Barrett, Rich Egosi , Jim Ottinger, Dr. Hayden
7:05 am	Frederic Transportation departs Teva DC office for FDA.
8:30 am - 9:30 am	Meeting at FDA with Dr. Janet Woodcock, Director, Center for Drug Evaluation & Research; John Jenkins, MD - Office of New Drugs (OND); Kathleen Uhl, MD - Office of Generic Drugs (OGD); Howard Sklamberg, JD - Office of Compliance; Sandra Kweder, MD – OND; Kristin Phucas - Office of Executive Programs Location: White Oak location, 10903 New Hampshire Avenue, Room: 1215 Silver Spring, MD 20993 Attendees: Dr. Levin, Larry Downey, Allan Oberman, Fran Zipp, Debra Barrett, Dr. Hayden, Jim Ottinger
Approx. 9:45 am	Frederic Transportation Car #1 proceeds to the White House Passengers: Debra Barrett, Dr. Levin, Dr. Hayden, Rich Egosi
11:30 am	Meeting with Valerie Jarrett, Senior Advisor to POTUS; Ari Matusiak, Special Assistant to the President and Director of Private Sector Engagement; Yohannes Abraham, Special Assistant to the President and Chief of Staff for the Office of Public Engagement and Intergovernmental Affairs Location: The White House Attendees: Debra Barrett, Dr. Levin, Dr. Hayden, Rich Egosi, Moses Boyd
12:30 pm	Frederic Transportation leaves White House and proceeds to Occidental Grille Passengers: Debra Barrett, Dr. Levin, Dr. Hayden, Rich Egosi
12:45 pm – 1:45 pm	Debra Barrett takes Dr. Levin and Dr. Hayden, Rich Egosi to lunch Location: Occidental Grille, 1475 Pennsylvania Ave NW 202-783-1475 *Note: Reservation under 'Barrett' (spoke to Alicia, requested secluded table)*
1:45 pm	Frederic Transportation departs Occidental for Chamber of Commerce building
2:00 pm	Meeting with Thomas Donohue, President and CEO, U.S. Chamber of Commerce; Lisa Rickard, Exec. VP, Chamber & Head of Institute for Legal Reform; Harold Kim,

AGENDA

Monday, September 23, 2013

VP of Institute for Legal Reform

Location: 1618 H Street, NW, 4th Floor, 202-659-6000
Note: Chamber will have escort waiting (McMickle will meet in lobby)

Attendees: Debra Barrett, Dr. Levin, Dr. Hayden, Rich Egosi, John McMickle

3:00 pm — Frederic Transportation departs Chamber of Commerce for PhRMA

Passengers: Debra Barrett, Dr. Levin, Dr. Hayden, Rich Egosi

3:30 pm — Meeting with John Castellani, President & CEO, PhRMA

Location: 950 F Street, NW, Suite 300, 202/835-3400

Attendees: Debra Barrett, Dr. Levin, Dr. Hayden, Bill Burke

t.b.a. — Frederic Transportation departs PhRMA and proceeds to Hotel George

As of 4:30pm — Frederic Car #2 on standby to take Dr. Hayden to Reagan Airport

4:30 pm – 5:00 pm — Break
Debra Barrett, Dr. Levin, Rich Egosi

t.b.a. — Frederic Transportation departs Hotel George for event at Ambassador Oren's residence.

Passengers: Dr. Levin, Rich Egosi, Debra Barrett

7:00 pm — Event at Ambassador Oren's Residence

Location: 2916 Chesapeake Street, NW, Washington, DC 20008

Attendees: Dr. Levin, Rich Egosi, Debra Barrett

Note: Frederic Transportation stays on standby at Oren residence to take Dr. Levin and Rich Egosi back to Hotel George.

AGENDA

Tuesday, September 24, 2013

7:45 am	Dr. Levin & Allan Oberman have breakfast at Hotel George *Note: Reservation under Dr. Levin (breakfast is served as of 7:30am)*
	Dr. Levin walks to Teva DC office
	Location: 25 Massachusetts Avenue, NW Suite 440, 202-639-3800
9:30 am	U.S. Government & Public Affairs staff gives presentation to Dr. Levin
	Location: Teva DC office large conference room
	Attendees: Dr. Levin, Rich Egosi, Debra Barrett, Teva DC Staff
12:00 – 1:30	Patient Advocacy Lunch
	Location: Teva DC office, Large conference room
	Participants: Debra Barrett, Dr. Levin, Rich Egosi, Chris Jennings, Deputy Assistant to the President for Health Policy and Coordinator for Health Reform; Dr. Mark McClellan, The Brookings Institution; John Rother, President and CEO, National Coalition on Health Care; Ron Pollack, Member, Board of Directors, Enroll America, Executive Director, Families USA; Nancy Davenport – Ennis, Founder and Chairman of the Board, National Patient Advocate Foundation; Alan Balch, PhD, CEO, National Patient Advocate Foundation
	Teva DC staff attendees: Nicole Mann, Terri Stewart, Susie Ahn. Also: Bill Burke, Ken Nahigian.
Approx. 1:30 pm	Frederic Transportation departs Teva DC office for Hill Meetings
	Passengers: Debra Barrett, Dr. Levin, Grant Erdel
2:00 pm	Meeting with Senator Pat Toomey (R-PA)
	Location: 502 Senate Hart Building, 202/224-4254
	Attendees: Debra Barrett, Dr. Levin, Grant Erdel, Ginger Loper
3:30 pm	Meeting with Senator Jerry Moran (R-KS)
	Location: 361A Senate Russell Building, 202/224-6521

AGENDA

Tuesday, September 24, 2013

Attendees: Debra Barrett, Dr. Levin, Grant Erdel, Ginger Loper

4:15 pm — Meeting with Senator Robert Casey (D-PA)

Location: 393 Senate Russell Building, 202/224-6324

Attendees: Debra Barrett, Dr. Levin, Grant Erdel, Bill Burke

6:00 pm – 7:30 pm — Dinner with New York Senator Charles Schumer (D-NY)

Location: Bistro Bis Restaurant

Attendees: Senator Schumer, Debra Barrett, Dr. Levin, Bill Burke

Wednesday, September 25, 2013

8:00 am — Dr. Levin has breakfast meeting at Hotel George
Note: no reservation made yet. Need number of people attending.

As of 9:15 am — Frederic Transportation on standby at Hotel George front
Dr. Levin proceeds to Union Station

10:00 am — Dr. Levin departs Union Station (Amtrak # 2160)
Hotel check-out for Rich Egosi

Notes and Numbers of Importance

Frederic Transportation: 202-345-2322
Debra Barrett cell: 202-494-2812
Denise Barksdale cell: 202-236-2258
Larry Downey: 816-522-5057
(Admins: Joyce Foutz, 816-508-5497 and Michelle Toczek, 816-508-5051)
Dr. Hayden Canadian cell: 604-338-3807; Int'l cell: +972548887888
(Admin: Ravit Kotek Sela, +972-3-906-2355)
Dr. Jeremy Levin: +972-54-8883333
(Admin: Ronit Wajsman, +972-3-926-7208, Nadine Peimer +972-54-8884701 or Marianne Streisel, 215-591-3034)
Allan Oberman cell: 215-266-5098

(Admin: Cynthia Prediger, 215-591-8726)
Jim Ottinger cell: 610-745-1230
(Admin: Darlene Mickey, 610-727-6678)
Fran Zipp
(Admin: Dolores Stolzer, 215-591-8503)

Hotel information

Hotel George
15 E Street, NW
202-347-4200

Bistro Bis Restaurant (inside Hotel George): 202-661-2700

Hotel Confirmation numbers

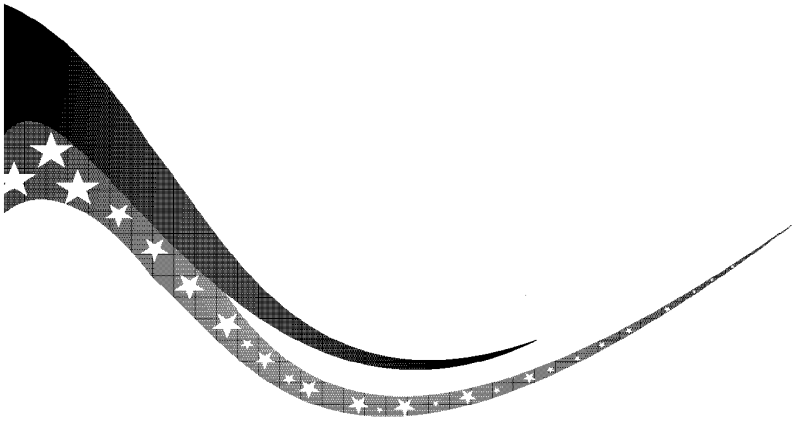
Dr. Jeremy Levin: In Sep 22 out Sep 25, CIPFSVM
Rich Egosi: In Sep 22 out Sep 25, CISQ0KZ
Dr. Hayden: In Sep 22 out Sep 23, CISRAEN

TABLE OF CONTENTS

PREPARED BY:

TEVA Global Government Affairs and Public Policy

FDA MEETING BRIEF



OVERVIEW

Given the breadth and scope of business Teva has before the U.S. Food and Drug Administration (FDA), it is critical to continue to pursue opportunities to expand our relationship and collaboration. Many of the officials you are meeting with have a long history with Teva and years of experience with our products, our facilities and our applications. Over this time, we have seen both cooperation and conflict with the agency and have weathered some high profile issues, such as Wellbutrin, drug shortages and Plan B to name only a few. We have more files pending before the FDA than any other pharmaceutical company and a number of pending issues, or ongoing "dialogues." This meeting is a chance to reintroduce and highlight Teva and our priorities, to demonstrate that the management team values the agency's work and is accessible to regulators, and to raise some critical issues, Redaction - Other Teva Product Copaxone. **We will have a slide presentation for the meeting which will come under separate cover.**

JANET WOODCOCK, M.D.

Director, Center for Drug Evaluation and Research

Dr. Janet Woodcock is the Director of the Center for Drug Evaluation and Research (CDER) at the FDA. The Center evaluates drugs for quality and effectiveness in clinical trials before they can be sold, provides healthcare professionals and patients with information about drugs and takes action against unapproved, contaminated or fraudulent drugs that are marketed illegally. The mission of CDER is to ensure that safe and effective drugs are available to improve the health of people in the United States. Dr. Woodcock has been at the agency since 1986 and maintains a great deal of control over the FDA's decisions and direction. Those who know her say that she is very confident about her leadership and vision and exerts tremendous influence over the agency's priorities She has an inner circle of advisors that she relies heavily on for support. She will probably discuss the quality initiative and the inspection metrics project with Teva, and also will likely ask about what Teva is doing about drug shortages.

Dr. Woodcock has led many of the FDA's drug initiatives. She introduced the concept of risk management in 2000 as a new approach to drug safety. Since 2002, she has led the Pharmaceutical Quality for the 21st Century initiative, the FDA's highly successful effort to modernize drug manufacturing and its regulation. In 2004, she introduced the FDA's Critical Path Initiative, which is designed to move medical discoveries from the laboratory to consumers more efficiently.

Most recently, Dr. Woodcock launched the Safety First and Safe Use initiatives, which are designed to improve drug safety management inside and outside the domain of the FDA.

Dr. Woodcock is often the face of the FDA during congressional hearings on controversial issues. She was the first at the FDA to suggest that biosimilar products could be approved in the U.S. market. Recently, she co-authored a scholarly paper discussing the causes of drug shortages. The paper states that the current pharmaceutical market does not reward quality, a claim that echoes industry concerns that low reimbursement is a principal reason for shortages.

Dr. Woodcock has previously served as the FDA's Deputy Commissioner and Chief Medical Officer. Prior to joining CDER, Dr. Woodcock oversaw the approval of the first biotechnology-based treatments for multiple sclerosis and cystic fibrosis in her position as Director of the Office of Therapeutics Research and Review in the FDA's Center for Biologics Evaluation and Research.

Dr. Woodcock received her medical degree from Northwestern University Medical School and her undergraduate degree from Bucknell University. She has held teaching appointments at Pennsylvania State University and the University of California at San Francisco.

JOHN JENKINS, M.D.

Director, Office of New Drugs

Dr. John Jenkins is the Director of the Office of New Drugs (OND) at the FDA. The OND provides regulatory oversight for investigational studies during drug development and makes decisions regarding marketing approval for new drugs, ensuring that safe and effective drugs are available in the U.S. Dr. Jenkins has a reputation as a no-nonsense personality who is fair, smart and sensible. He has testified before Congress many times and always looks, acts, and speaks very professionally. As Director of OND, he leads the FDA's effort to make decisions regarding the development and marketing of new generic and branded drugs and provides guidance to the industry on a number of clinical, scientific and regulatory matters. It should be noted that Dr. Jenkins' interest in generic issues has always been limited, with his preference

being that his subordinates should handle those issues.

Dr. Jenkins began his career with the FDA as a medical officer in the Division of Oncology and Pulmonary Drug Products. He subsequently served as Pulmonary Medical Group Leader and Acting Division Director before he was appointed as Director of the Division of Pulmonary Drug Products. Later, he became the Director of the Office of Drug Evaluation II, where he served until he was appointed to his current position.

Dr. Jenkins received his medical degree from the University of Tennessee at Memphis. He completed his postgraduate medical training in internal medicine, pulmonary disease and critical care medicine at the Medical College of Virginia at Virginia Commonwealth University. He is certified in Internal Medicine and Pulmonary Diseases by the American Board of Internal Medicine, and he is a Fellow of the American College of Chest Physicians. Dr. Jenkins has served as an associate professor of pulmonary and critical care medicine at the Medical College of Virginia and as a staff physician at the McGuire V.A. Medical Center. He joined the FDA in 1992.

KATHLEEN UHL, M.D.

Acting Director, Office of Generic Drugs

Dr. Kathleen Uhl (pronounced Yule) is the Acting Director of the Office of Generic Drugs (OGD) at the FDA. The OGD works to ensure that FDA-approved generic drugs meet the same safety and quality standards as their branded counterparts. She has garnered significant respect within OGD since her arrival at the beginning of this year and clearly wants to see the office succeed. She is a hands-on manager and is steeped in the details, which is in contrast to her predecessor, Dr. Gregory Geba, who rarely was present at the OGD metropark office. She is very goal oriented, and her expectations often exceed what is possible. She has said she is not interested in the OGD Director job, but if her methods succeed in turning around the downward slide of the office, she may not have a choice.

Dr. Uhl first served the FDA as a medical officer in the Office of Clinical Pharmacology and Biopharmaceutics with the Division of Anti-infective Drug Products and subsequently served as the Deputy Division Director in the Office of Post-marketing Drug Risk Assessment. She was the Medical Team Leader for the Pregnancy and Lactation Labeling Team and later became the Director of the Office of Women's Health.

Dr. Uhl has worked with the FDA on a number of initiatives concerning women's health issues, including advocating for the inclusion of women and minorities in clinical trials. Dr. Uhl served as an officer in the U.S. Army and was an investigator in malaria research and drug metabolism at the Walter Reed Army Institute of Research where she continues to be an active contributor. She received her medical degree from the Medical College of Pennsylvania and retains dual faculty appointments as an associate professor in Family Medicine and Internal Medicine at the Uniformed Services University of the Health Sciences. Dr. Uhl joined the FDA in 1998.

HOWARD SKLAMBERG, J.D.

Director, Office of Compliance

Howard Sklamberg joined the Office of Regulatory Affairs at the FDA in 2010 and was appointed as Director of the Office of Compliance in 2013. In this position, he leads the FDA's effort to ensure that companies comply with federal safety and quality standards. He hopes to improve the relationship of his office and the drug industry. He has previously worked for the U.S. Department of Justice, and he is an adjunct professor at the American University Washington College of Law.

SANDRA KWEDER, M.D.

Deputy Director, Office of New Drugs

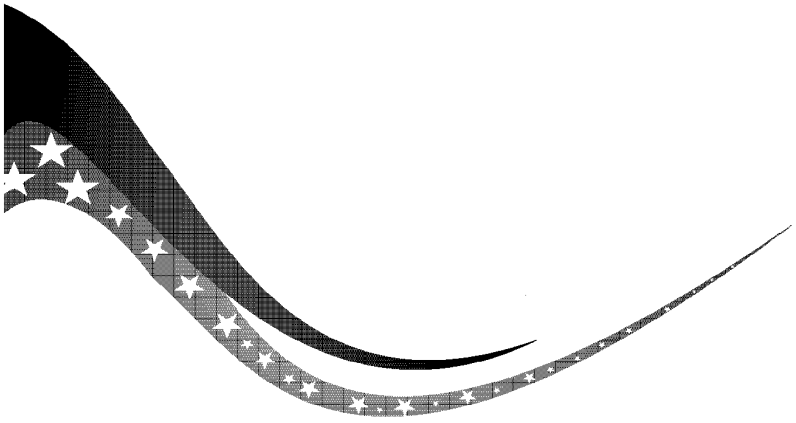
Dr. Sandra Kweder joined the Division of Anti-Viral Drugs at the FDA in 1988 and began working to address the growing field of HIV drug development. She has held several leadership positions with the FDA and is currently the Deputy Director of the Office of New Drugs, which oversees investigational studies during new drug development. Sandy was the runner-up to Dr. Jenkins in the selection process to be the OND Director and served as the acting director during this process. Her role in OND is somewhat vague. She handles all Commissioned Corps (PHS Officers)-related issues and attends to the ceremonial aspects associated with being in the U.S. Public Health Service.

KRISTEN PHUCAS

Regulatory Health Project Manager, Office of Executive Programs

Kristin Phucas is a member of the Drug Shortages Task Force with the FDA, which works to address the underlying causes of drug shortages and to enhance product availability. She currently serves as the Regulatory Health Project Manager in the Office of Executive Programs as a part of the task force. Previously, she has worked with the Office of Surveillance and Epidemiology as the project manager for a series of review and evaluation studies concerning various treatments for ADHD.

VALERIE JARRETT MEETING BRIEF



VALERIE JARRETT MEETING

OVERVIEW

Valerie Jarrett is one of three senior advisors to President Obama, holding the position of Assistant to the President for Intergovernmental Affairs and Public Engagement. She has been entrusted with managing the relationships between industry and the White House and is currently focused on gaining public acceptance for President Obama's healthcare reform initiatives and helping individuals and businesses to navigate the law's implementation. She has had a long-standing personal relationship with both the President and the First Lady for over twenty years and is widely viewed as part of his "brain trust" on key issues. We want to use this opportunity to introduce Teva and its significance as a U.S. employer and manufacturer and as the largest supplier to the U.S. market, as well as to remind Jarrett and her team about the significant savings to the government we have helped to generate through our medicines and our model. The goal is to establish a rapport and trust, remind her of our support for health care reform, and seek to work with this White House on some key issues moving forward.

BIOGRAPHY

VALERIE JARRETT
Assistant to the President

In her role as Assistant to the President, Valerie Jarrett manages the White House Office of Public Engagement, Office of Intergovernmental Affairs, Office of Urban Affairs, and Chairs the White House Council on Women and Girls, and White House Office of Olympic, Paralympic, and Youth Sport.

Prior to joining the Obama Administration, she was the Chief Executive Officer of The Habitat Company. She also served as Co-Chair of the Obama-Biden Presidential Transition Team, and as a Senior Advisor to Obama's presidential campaign.

Ms. Jarrett has held positions in both the public and private sector, including the Chairman of the Chicago Transit Board, the Commissioner of Planning and Development for the City of Chicago, and Deputy Chief of Staff for Mayor Richard M. Daley. She also practiced law with two private law firms.

In 1991, as Deputy Chief of Staff to Mayor Richard Daley, she interviewed Michelle Robinson for an opening in the mayor's office and offered her the job immediately. Michelle Robinson asked for time to think and also asked Jarrett to meet her fiancé, Barack Obama. The three ended up meeting for dinner. After the dinner, Michelle took the job with the mayor's office, and Valerie Jarrett reportedly took the couple under her wing. She later took Michelle with her when she left the mayor's office to head Chicago's Department of Planning and Development.

Jarrett also served as a director of corporate and not for profit boards, including Chairman of the Board of the Chicago Stock Exchange, Director of the Federal Reserve Bank of Chicago, and Chairman of the University of Chicago Medical Center Board of Trustees.

Jarrett received her B.A. from Stanford University in 1978 and her J.D. from the University of Michigan Law School in 1981.

BACKGROUND

This Administration has had a volatile relationship with the pharmaceutical industry, particularly on the branded side. Theis White House relied on the industry in 2010 to support the passage, through a multi-million dollar ad/lobbying campaign, of their health reform bill in exchange for passing over some key policy ideas the industry opposed—i.e. direct negotiating power for the government, additional rebates on Medicare/ Medicaid dual eligible beneficiaries and one policy the industry wanted very badly—12 years of market exclusivity on biologics. Relations have cooled since that time and this White House is often seen vilifying the industry on battles over IP protection, drug safety, drug shortages and transparency. Jarrett has been exposed to Teva a bit; for example, through our support of Enroll America, the organization which has raised $25 million to lead the effort to encourage citizens to sign up for the new health care coverage and expand the awareness and benefits of the law. She met Jeremy at a dinner honoring President Obama hosted by President Shimon Peres this spring. This is a great opportunity to introduce Teva to her and create a working relationship.

KEY ISSUES

Deficit Reduction [*also see backgrounder included in the briefing book*]: Faced with enormous fiscal pressures and a national debt of over $16 trillion, this Administration is struggling to find ideas for deficit reduction. Unfortunately, some of the "solutions" being considered would be harmful to the industry, such as a proposal to increase rebates for beneficiaries who are eligible for Medicare and Medicaid. This proposal is very attractive to policymakers as it would provide $112 billion over 10 years in savings. It would be terrible for the industry and for Teva in particular, as the estimated cost to our company is $500-$600 million annually. It is also an ill-advised policy as the result will most certainly be cost-shifting in the system, rather than reducing or restraining costs. There are other policies, including

increased generic utilization among low income Medicare beneficiaries, that would result in true savings and efficiencies in the system.

Teva has identified the following areas to generate savings:

- **REMS (Risk Evaluation and Mitigation Strategies)**: REMS is a program used by the FDA to ensure a restricted distribution of products with serious side-effects or a higher probability of misuse. Some brand companies are using these programs to deny generic manufacturers product samples for testing, a barrier to market competition.

- **Donut Hole**: The current federal subsidy for brand drugs in the Medicare Part D donut hole should apply only to single source products. If patients begin treatment using a brand and then the federal government subsidizes the payment for that brand, needless government spending is occurring if a generic is available for the brand product.

- **LIS**: The Low Income Subsidies population within Medicare is using less generic drugs than the general population. Cost sharing modifications, or differential co-pays could be used to ensure LIS beneficiaries use generic drugs more. Currently only the government pays more when the brand is selected and not the patient.

Biomedical Research Partnership: In the current environment of fiscal restraint and uncertainty, the Obama Administration has actively promoted opportunities for partnerships between the public and private sectors. This effort is an attempt by the Administration to encourage the use of private capital in projects designed to benefit the public.

One such project with relevance to the pharmaceutical industry came out of the National Center for Advancing Transitional Sciences with the announcement of an innovative new program designed to develop partnerships between pharmaceutical companies and the biomedical research community with the goal of advancing therapeutics development. This program, known as *[Discovering New Therapeutic Uses for Existing Molecules (New Therapeutic Uses)]*, seeks to identify new uses for compounds that have undergone significant research and development by industry, including safety testing in humans.

The first round of project funding was announced in June of this year pairing academic researchers with compounds to explore treatments in 8 different disease areas, including Alzheimer's and schizophrenia.

Pharmaceutical industry partners in this program to date include AbbVie, AstraZeneca, Bristol-Myers Squibb Company, Eli Lilly and Company, GlaxoSmithKline, Janssen Research & Development, LLC, Pfizer, and Sanofi. Combined these companies contributed 58 compounds for the project.

Prescription Drug Abuse [*also see backgrounder included in briefing book*]: This White House, particularly Vice President Joe Biden, has been concerned about the growing epidemic of prescription drug abuse in the U.S. In fact, Teva had a meeting with the Vice President's staff and the Director of the Office of National Drug Control Policy, Gil Kerlikowske, a few years ago to discuss growing concerns about abuse. According to a government survey on drug use and health, U.S. teenagers, aged 12-17 years, abuse prescription drugs more than ecstasy, heroin, crack/cocaine and methamphetamines combined. Lawmakers and regulators have taken notice. In the U.S. Congress, there have been several hearings and numerous bills introduced to largely restrict the number of opioid prescriptions that are written and filled.

In the absence of better ideas, policymakers have offered a variety of legislative and regulatory initiatives that target the individual links in the supply chain that will, at best, have a minimal impact on truly addressing the problem. Furthermore, this approach has generated fear among prescribers of intensified scrutiny by law enforcement and caused many to stop or greatly reduce the number of prescriptions they write for "pain patients." Pharmacies are also proactively questioning both physicians about their prescribing practices and patients on their need for these medicines. The bottom line is that legitimate access for those patients who truly need these medicines is being reduced.

As a manufacturer of opioids and a committed stakeholder, Teva is seeking to support solutions to this epidemic while preserving legitimate access to these medicines for the patients who need them – currently 8.8 million patients take opioids for chronic pain. In this effort, Teva has brought together an unlikely coalition of CVS-Caremark (the nation's largest pharmacy health provider in the U.S.), Cardinal Health (the second largest wholesaler in the country) and the American Medical Association (largest representative of the nation's doctors) to study the issue and recommend a series of policy solutions that would seek to reduce the diversion and abuse without indiscriminately limiting access to these medicines.

DISCUSSION RECOMMENDATIONS

- Valerie will be interested in knowing more about Teva and our long-term vision for the company.
    - Teva's diverse portfolio of specialty, generics and OTC
    - Upcoming brand launches and therapeutic areas of focus for us
    - Teva's initiative to enable an industrial scale pipeline of New Therapeutic Entities (NTE).

- This is a great opportunity to discuss the new analysis *(included in a separate document)* just completed on Teva's impact on the U.S. health care system and how Teva has optimized the system designed under Hatch-Waxman for patients and sustainability.

- Our impact on the U.S. and the credibility it should build could lead into a discussion about the need for a reassessment moving forward about the adequacy of the incentives and system to support the sort of innovation we believe is possible. *(Note: see Key Messaging Points)*

- We should note that Teva believes that the Affordable Care Act (the official name of the health reform bill) is good for health care access in America, was one of the original supporters, and is actively supporting the effort by Enroll America, which has already completed almost 80 outreach events in 24 states and raised $25 million.

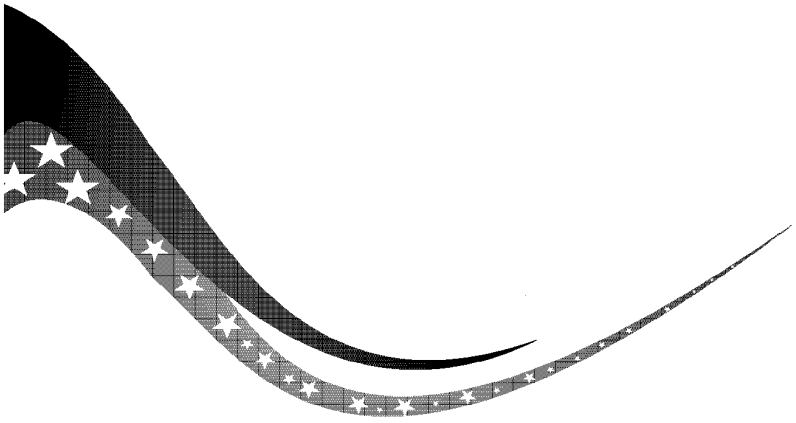
- We should underscore the concern regarding "savings solutions" and propose working together with their policy advisors as Teva has ideas about generating savings that involve increased competition or other efficiencies that would mean true savings and not simply cost-shifting.

- We may want to talk about Teva's commitment to supporting research and boosting therapeutic development in a key area of focus, i.e. neurodegenerative diseases and our recently established "National Network of Excellence" (NNE) in Israel with our support for 10 of the leading universities and teaching hospitals in Israel.

NOTE: You may be asked if we have any plans to expand Teva's footprint in the U.S. Job creation, particularly in manufacturing, is a focus of the administration's efforts to improve the economy. At a minimum, we should be able to emphasize Teva's current breadth of 37 facilities in 13 states with 7,400 employees.

You may also be asked to do even more to support healthcare reform. You could remind them that we are the **only** pharmaceutical company openly supporting the enrollment efforts through Enroll America and will continue to do so. You have spoken publicly about your support for expanding coverage. We, of course, can be open to listening to any specific asks, but wanted you to be prepared for an "appeal" as we near the open enrollment date.

U.S. CHAMBER MEETING BRIEF

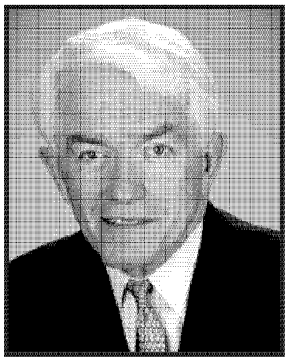


U.S. CHAMBER MEETING

OVERVIEW

Teva is a member of the U.S. Chamber of Commerce, the world's largest business federation representing the interests of more than 3 million businesses of all sizes, sectors and regions, as well as state and local chambers and industry associations. The Chamber is considered a leading voice for businesses and often enters the political fray to prevent legislation and regulation that is overly burdensome and harmful to industry. The Chamber has been an important partner for Teva on the regulation of generic drug labels and preserving the right for pharmaceutical companies to enter into patent litigation settlements. We want to remind Tom Donohue about the role Teva plays as a U.S. employer and manufacturer and policy stakeholder and continue to look for issues we can work on together.

BIOGRAPHY



THOMAS J. DONOHUE
President and CEO, U.S. Chamber of Commerce

Thomas J. Donohue is President and CEO of the U.S. Chamber of Commerce. Since assuming his position in 1997, Donohue has built the Chamber into a lobbying and political powerhouse with expanded influence across the globe.

In an era of economic and fiscal challenges, Donohue has aggressively advanced The American Jobs and Growth Agenda, a plan that includes expanding trade and domestic energy production, rebuilding America's infrastructure, combating an avalanche of new regulations, protecting intellectual property, revitalizing capital markets and reforming entitlements and the tax system.

Under Donohue's leadership, the Chamber has emerged as a major political force in races for the Senate and the House of Representatives. As part of this bipartisan effort, millions of grassroots business advocates, as well as the Chamber's federation of state and local chambers and industry associations, mobilize in support of pro-business candidates.

Previously, Donohue served for 13 years as President and CEO of the American Trucking Association, the national organization of the trucking industry. Earlier in his career, Donohue was Deputy Assistant Postmaster General of the United States and Vice President of Development at Fairfield University in Connecticut. He serves on the boards of Union Pacific Corporation and Sunrise Senior Living Corporation.

Born in New York City, Donohue earned a bachelor's degree from St. John's University and a master's degree in business administration from Adelphi University. He holds honorary doctorate degrees from Adelphi, St. John's, and Marymount universities, as well as the National University of Ireland at Maynooth. Donohue and his wife, Liz, live in Potomac, Maryland. They have three sons and five grandchildren.

BACKGROUND

The Chamber is a Republican-leaning organization, widely regarded as one of the most powerful voices in DC, and often critical of the current Administration for "over-reaching in its authority to regulate businesses." They do not support Obama's health care reform because of the mandates on businesses—i.e. mandating that companies with more than 50 employees provide health care benefits and taxing businesses with generous healthcare plans unless those plans are scaled back. (Note: Teva, shortly after passage of the bill, scaled back the benefit plan we offer to employees.)

The Chamber houses two institutes that are of importance to Teva:

1) Institute for Legal Reform (ILR)
Teva is a member of ILR whose mission is to reduce "excessive and frivolous litigation while restoring fairness and balance to the nation's civil justice system." Teva's experience with product liability cases and outsized judgments is at the heart of ILR's focus and they have an enormous grassroots network throughout the country to advocate on these issues. They are the key policy adversary of the trial lawyers.

2) The Global Intellectual Property Center
The mission of this center addresses the serious criminal and policy threats facing innovators, IP-based industries and consumers. The U.S. Chamber of Commerce created the Global Intellectual Property Center (GIPC), which is leading a worldwide effort against the assault on IP. The center often argues for longer patent terms, exclusivities, and other protections for IP.

KEY ISSUES

Generic Drug Labeling [*backgrounder is included in briefing book*]: The Teva team has been working closely with the Chamber on this issue, resulting in a Chamber-authored brief to the Supreme Court supporting preemption legal arguments. On

the legislative front, the Chamber has sent letters to the Hill and made clear that any amendment to undo preemption in these cases would be viewed negatively in the "pro- business" rating members receive from the Chamber.

Now that we are facing new regulation by the FDA on generic labels, the Chamber is in the process of authoring an op-ed questioning the FDA's authority to make fundamental changes to the intention of a federal statute through regulation. The Chamber will seek to place the op-ed in a major national publication. Recently, the Chamber hosted a briefing for Hill staff to discuss the issue, including the FDA's role and the potential economic impact for patients if product liability results in higher prices or the withdrawal of some products from the market.

Patent Settlements: For the past six years, the Federal Trade Commission has been asking lawmakers and the courts to deem settlement agreements between brand and generic drug manufacturers a per se violation of anti-trust law if the agreements include the brand give something of value to the generic in addition to an agreed upon entry date. The government has long held the position that when drug companies enter into these agreements, the value transfer from the brand to the generic can only be in exchange for a delayed entry date, thus harming consumers. The courts, on the other hand, have held that any generic entry prior to the expiration of the brand's patent must necessarily be pro-competitive, even if value was transferred from the brand to the generic, because the government, by issuing a patent, has allowed the brand to have a monopoly.

The Teva team has worked with the Chamber over the years to defeat legislative efforts that would make any pharmaceutical patent litigation settlement an anti-trust violation and per se illegal. In June, there was a major shift in the landscape when the U.S. Supreme Court set a new standard for reviewing settlements. The court did not enumerate factors for the courts to weigh and it will likely take years for us to know exactly what this new standard means for Teva. Nevertheless, members of the Senate have vowed to move forward with legislation that would make patent settlements per se illegal. It is extremely unlikely that legislation banning patent settlements will become law in this Congress, but partnering with strong business advocates, such as the Chamber, is critical to preventing legislative action.

International Trade: The Chamber is one of the leading voices seeking enhanced trade liberalization. Teva is very interested in a number of the pending Free Trade Agreements, including the Trans Pacific Partnership and the upcoming one between the EU and the U.S. On the IP front, we are looking for a balance of incentives for innovation with a system that allows for appropriate access to generics. On the regulatory front, we are hopeful to see the harmonization of regulatory approval requirements, for example, on biosimilars, across regions. As an importer, Teva cares about an issue the Chamber has been involved in regarding certain fees paid when goods arrive by ship at American ports. The proposal is to reduce or waive such fees for nations that sign onto an FTA. These fees are known as Harbor Maintenance Fees and Merchandise Processing Fees. Internally, Teva has estimated that the company would have saved $513k last year if the Merchandise Processing Fee had been waived. Harbor Maintenance Fees are more difficult to reduce or eliminate, but Teva would have saved $3.8 million last year if such fees had been eliminated. It may be worth pressing on Chamber support for reductions in both fees.

DISCUSSION RECOMMENDATIONS

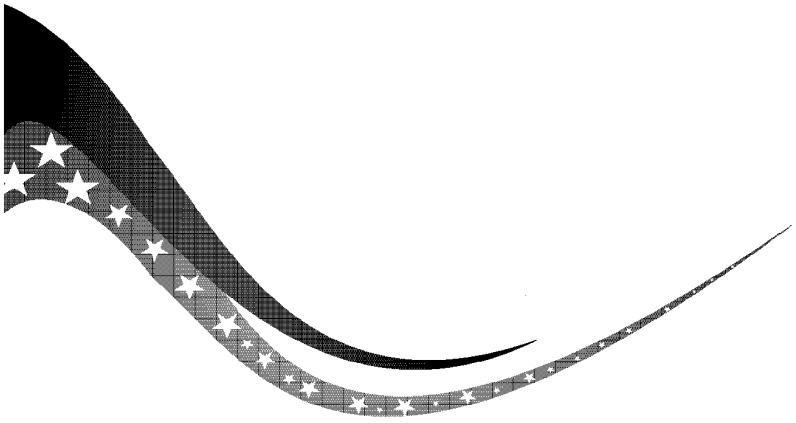
- We should open the meeting discussing the uniqueness of Teva – our diverse specialty and generic portfolio, OTCs, NTEs, and new product launches. Tom's knowledge of the pharmaceutical industry is high level and focused on political strategy. Explain terms such as NTE.

    - Use Key Messaging Points

- He will be interested in our global footprint and the pending EU – US trade agreement. Teva would benefit from the harmonization of regulatory approval requirements and the reduction of fees for imports.

- We want to emphasize the importance of the work that we are currently doing with the Chamber on federal Preemption and the generic drug label issue, safeguarding companies like Teva from lawsuits. They are a strong partner on this issue and it is a top priority for Teva in the U.S. The cost to Teva of an onerous FDA regulation or piece of legislation has been estimated in the hundreds of millions.

PhRMA MEETING BRIEF

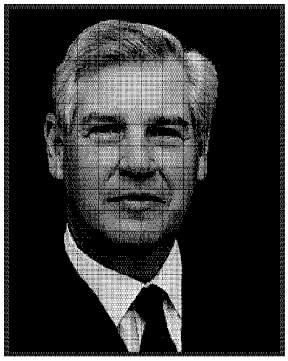


OVERVIEW

PhRMA is the long standing trade association of the brand pharmaceutical industry. They are both beloved and hated in various Washington circles, but no one can dispute that their well-financed lobbying efforts are among the most successful. The brand industry in general and PhRMA specifically have not embraced Teva's mixed-model approach. The history on Capitol Hill and in litigation between brand and generic interests has created what many consider to be a damaging rift in the pharmaceutical industry. Despite this history of disagreement and given Teva's diverse portfolio, there are several key issues that we share with PhRMA and on which collaboration (not membership) would increase the likelihood of generating policy changes.

BIOGRAPHY

John Castellani joined PhRMA in August 2010. He has pledged that PhRMA will continue to "lead efforts to find patient-centered solutions to healthcare challenges in America and around the globe." In particular, PhRMA will focus on helping to successfully implement and improve the healthcare reform law and on promoting rewards for medical innovation.



JOHN CASTELLANI
President and CEO, PhRMA

Before joining PhRMA, Castellani was President and Chief Executive Officer of Business Roundtable (BRT). The BRT is an association whose membership includes chief executive officers from leading corporations that are headquartered in the United States. Castellani served at the BRT from May 2001 to July 2010, where he significantly strengthened their national and international reputation. Prior to the BRT, Castellani was Executive Vice President of Tenneco, Inc. and served as part of the senior management team that turned the failing Tenneco conglomerate into seven strong companies. In 2007, Castellani was named one of the 100 most influential people in corporate governance by *Directorship Magazine*.

Castellani's Washington experience includes serving as Vice President for Resources and Technology with the National Association of Manufacturers and as Vice President of State, Federal and International Government Relations for TRW, Inc. He started his career at General Electric as an environmental scientist and strategic planner.

A graduate of Union College in Schenectady, NY, Castellani now serves on its board of trustees. He and his wife, Terry, reside in Washington and have two sons.

BACKGROUND

PhRMA was founded in 1958 to promote incentives for pharmaceutical research. The organization has over 56 members and a budget of over $200 Million Dollars a year. PhRMA focuses their efforts on representing the biopharmaceutical industry as the global leader in medical innovation. The industry is credited with more than 300 new medicines approved by the Food and Drug Administration in the last decade, more than 810,000 employees in the industry as well as supporting a total of nearly 3.4 million jobs across the U.S. economy.

Over the past almost 30 years, PhRMA and the generic industry have been at odds on many issues. Amendments to the original Hatch-Waxman Act in 2003 that would allow for timely access to generics by removing statutory loopholes and legal barriers were a source of tremendous conflict between the two industries. PhRMA has combated generic substitution with statewide campaigns questioning the quality and safety of the medicines and has opposed the pathway for biosimilar medicines on the same grounds, questioning the capability of generic manufacturers to safely produce complex products. The organization, and a few of its largest members, continue to pursue barriers to any future biosimilar substitution now that a pathway is in place.

Teva has been a leading proponent of collaboration where possible between PhRMA and generics. While there have been a limited number of issues where the two sides of the industry agree, Teva is trying to use our mixed-model approach to change that dynamic. There are increasing number of issues where PhRMA and Teva agree.

KEY ISSUES

Deficit Reduction: One proposal that Congress has been contemplating to off-set government spending, by $112 billion over 10 years, is to apply Medicaid level rebates to beneficiaries eligible for Medicare and Medicaid. The potential net impact could add a $500 - $600 million annual cost to Teva's U.S. brands, making this a top priority for Teva and all of PhRMA's members.

Medication Adherence: PhRMA has made this issue one of their top priorities with Castellani and the organization touting a new partnership in May, Prescriptions for a Healthy America, to highlight the issue of medication adherence. A significant amount of data has demonstrated the breadth of this problem.

Today, 145 million Americans suffer from chronic diseases and yet, only one-third are taking their medications as prescribed. Teva has supported similar efforts in the past and there is some traction with patient and consumer groups, as well as the government as payor. For the first time, the government is acknowledging the importance of adherence to medicines for both better health and controlling healthcare costs. The U.S. Congressional Budget Office has estimated that for every 1 percent increase in the total number of prescriptions filled in Medicare, medical spending will decrease by 0.2 percent. This is a significant recognition of the impact of this policy.

Counterfeit Drugs: PhRMA and Teva both strongly support the implementation of a nationwide system that can track pharmaceuticals through the domestic supply chain and detect counterfeit or adulterated drugs before they are delivered to the patient. After three years of debate, there is legislation currently before Congress that would allow specific product transaction information to be passed down the supply chain when there is a change in ownership and this information would be verified in each instance. If there is a determination that there may be a counterfeit or adulterated product, it would be reported within specific timelines according to a specified notification process. Teva, PhRMA and virtually all the key players in the domestic supply chain support the approach taken in the legislation.

Disclosure of Clinical Trials: In July, PhRMA and the European version of PhRMA jointly endorsed principles for clinical trial data sharing. Under the new commitments, companies will work with regulators to provide a factual summary of clinical trial results to patients who participate in clinical trials. The synopses of clinical study reports for clinical trials in patients submitted to the Food and Drug Administration (FDA) and European Medicines Agency (EMA) or national authorities of EU member states will be made publicly available upon the approval of a new medicine or new indication. The PhRMA companies also reaffirmed their commitment to publish clinical trial results regardless of the outcome. At a minimum, results from all phase 3 clinical trials and clinical trial results of significant medical importance should be submitted for publication.

Patent Settlements: PhRMA and Teva have a common interest in being able to settle litigation and make business decisions that our management team believes reflect the specific circumstances surrounding any given product. Teva has worked with the PhRMA lobbying shop over the years to prevent passage of legislation that would ban settlements. It is fair to say that over the past 6 years the success on this issue can be attributed to the combined efforts of the industry, and the efforts are unlikely to have been as successful in the absence of either the brands or the generics.

DISCUSSION RECOMMENDATIONS

- The discussion should be focused on areas where we feel that collaboration between Teva and PhRMA could be mutually beneficial—for example, medication adherence, full funding for the FDA, and deficit reduction. We have been clear that Teva does not have an interest in joining PhRMA at this time but we believe the industry needs to be led past the generic versus brand battles of old and focus on the value and innovation we bring patients.
- Teva is investing in NTEs and we feel there should be greater protection for the products, both in the U.S. and abroad. We provide a more balanced voice on this issue because of our business model.
  - We know that there are some members of Congress that are contemplating restructuring brand exclusivities. It is our opinion that the 3 year exclusivity for new clinical studies should be increased because the industry should be encouraged to continue testing in a meaningful way and to make improvements for patients.
  - Of course, the innovation of a new molecule should still be rewarded by the largest period of exclusivity, so the five year exclusivity for New Chemical Entities would also need to be increased to reflect the proportional amount of investment and risk.
- Teva will continue our efforts to avoid the expansion of the Medicaid rebates to "dual eligibles" (those that meet the qualifications of both the Medicaid and Medicare programs). This is an area that we have worked on together in the past, and the issue continues to be a priority for Teva.
- On August 16th, Castellani posted an article on his blog discussing the need for public-private partnerships to address the challenges of neurologic diseases. He says in the blog that "by bringing together the best minds from throughout the health care ecosystem to work collaboratively and share ideas, we get closer and closer to new treatments or cures for neurological diseases."
  - This is worth mentioning in order to remind Castellani of our commitment to CNS and our work with Shared Solutions, to commend him for expressing an interest in these medicines and to demonstrate that he has spoken publicly about the positive effects of collaboration.
  - Teva's own commitment to supporting research and boosting therapeutic development in the area of neurodegenerative diseases and our recently established "National Network of Excellence" (NNE) supporting 10 leading universities and teaching hospitals in Israel would be of interest.

PUBLIC-PRIVATE PARTNERSHIPS HOLD KEY TO FUTURE TREATMENT OF NEUROLOGIC DISEASES

John Castellani
August 16, 2013
The Catalyst: PhRMA Blog

Despite the great medical advances of the last century, there is still a lot of work to be done when it comes to developing medications and treatments to deal with neurological disorders such as Parkinson's disease. These conditions pose vexing challenges for researchers trying to unlock the secrets that will improve the lives of millions living with the daily challenges that neurological diseases pose.

Public-private partnerships have proven invaluable in in addressing medical challenges, convening researchers from academia and industry in search of root causes of diseases and developing new ways to treat them. Given the huge task of combing through and synthesizing the ever-growing reams of research data available, public-private partnerships are crucial to future medical breakthroughs and that's why we posed this week's Conversations question:

How can we better utilize public-private partnerships to advance translation of science into new medicines for some of our most challenging diseases, such as neurological disorders?

In the coming years, neurological diseases will become an ever greater public health issue. As Amy Comstock Rick, CEO of the Parkinson's Action Network, pointed out in her response to this week's question, the economic burden of Parkinson's disease is at least $14.4 billion per year in the U.S., on top of the personal burden exacted on the 500,000 to 1.5 million Americans living with the disease. And the number of Alzheimer's disease cases is expected to triple in the next 40 years, with annual costs reaching $1.2 trillion by 2050.

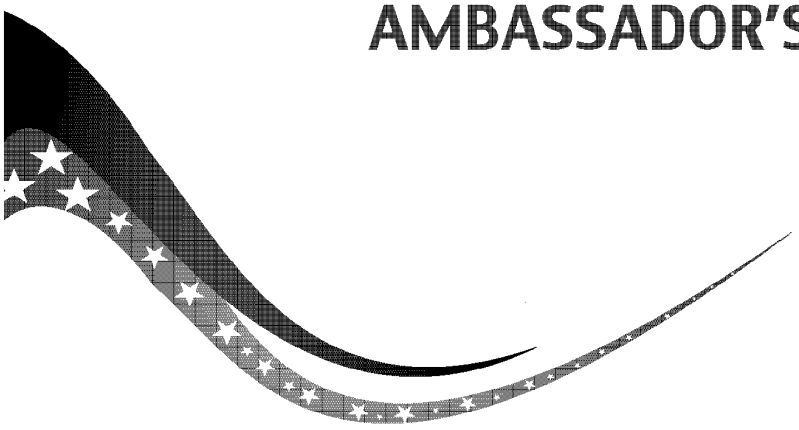
One of the great traits of public-private partnerships is that they are all different. These relationships are continually adapting and evolving as necessary, taking advantage of each partner's strengths in pursuit of answers to some of medicine's most challenging issues. Stevin Zorn from Lundbeck illustrated this in his response to the question. As Stevin explains, NIH is very adept at understanding disease and generating background knowledge about the underlying basis of disease, but is limited with taking that information and knowledge and developing effective treatments for diseases. Working together, federal organizations, such as NIH, and biopharmaceutical companies, such as Lundbeck, can lean on each other's expertise to do more than either could accomplish individually.

Public-private partnerships extend beyond the confines of the research and development lab. Randy Rutta of Easter Seals discussed the Easter Seals Brain Health Center as a "nexus of information" that draws on a national network of service providers to expand awareness of how people can use new and emerging brain training regimens to improve cognitive function.

While the answers to some of the more vexing medical challenges won't be easy to find, one thing is certain: we will keep hunting for them. By bringing together the best minds from throughout the health care ecosystem to work collaboratively and share ideas, we get closer and closer to new treatments or cures for neurological diseases.

We see this Conversations forum as one small part of the ongoing dialogue in search of answers. We encourage you to join us by sharing your thoughts in the comment section or becoming a contributor. In the meantime, stay tuned for the next Conversations question.

BRIEF FOR DINNER AT AMBASSADOR'S RESIDENCE



DINNER AT AMBASSADOR'S RESIDENCE

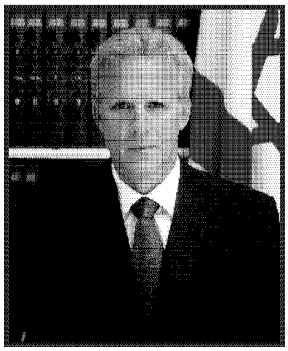
OVERVIEW

Ambassador Oren is hosting a small, sit down dinner (25 people) at his personal residence with invitations extended to members of the diplomatic core, Congress, friends of the Ambassador, media, a few prominent business people and Jewish leaders. This dinner will be the final event in the Ambassador's current capacity, as he will be returning to Israel at the end of September and replaced by Ron Dermer. Since the event is taking place during the Sukkot holiday, the dinner will be outside in the Ambassador's Sukkah.

This event provides an opportunity to mingle with Washington, DC's "friends of Israel." Many of the attendees will be individuals we have interacted with regarding our issues and this celebration will provide a more social environment to strengthen their connection to Teva. Attendee list is being finalized, and a separate briefing document will be provided.

Ambassador Oren has been serving in Washington, DC since 2009. His wife Sally Oren has years of experience working for Birthright in the Israel office. Additional biographical information follows at the end of this document.

BIOGRAPHY



MICHAEL B. OREN
Israeli Ambassador to the United States

Michael B. Oren (born Michael Scott Bornstein) was appointed Israel's Ambassador to the United States in June 2009. In this capacity, he meets regularly with officials in the White House, the State Department and the Pentagon, as well as with members of Congress from both parties. He regularly briefs Prime Minister Benjamin Netanyahu and other Israeli leaders on issues vital to the U.S.-Israel alliance.

SALLY OREN
Ambassador Oren's wife

During his tenure, Ambassador Oren has been instrumental in securing U.S. support for Israel's defense. This includes securing funding assistance from the U.S. for the "Iron Dome" System and support in Congress and the Administration for sanctions against Iran. *The Forward* named Ambassador Oren one of the five most influential Jews in America and *The Jerusalem Post* listed him as one of the ten most influential Jews worldwide.

Born and raised in the United States (West Orange, New Jersey) and educated at Princeton and Columbia, Dr. Oren has been a visiting professor at Harvard, Yale, and Georgetown. He has received fellowships from the British and Canadian governments as well as from Tel Aviv University and Hebrew University. His last two books, *Power, Faith, and Fantasy: America in the Middle East from 1776 to the Present* and *Six Days of War*, were both *New York Times* bestsellers.

Oren is 58 years old. The article follows this briefing. The couple has three children. Both Michael and Sally are from conservative Jewish households and are outspoken proponents of liberal Judaism and critics of the state-religion status-quo in Israel. Their eldest son, Yoav, currently lives in Shanghai with his new wife. The young couple were wed in an "unofficial" reform-Jewish wedding in Israel (and in a civil marriage in the U.S. overseen by Supreme Court Justice Elena Kagan). The Orens' only daughter was married in Israel this summer.

OREN AND TEVA

Teva has had an amicable relationship with the Ambassador and he publicly has expressed his enthusiasm for the company. Most recently, in July, Oren visited Teva in Israel for a meeting with our Chairman, Dr. Frost, and Teva Senior Management. Oren discussed rallying support for Israel in the U.S., and the current anti-Israeli sentiment led by the Boycott, Divestment and Sanctions (BDS) movement. Oren hopes that Teva will consider adopting more of an Israeli identity in the U.S. During this visit, Oren commented on how he views Teva as a leading player in strengthening the U.S.-Israel strategic relationship by continuing to develop the commercial relationship. "Israel exports health to Americans and other countries around the world…," he said at the time.

- In December 2012, the Ambassador met with Debra Barrett and Mati Gill in Washington, DC where we briefly touched on our issues and Oren expressed support for the importance of Teva's work with U.S. legislators. Teva Government Affairs was also invited to and attended an event celebrating Director General of the Finance Ministry Doron Cohen's visit and the signing of the Memorandum of Understanding with U.S. Secretary of the Treasury Timothy Geithner.
- This past March, Oren attended the State dinner in Jerusalem at President Peres' house in honor of President Obama. At this dinner, Oren expressed interest in the pending decision

from the Supreme Court on settlements. Teva Government Affairs compiled an extensive briefing book on the issue for Oren in preparation for a meeting between Oren and Supreme Court Justice Breyer.

- Previously, Oren visited Teva's facility in Puerto Rico and is the only Israeli Ambassador to have done so. He often references this trip as an example of investment by Israeli companies in the U.S.

KEY ISSUES

- The current situation in Syria and the U.S. response

  - The press reported that Ambassador Oren and Israel National Security Advisor Yaakov Amidror, who came to DC for high-level political and security talks, met with National Security Advisor Susan Rice, as well as senior National Security Council, State Department, Pentagon and intelligence officials to discuss U.S. preparations for a possible attack on Syria. The situation remains very fluid, and we will provide a further update prior to the dinner.

- U.S. budget cuts and impact on Israel

  - Oren told the press that Israel was not seeking special treatment as the U.S. government enacted across-the-board budget cuts. He said that Israel wanted to "share in the burden" and could potentially give up nearly $55 million of the annual military aid that the U.S. provides for the Iron Dome anti-missile system (June 22, 2013 *UPI*)

  - Ambassador Oren commented that Israel would not oppose U.S. arms sales to the Middle East, despite Israeli concerns over their collective impact over time on Israel's qualitative military edge in the region. Israel will continue to work with the executive branch and Congress to enhance U.S. security assistance and bilateral strategic cooperation. Oren stated "we understand that if America doesn't sell these weapons, others will. We also understand the fact that each of these sales contributes to hundreds or thousands of American jobs." (August 26, 2013 *DefenseNews.com*)

- Muslim relations in the U.S.

  - Oren and his wife, Sally, held an Iftar at their residence. In attendance were Rep. Keith Ellison (D-MN), the first Muslim elected to the U.S. House; Farah Pandith, the State Department's special representative to Muslim communities; Duke University's Imam Abdullah Antepli; author and professor Akbar Ahmed of American University; *New York Times* columnist Thomas Friedman and his wife, Ann; and various ambassadors and rabbis. (July 19, 2013 *The Washington Post*)

  - Ambassador Oren held a conference call with dozens of U.S. rabbis. He touched on a wide range of issues, including peace talks, Iranian nuclear ambitions, the developing situations in Syria and Egypt and religious pluralism in Israel, an issue that has garnered significant attention from American Jewry. Press reports state that there was progress toward the compromise proposal currently being brokered by Jewish Agency head Natan Sharansky, and emphasized the Netanyahu government's willingness to reach a negotiated solution to egalitarian prayer at the Western Wall. (August 25, 2013 *The Times of Israel*)

- The recent developments in Egypt and the U.S. aid package

  - Oren said that Israel wanted the U.S. to continue providing foreign military assistance to Egypt. "We have an interest in maintaining US influence and leverage in Egypt and an overriding interest in preserving our peace treaty." (August 18, 2013 *The Jerusalem Post*)

- Status of negotiations with the Palestinians

  - Ambassador Oren appeared on "Andrea Mitchell Reports" to discuss negotiations to free more than 100 Palestinian prisoners. "Settlements are part of the territorial issue. Territory borders are going to be a core issue, security, and yes, Jerusalem will be a core issue...We're willing and ready to discuss all of these very complex issues because we know that's the only way to get to peace. Negotiations aren't about negotiations. They're actually about getting to the peace agreement that we all want" he said." (July 31, 2013 *MSNBC*)

  - Ambassador Oren wrote a letter to *The New York Times* criticizing their coverage of Palestinian stone-throwing against Israelis. "While Palestinian protagonists are described in detail, their Israeli victims are largely dehumanized 'settlers'— no name, age or gender...The article could have added another chart: the names of Israelis who have been killed or permanently maimed by rock throwers and the time they have spent hospitalized." (August 6,

2013 *The New York Times*)

- Whether the U.S. will renew talks with Iran on its nuclear programs since the election of new President Hassan Rouhani, who is widely considered a moderate compared to his predecessor Mahmoud Ahmadinejad.

    - Referencing that Israel cannot rely on the U.S. to prevent a nuclear Iran, Oren commented "The question isn't whether or not we believe Obama. The question is what our responsibility is as a sovereign nation. We cannot outsource our national security… All diplomatic options must be exhausted – but we cannot flee from this responsibility." (July 11, 2013 *Times of Israel*)

BACKGROUND ON OREN'S REPLACEMENT, RON DERMER

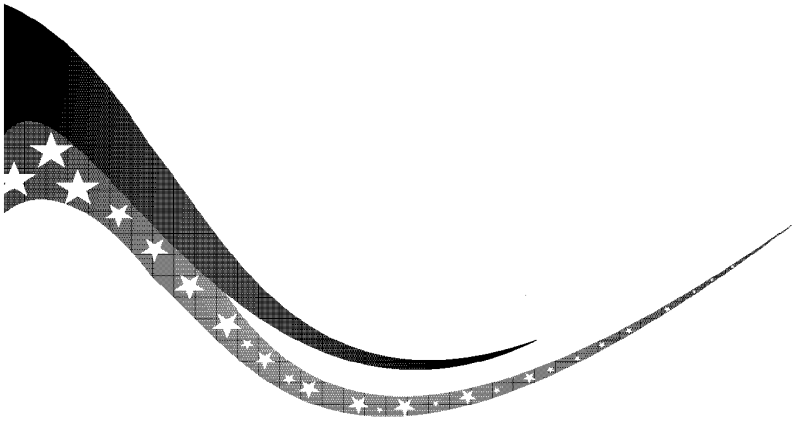
While Ron Dermer will not be attending the event, we thought it may be useful to include some background.

For the past four years Ron Dermer has served as a senior advisor to Prime Minister Netanyahu. Previously, from 2005 to 2008 he was Israel's economic envoy to the United States. Dermer is considered Netanyahu's closest advisor and strategic consultant. According to *The Jerusalem Post*, he "runs much of the interference with the White House, and is intimately involved in the diplomatic process with the Palestinians, [... and] writes many of Netanyahu's speeches."

He began his career working in Washington as an assistant to Frank Luntz, the Republican consultant who engineered the watershed 1994 "Contract with America" House campaign for Newt Gingrich.

Dermer is also well known for taking on the *The New York Times* in December 2011. He authored an open letter explaining that Netanyahu will not write an op-ed for *The Times* because they "cavalierly defame" Israel.

PATIENT ADVOCACY LUNCH BRIEF



PATIENT ADVOCACY LUNCH

OVERVIEW

When changes are being contemplated to health care laws in the U.S., long standing health policy experts are called on to draft, implement, and coordinate efforts with industry. You will be meeting with some of the most notable health policy advisors in recent years. In order to have an influential voice in Washington, it is important that these experts, and others, view Teva as an accessible source for information on the pharmaceutical industry and understand the role that we play with legislators, regulators, and, most importantly, patients. The lunch also includes 3 key groups representing patients and consumers access therapeutic areas. Our goal is to expose Teva as patient-oriented, committed to expanding access and innovation and as a potential partner.

DR. MARK McCLELLAN

Co-Staff Director, Bipartisan Policy Center's Leaders' Project: State of American Health Care

Director, Health Care Innovation and Value Initiative

Senior Fellow, Economic Studies at The Brookings Institution

Director, The Engelberg Center for Health Care Reform

Former Administrator, Centers for Medicare & Medicaid Services

Former Commissioner, the U.S. Food & Drug Administration

A doctor and economist by training, McClellan has a highly distinguished record in public service and in academic research. McClellan is a former administrator of the Centers for Medicare & Medicaid Services (CMS) and former commissioner of the U.S. Food and Drug Administration (FDA), where he developed and implemented major reforms in health policy.

A notable initiative that Dr. McClellan championed as FDA Commissioner was the implementation of the Medicare Prescription Drug Benefit (Part D), which established an outpatient prescription drug benefit for 40 million elderly and disabled Medicare recipients. **For purposes of your discussion with Dr. McClellan he will drawn on this implementation experience; Part D is widely heralded as a successful initiative that has both saved money and enrolled millions of patients.**

As Commissioner, he pushed to drive innovation in the scientific processes through which medical products are developed, evaluated and manufactured through the FDA's Critical Path Initiative, and he has been a champion of public-private partnerships to develop better information on the quality of care for patients. McClellan vigorously opposed the importation of prescription drugs into the United States despite significant pressure by key policymakers representing border-states. As an economist and a physician, **Dr. McClellan has focused on payment systems and incentives for healthcare market participants, writing extensively on these topics, and he has been a champion of FDA efficiency in drug application reviews.**

Mark McClellan has served as Co-Director (along with Chris Jennings) of the Bipartisan Policy Center's Leaders' Project on the State of American Health Care – led by former Senate Majority Leaders' Howard Baker, Tom Daschle, Bob Dole and George Mitchell. He also serves as senior fellow and director of the Health Care Innovation and Value Initiative at the Brookings Institution. McClellan chairs the FDA's Reagan-Udall Foundation, is co-chair of the Quality Alliance Steering Committee, sits on the National Quality Forum's Board of Directors, is a member of the Institute of Medicine, and is a research associate at the National Bureau of Economic Research. He previously served as a member of the President's Council of Economic Advisers and senior director for health care policy at the White House, and was an associate professor of economics and medicine at Stanford University where he directed the Stanford Program on Health Outcomes Research. Twice he has received the Kenneth J. Arrow Award for Outstanding Research in Health Economics.

McClellan frequently advises U.S. government officials on health care policy issues. In his work for the Bipartisan Policy Center, he is the co-chair of the Robert Wood Johnson Foundation Commission to Build a Healthier America and chair of the FDA's Reagan-Udall Foundation. McClellan is also co-chair of the Quality Alliance Steering Committee, sits on the National Quality Forum's Board of Directors, is a member of the Institute of Medicine of the National Academy of Sciences, and is a research associate at the National Bureau of Economic Research.

McClellan holds an MD from the Harvard University–Massachusetts Institute of Technology (MIT) Division of Health Sciences and Technology, a PhD in economics from MIT, an MPA from Harvard University, and a BA from the University of Texas at Austin. He completed his residency training in internal medicine at Boston's Brigham and Women's Hospital, **is board-certified in Internal Medicine, and has been a practicing internist during his career.**

CHRIS JENNINGS

Deputy Assistant to the President for Health Policy and Coordinator for Health Reform

Chris Jennings is the Deputy Assistant to the President for Health Policy and Coordinator for Health Reform. Appointed in July of this year, Jennings will help coordinate the continued implementation of the Affordable Care Act (ACA). **For purposes of your discussion, Chris is dedicated to the success of healthcare reform and will be seeking solutions to any perceived problems along with support from those around the table for implementing the law.**

A leading authority on healthcare policy with a specific expertise coordinating Federal policy, Jennings spent more than two decades working with Congress, the White House, and the private sector. Most recently, he was Co-Staff Director with Mark McClellan of the Bipartisan Policy Center's Leaders' Project on the State of American Health Care. The center is led by former Senate Majority Leaders' Howard Baker, Tom Daschle, Bob Dole and George Mitchell.

Jennings was also the President of Jennings Policy Strategies, a consulting firm that "serves clients that share a commitment to affordable, quality health care for all Americans." His clients included consumer groups, labor organizations, businesses, public and private health plan purchasers, generic drug manufacturers, and not-for-profit foundations. **Jennings has worked closely with the Teva GA team over the past decade.**

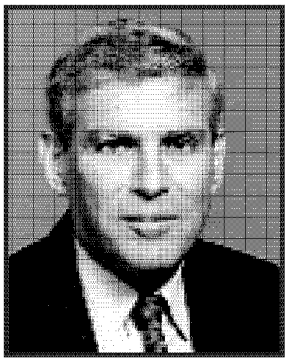
In 2008, he served on the Democratic Platform Drafting Committee, and as a senior health care advisor to Senator Hillary Clinton's Presidential campaign. Before this position, Jennings served in the White House as senior health care advisor to President Bill Clinton at the Domestic Policy and National Economic Councils. In this role, he was charged with developing and implementing the Administration's health care policy. Jennings made significant contributions to major bipartisan health legislation, including the State Children's Health Insurance Program, the Health Insurance Portability and Accountability Act, the Mental Health Parity Act, the Food and Drug Administration Modernization Act, and many others. Jennings also coordinated and oversaw the health policy work of numerous Federal agencies, including the Office of Management and Budget and the Departments of Health and Human Services, Treasury, and Labor while leading efforts to communicate and advocate Administration health policy to Congress, state and local governments, health care interest groups, and the media.

Prior to joining the Clinton Administration, Jennings served as Committee staff for three U.S. Senators over almost a ten year period on Capitol Hill.

RON POLLACK

Member, Board of Directors, Enroll America

Executive Director, Families USA



Ron Pollack is the Founding Executive Director of Families USA, the national organization for health care consumers. Families USA's mission is to achieve high-quality, affordable health coverage for everyone in the U.S.

Families USA's numerous reports and analyses – on matters such as health coverage for the uninsured and underinsured, Medicaid, Medicare, prescription drug issues, long-term care, and others – are frequently cited at Congressional hearings, in state legislatures, by the media, and by consumer organizations.

Pollack is a frequent guest on a variety of television and radio programs, such as *The PBS NewsHour*, NBC's *Today* show, ABC's *Good Morning America*, all of the network nightly news programs, and NPR's *All Things Considered* and *Morning Edition*. He is often quoted in leading newspapers including *The New York Times, The Washington Post, The Wall Street Journal*, and *The Los Angeles Times*.

Pollack's work has been recognized through various honors. *The Hill*, a weekly newspaper covering Congress and their staffs, named Pollack one of the top nonprofit lobbyists. *Modern Healthcare* named Pollack one of the 100 Most Powerful People in Health Care. National Journal named him one of the top 25 players in Congress, the Administration, and the lobbying community on Medicare prescription drug benefits.

Pollack is the Founding Board Chairman of Enroll America, an organization composed of very diverse stakeholders working together to secure optimal enrollment of uninsured people through effective implementation of the Affordable Care Act.

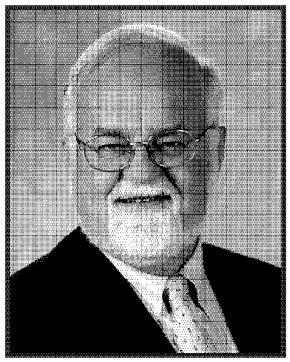
In 2007, at the 25th anniversary of Search for Common Ground, a nationally renowned conflict management organization, Pollack received the Common Ground co-award for his work with a group of ideologically diverse health organizations that reached a historic consensus proposal about expanded health coverage for the uninsured. Previous winners of the award included former President Jimmy Carter, Archbishop Desmond Tutu, and Muhammad Ali.

In 1997, Pollack was appointed by President Clinton as the sole consumer representative on the Presidential Advisory Commission on Consumer Protection and Quality in the Health Care Industry. In that capacity, Pollack helped prepare the Patients' Bill of Rights that has been enacted by many state legislatures.

Pollack received his law degree from New York University where he was an Arthur Garfield Hays Civil Liberties Fellow.

JOHN ROTHER

President and CEO, National Coalition on Health Care



John Rother is President and CEO of the National Coalition on Health Care, America's oldest and most diverse group working to achieve comprehensive health system change. The Coalition's membership of more than 80 participating organizations includes medical societies, businesses, unions, health care providers, faith-based associations, pension and health funds, insurers, and groups representing consumers, patients, women, minorities, and persons with disabilities. **Teva is a member of this organization and Debra Barrett sits on their board.**

Prior to joining the Coalition in 2011, Rother served as the longtime Executive Vice President for Policy, Strategy, and International Affairs at the American Association of Retired Persons (AARP). There he led the development of AARP's policy positions and advocacy strategies. Under his leadership, AARP engaged in robust public policy research and analysis, public education, and advocacy on health and retirement issues at the federal, state and international levels. Rother wrote numerous articles and was a frequent speaker on health, retirement security, the federal budget, and the boomer generation. **Chris Jennings represented AARP as a consultant during health care reform and worked closely with Rother.**

From 1981 to 1984, Rother was Staff Director and Chief Counsel for the U.S. Senate Special Committee on Aging under the direction of Chairman John Heinz (R-PA). From 1977 to 1981, he served as Special Counsel for Labor and Health to U.S. Senator Jacob Javits (R-NY).

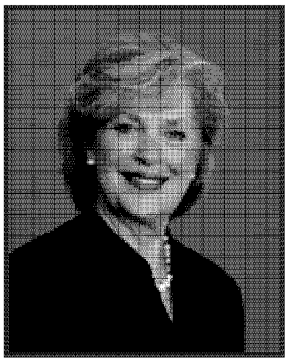
Rother is a graduate of Oberlin College and the University of Pennsylvania Law School. He is a member of the DC Bar, the National Academy of Social Insurance, and the Gerontological Society of America.

Rother serves on several boards, including the American Board of Internal Medicine Foundation, the National Quality Forum, the Alliance for Health Reform, the Pension Rights Center, and Generations United. He also serves on the MacArthur Foundation's Aging Society Network and the Institute of Medicine's National Roundtable on Value and Science-Driven Health Care. He has consistently been named as one of the Most Powerful People in Healthcare.

In 2010, Rother received the Robert Ball Award for Outstanding Achievements in Social Insurance from the National Academy of Social Insurance for "lifetime advocacy to strengthen Social Security and Medicare."

NANCY DAVENPORT - ENNIS

Founder and Chairman of the Board, National Patient Advocate Foundation

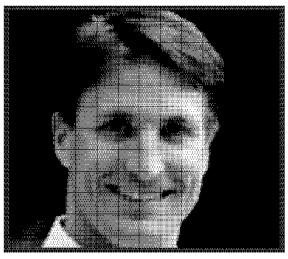


Nancy Davenport-Ennis, a two time breast cancer survivor, is the Founder and Chairman of the Board of two organizations – Patient Advocate Foundation and National Patient Advocate Foundation – both founded in 1996 to serve the needs of patients battling chronic, life threatening and debilitating illness. National Patient Advocate Foundation (NPAF), is a policy organization, headquartered in Washington, DC that seeks to improve access to care through regulatory and policy initiatives at the state and federal levels and Patient Advocate Foundation (PAF), is a 501(c) 3 direct patient services non-profit organization, headquartered in Virginia, providing professional case management services in order to resolve patient access issues.

Ms. Davenport-Ennis holds a B.A. degree in English from Campbell University. She resides in Yorktown, Virginia with her husband, John H. Ennis, Jr., and has two daughters and four grandchildren.

ALAN BALCH

CEO (as of July 2013), National Patient Advocate Foundation



Dr. Balch began his role as CEO in July 2013, succeeding founder Nancy Davenport-Ennis in day to day management and onsite leadership for Patient Advocate Foundation.

Dr. Balch brings a decade of executive leadership in the non-profit sector with an emphasis on consensus-building and

collaboration to his position as Chief Executive Officer. Dr. Balch has led numerous federal advocacy efforts on a range of issues both at the legislative and regulatory level over the years. For example, he helped to organize and lead a coalition that successfully fought for improvements in the regulatory process for the review of cancer drugs at the Food and Drug Administration (FDA). He also contributed key concepts and statutory language to important provisions in the Affordable Care Act.

From 2006 to 2013, he served as the Vice President of the Preventive Health Partnership—a nation-wide health promotion collaboration between the American Cancer Society, American Diabetes Association, and American Heart Association. He also negotiated and helped to oversee a formal partnership between the three organizations on a multi-million dollar quality improvement program known as The Guideline Advantage that is designed to improve patient care by providing performance feedback to physicians and their practices across various quality of care measures. Dr. Balch also served as the Executive Director of Friends of Cancer Research. Dr. Balch worked closely with the Chair and board of directors of Friends to develop and implement a strategic growth plan that significantly expanded programmatic activities while tripling average annual revenues and net assets to more than $1 million.

He earned his PhD in environmental studies in 2003 from the University of California, Santa Cruz; his master's degree in environmental sciences in 1997 from the University of Texas in San Antonio; his bachelor's degree (cum laude) in biology in 1994 from Trinity University in San Antonio.

BACKGROUND

Teva currently sits on the board of the National Coalition on Healthcare, is a supporter and board member of Enroll America, the program spearheaded by Ron Pollack, and has worked closely with NPAF on several initiatives, including their Elite President's Council of Volunteer Activists and their Policy Consortium. Teva also serves on the advisory committee for the Consumer-based Cancer Care Value Index (CCCVI) Project under the NPAF. The CCCVI is a standardized index of quality measurements patients will use to identify and measure specific types of cancer care and services that represent value to them, their families and their caregivers. This Index is being implemented to complement CMS quality indicators and ensure the patient voice is taken into consideration.

The expansion of health coverage, for which open enrollment begins on October 1, is the issue on everyone's mind. We have prepared a background page on health reform and have picked 4 specific topics to have our guests discuss. We would start with Jeremy talking about Teva, his vision and what we are doing for patients and the system. Then we would have a lively discussion (facilitated by Debra Barrett) drawing out the participants on these issues.

Implementation
Implementation of the Affordable Care Act (ACA) is moving forward. On October 1, open enrollment begins in the exchanges, or mini marketplaces. Almost half of the states have decided to expand their Medicaid programs. One provision – the employer mandate – has been delayed. The law requires most employers to provide insurance, or pay a fine, but the Obama administration recently delayed enforcing that provision for a year.

Exchanges
Beginning in 2014, the health reform law creates a new mechanism for purchasing coverage through exchanges. The exchanges – also referred to as "marketplaces" – will be set up in states to offer a choice of health plans, establish common rules regarding the offering and pricing of insurance, and provide information to consumers. Premium subsidies are available to low and moderate income individuals. So far, 16 states and the District of Columbia have declared they will create their own state-based exchanges, while the remaining states will default to either a federally-run exchange or a joint state and federally-run exchange.

All plans offered through the exchanges must comply with various requirements set forth in the health reform law. For example, the law eliminates pre-existing condition exclusions, and requires all plans to offer essential health benefits, such as prescription drugs.

Medicaid Expansion
Medicaid provides health coverage for low-income children and adults, people with disabilities, and assistance with long-term care expenses for low-income seniors. The ACA expands Medicaid eligibility to 138% of the federal poverty level ($15,415 for an individual or $26,344 for a family of three.) The mandatory expansion of Medicaid was held unconstitutional by the Supreme Court in June 2012, and remains a controversial issue. Almost half of the states have decided to voluntarily expand their Medicaid programs, and the majority of Republican governors are opposed to expansion because of the associated costs.

Prescription Drugs
Another goal of the health reform law is to reduce prescription drug costs. The law gradually eliminates the so-called Medicare prescription drug "donut hole" or gap in coverage, and requires drug coverage in all plans offered in an exchange.

Donut Hole
The Medicare prescription drug program, which serves primarily individuals 65 and older, has been operational since 2006. Under the program, also referred to as "Part D," drug coverage

is provided through private plans that must be approved by the federal government. Prior to the ACA, the program had a large gap in coverage known as the "donut hole," where beneficiaries were responsible for the full cost of their drugs until hitting a catastrophic threshold. The ACA eliminates the donut hole by gradually reducing the cost-sharing in the coverage gap for both brand name and generic drugs and requiring a 50% discount on all brand drugs in the gap.

Drug Coverage
The health reform law requires all plans offered in the exchanges to cover prescription drugs, but the level of coverage will vary state by state. While plans cannot discriminate in terms of coverage benefits, they can define which drugs and how many drugs are covered. Insurers are only required to provide coverage for at least 1 medication per drug class, but the majority of plans are expected to exceed this minimum requirement.

Coordinated Care
Health care experts have identified the U.S. "fee-for-service" (FFS) system, which compensates providers for each service a patient receives, as a major cause of high-cost, low-quality care. The FFS system incentivizes the delivery of more tests and procedures at greater cost. The ACA takes steps to move away from a FFS system through programs like "medical homes" and "accountable care organizations (ACOs)." These programs encourage primary care providers to coordinate care for patients, while improving quality and reducing costs. While health experts support coordinated care, many providers, patient groups, and manufacturers remain concerned that the emphasis on reduced costs will limit access to innovative therapies.

DISCUSSION RECOMMENDATIONS

- Redaction - Other Teva Product
  - Copaxone Redaction - Other Teva Product
- Expect the discussion portion of the lunch to touch on the issues outlined in this brief. The experts in the room will have a great deal to contribute to the discussion and Debra will facilitate and offer questions.
- Redaction - Other Teva Product
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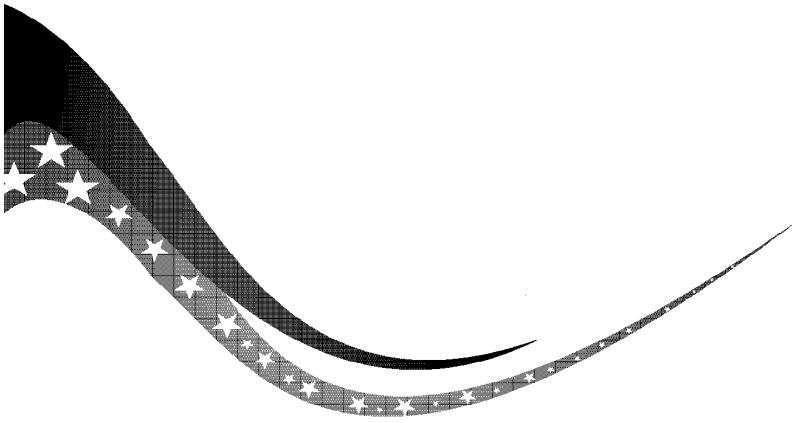
  Redaction - Other Teva Product
- Redaction - Other Teva Product
- A few questions Jeremy might want to consider:
  - **[Mark/Chris/Ron]** What do you foresee in the implementation of health reform that is not readily apparent that you think a company like Teva would want to know?
  - **[Barry/Nancy/Mark/Chris]** For patients taking our medicines, what, if any, unintended consequences or market disruptions could they experience in the future? And in what form?
  - **[All]** Can you paint a picture of what the U.S. health system looks like 36 months from now?

HILL MEETING BRIEFS



SENATOR TOOMEY

OVERVIEW

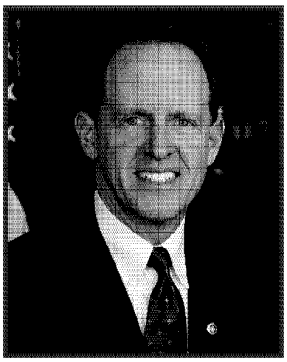
Senator Toomey is a pro-business Republican currently serving in his first term as Pennsylvania's junior Senator. As a representative of Teva's U.S. headquarters, Toomey has developed a close working relationship with Teva on several key issues. As a member of the Senate Committee on Finance, Senator Toomey's support for Teva objectives is particularly relevant on issues related to tax and trade.

Senator Toomey is very well respected within the Senate Republican Caucus and was chosen by his colleagues to lead the Caucus Steering Committee, a position that requires him to resolve differences and attempt to build consensus on issues. He is also widely recognized as an expert in financial issues and was chosen by Republican Leadership to serve on the task force on deficit reduction. Although the task force ultimately failed to come to a bipartisan agreement, Senator Toomey will likely be a key player in any issues related to the federal budget and deficit reduction that will arise when the issue of raising the debt ceiling is debated later this fall.

The objective of this meeting is to reinforce Teva's presence and economic footprint in the State of Pennsylvania, offer to work as a partner in his efforts to find savings in government spending and stress the importance of increasing incentives for the development of branded and generic medicines.

BIOGRAPHY

Senator Pat Toomey is the junior Senator for Pennsylvania who is known for being a champion of fiscal responsibility. Previously, Sen. Toomey served as a Congressman for three terms. Toomey is a member of the Banking, Budget, and Finance Committees, and the Congressional Joint Economic Committee. Since April 2012, Sen. Toomey has been the chairman of the Senate Republican caucus.



PAT TOOMEY
U.S. Senator for Pennsylvania (R-PA)

He graduated from Harvard with an A.B. in government. Sen. Toomey previously worked for Chemical Bank and Morgan, Grenfell & Co. where he was involved in currency swap transactions, multiple foreign currencies, interest rates, and currency-related derivatives. He also opened a restaurant with his two younger brothers in Allentown, PA.

BACKGROUND

Deficit Reduction *(also see backgrounder included in the briefing book)*: Faced with enormous fiscal pressures and national debt, Congress is struggling to find ideas for deficit reduction. Unfortunately, some of the "solutions" being considered would be harmful to the industry. For example, a proposal to increase rebates for beneficiaries who are eligible for Medicare and Medicaid would cost Teva $500-$600 million annually. It would shift costs in the system rather than reducing or restraining costs. Teva has identified the following areas to generate savings:

REMS (Risk Evaluation and Mitigation Strategies): REMS is a program used by the FDA to ensure a restricted distribution of products with serious side-effects or a higher probability of misuse. Some brand companies are using these programs to deny generic manufacturers product samples for testing, a barrier to market competition.

Donut Hole: The current federal subsidy for brand drugs in the Medicare Part D donut hole should apply only to single source products. If patients begin treatment using a brand and then the federal government subsidizes the payment for that brand, needless government spending is occurring if a generic is available for the brand product.

LIS: The Low Income Subsidies population within Medicare is using less generic drugs than the general population. Cost sharing modifications, or differential co-pays, could be used to ensure LIS beneficiaries use generic drugs more. Currently, only the government pays more when the brand is selected and not the patient.

Taxes: Congress is currently in the beginning stages of preparing legislation to overhaul the tax system in the United States. As a member of the Finance Committee, Senator Toomey will be heavily involved in the debate over this issue. Philosophically, the two parties differ on how to best approach this reform and, specifically, how to generate revenue. Republicans believe that lowering tax rates and broadening the base will lead to a more favorable economic environment in which to conduct business. Democrats disagree with this approach and believe that the top income brackets should pay more in taxes. Sen. Toomey has been a vocal proponent of lowering the corporate tax rate in the United States.

Healthcare: Sen. Toomey opposed passage of the Affordable Care Act (ACA) and has voted on several occasions to defund or repeal the law. With the end of the fiscal year approaching on Sept. 30th, some conservative Republicans are using the year-end budget fight to defund the ACA. Congress is faced with having to pass a temporary funding measure, known as a Continuing Resolution (CR), in order to keep the federal government funded and running. CR's are generally not controversial, but efforts by conservatives to tie the CR to the defunding of the ACA have led to a stalemate over its passage and could result in a shutdown of the government. Of note, Sen. Toomey does not support this approach.

Patent Settlements: Sen. Toomey voted **against** an amendment by Sen. Bingaman last year that would restrict patent settlements between brand and generic pharmaceutical manufacturers.

Importation: Senator Toomey has often cited concerns over the availability of lower cost medicines in foreign countries, believing that the United States is subsidizing the cost of medication for the rest of the world. On several occasions, Senator Toomey has voted to allow for the importation of prescription drugs from foreign countries.

DISCUSSION RECOMMENDATIONS

(1) Provide a general overview of Teva:

- Use Key Messaging Points

(2) Reinforce Teva's presence in Pennsylvania:

- Teva's North American headquarters are located in North Wales.
- Teva employs 2,356 Pennsylvanians in 8 different locations – North Wales, Sellersville, Frazer, Horsham, West Chester, Chalfont, Malvern, and Kutztown.
- These facilities make up an intricate network of Teva's manufacturing, warehousing and distribution facilities for finished dose medicines.

Note: *It is important to note that Teva recently announced that the facility in Sellersville will be closing by 2017. The facility currently employs approximately 400 people.

(3) Propose ideas for deficit reduction:

- Expanding drug rebates to duals would cost Teva $500-$600 million annually and would shift costs instead of reducing or restraining them.
- Ideas that would constrain costs rather than shifting them include: REMS, Donut Hole, and LIS.
- Increased generic utilization in Medicare would result in true savings and efficiencies in the system.

(4) Garner support for NTE program:

- Teva believes the current legislative landscape does not adequately reward the continued examination of existing molecules for new uses or for use in new products.
- This is an important area where the U.S. could be a leader.
- More work can and should be done to develop combinations, innovative uses and other improvements to existing molecules that enhance patient benefits.
- Additional exclusivities are needed to protect these products as it is unlikely that patent protection for these products will be adequate.

SENATOR MORAN

OVERVIEW

Senator Moran is a Republican Senator from Kansas currently serving in his first term. Earlier this year, Senator Moran was elected by his colleagues to serve as the Chairman of the National Republican Senatorial Committee, the political committee dedicated to electing Republicans to the United States Senate.

Healthcare is an important issue to Senator Moran, demonstrated by his commitment to advancing medical research. As the ranking Republican member of the Senate Appropriations Subcommittee on Labor, Health and Human Services, Education and Related Agencies, Senator Moran has jurisdiction over funding for agencies such as the National Institutes of Health. The Senator is a long standing supporter of NIH and believes in the importance of sustained funding for the agency to perform its mission.

Senator Moran will soon be representing Teva's newest facility in Overland Park, Kansas.

The objective of this meeting is to establish a relationship between you and the Senator and offer Teva as a resource and partner for him as he works on issues related to improving healthcare and medical research.

BIOGRAPHY

JERRY MORAN
U.S. Senator for Kansas
(R-KS)

Prior to his election to the Senate in 2010, Moran served seven terms in the U.S. House of Representatives. As a senior member of the House Veteran's Affairs Committee, he served as the chairman of the Subcommittee on Health.

Before being elected to federal office, Moran served eight years in the Kansas State Senate.

Moran received a degree in economics from the University of Kansas and a J.D. from the University of Kansas School of Law. Moran volunteers his time in Kansas as the trustee of the Eisenhower Foundation, a member of the board of trustees of the Fort Hays State University Foundation and a member of the executive committee of the Coronado Area Council of the Boy Scouts of America. He and his wife, Robba, live in Kansas and have two daughters.

BACKGROUND

Health Care: Senator Moran believes that, in order to improve patient treatment, care, and diagnosis, it is essential to remain committed to advancing medical research. He sees this research as being vital to saving and improving lives, strengthening the economy, and maintaining America's role as a global leader in medical innovation. In his capacity as Ranking Member of the Appropriations Subcommittee with jurisdiction over the budget of NIH, Senator Moran has used his position to advocate for restoring budget cuts to the agency over the past few years. On several occasions during the annual budget and appropriations debates, Senator Moran has offered amendments increasing funding for NIH.

Recently, the University of Kansas Cancer Center (KUCC) was selected as a National Cancer Institute – Designated Cancer Center. National Cancer Centers are a part of the National Institutes of Health and the principal agency for cancer research and training. They focus on turning research discoveries into new treatments for cancer patients. Senator Moran was very involved in the effort to help KUCC secure this important designation and believes this represents another step in enabling Kansas to develop into a research corridor for medical, pharmaceutical and technological advancement.

Senator Moran is a member of the following health care caucuses:

- Congressional Caucus on Parkinson's Disease
- Congressional Multiple Sclerosis Caucus
- Congressional Task Force on Alzheimer's Disease
- Senate Cancer Caucus
- Senate Diabetes Caucus

DISCUSSION RECOMMENDATIONS

This meeting will be the first official introduction of Teva to Senator Moran and is about establishing a relationship with him.

(1) Provide a general overview of Teva:

- Use Key Messaging Points

(2) Discuss the opening of the new facility in Kansas and how Teva is looking forward to becoming an active member of the community:

- Teva's new facility is located at 11100 Nall Avenue in Overland Park, KS.
- This new facility will house approximately 400 employees, including Teva's Shared Solutions Call Center.

(3) As Senator Moran is a member of the Congressional Multiple Sclerosis Caucus, describe Teva's Shared Solutions and its positive impact on patients:

- Helps patients with critical diseases secure reimbursement, ensures timely arrival and administration of medicines, and assists with adherence.
- The program serves 100,000 patients with MS or other critical diseases.
- Offers support 24 hours a day.
- Processes 900,000 calls per year and provides support to 40,000 patients requiring financial assistance.

(4) Acknowledge Senator Moran's commitment to supporting biomedical research and comment on how his work to support and increase funding for the National Institutes of Health is a critical component to how we can continue to make groundbreaking advances in the treatment of disease.

(5) Inform him of Teva's National Network of Excellence project in Israel and how we believe this could serve as a model of how public/private partnerships can support medical research:

- Intended to support innovative neuroscience research and strengthen neuroscience research capabilities.
- Encourage multi-institutional collaboration.

(6) Given the recent National Cancer Institute designation as the University of Kansas' Cancer Center, highlight Teva's contribution to cancer care through fulfilling unmet medical needs through the development of important new treatment options:

- Teva continues to invest in the development of novel oncology therapeutics.
- The upcoming launch of Granix (tbo-filgrastim) represents Teva's approach of balancing innovation with providing affordable medicines to patients.

SENATOR CASEY

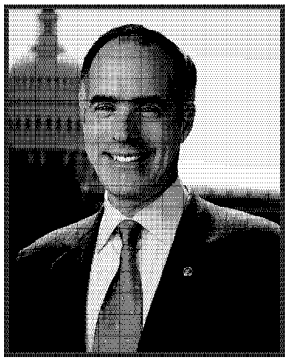
OVERVIEW

Senator Casey is a Democrat currently serving in his second term as Pennsylvania's senior Senator. As a representative of Teva's U.S. headquarters, Teva has developed a close working relationship with his office on several key issues, including patent settlements and trade. As a member of the Senate Finance Committee, Senator Casey's support for Teva objectives is particularly relevant on issues related to tax and trade.

With the strong pharmaceutical industry presence in the state of Pennsylvania, Senator Casey has been supportive of many of the issues of importance to the industry. In June of this year, Senator Casey sent a letter to Secretary of State John Kerry in advance of his visit to India requesting that he confront the Indian government about the ongoing violation of U.S. pharmaceutical companies' intellectual property (IP) rights. Senator Casey is the current Co-chair of the Congressional MS Caucus, and is a proponent for continued investment in medical research by the federal government.

The objective of this meeting is to reinforce Teva's presence and economic footprint in the State of Pennsylvania, offer to work as a partner in his efforts to find savings in government spending and stress the importance of increasing incentives for the development of branded and generic medicines.

BIOGRAPHY



BOB CASEY
Senator (D), Pennsylvania

Senator Robert Patrick "Bob" Casey Jr. is the senior Senator representing Pennsylvania. First elected in 2006, he is currently serving his second term. Prior to entering the Senate, Senator Casey served for eight years as the Pennsylvania Auditor General and for two years as State Treasurer. In the Senate, Senator Casey serves on five committees, including Finance and Health, Education, Labor and Pensions.

Born in Scranton, PA, Sen. Casey is the son of Bob Casey, Sr., a former Governor of PA. He graduated from The College of the Holy Cross and received his law degree from Catholic University. Sen. Casey and his wife, Terese, live in Scranton, PA and have four daughters.

BACKGROUND

DEFICIT REDUCTION *(also see backgrounder included in the briefing book)*: Faced with enormous fiscal pressures and national debt, Congress is struggling to find ideas for deficit reduction. Unfortunately, some of the "solutions" being considered would be harmful to the industry. For example, a proposal to increase rebates for beneficiaries who are eligible for Medicare and Medicaid would cost Teva $500-$600 million annually. It would shift costs in the system rather than reducing or restraining costs.

Teva has identified the following areas to generate savings:

REMS (Risk Evaluation and Mitigation Strategies): REMS is a program used by the FDA to ensure for a restricted distribution of products with serious side-effects or a higher probability of misuse. Some brand companies are using these programs to deny generic manufacturers product samples for testing, a barrier to market competition. — Savings estimated at more than $750 million over ten years.

Donut Hole: The current federal subsidy for brand drugs in the Medicare Part D donut hole should apply only to single source products. If patients begin treatment using a brand and then the federal government subsidizes the payment for that brand, needless government spending is occurring if a generic is available for the brand product. — No savings estimate available.

LIS: The Low Income Subsidies population within Medicare is using less generic drugs than the general population. Cost sharing modifications, or differential co-pays, could be used to ensure LIS beneficiaries use generic drugs more. Currently, only the government pays more when the brand is selected and not the patient. — Savings estimated at $17 billion over ten years.

TAXES: Congress is currently in the beginning stages of preparing legislation to overhaul the tax system in the United States. As a member of the Finance Committee, Senator Toomey will be heavily involved in the debate over this issue. Philosophically, the two parties differ on how to best approach this reform and, specifically, how to generate revenue. Republicans believe that lowering tax rates and broadening the base will lead to a more favorable economic environment in which to conduct business. Democrats disagree with this approach and believe that the top income brackets should pay more in taxes. Sen. Casey believes tax reform should include incentives for domestic manufacturing and life science innovation.

HEALTHCARE: Like most Democrats, Sen. Casey voted for the health reform law and opposes cuts to federal health care programs such as Medicare and Medicaid. However, he differs from his party due to his support of the pharmaceutical industry and his pro-life stance. For example, he supports robust exclusivity for brand biologics. He is a nationally recognized advocate for children, and was a strong supporter of the law that expanded the Children's Health Insurance Program (CHIP), a federal and state program that provides low-cost health care to children. Sen. Casey also helped to include a number of provisions in the health reform law to improve care for children.

PATENT SETTLEMENTS: Sen. Casey voted against an amendment by Sen. Bingaman last year (commonly referred to as "Bingaman Vitter"). The amendment would restrict patent settlements between brand and generic pharmaceutical manufacturers.

DRUG SHORTAGES *(also see backgrounder included in the briefing book)*: The issue of drug shortage is one where Senator Casey has been particularly interested. In 2011, Senator Casey joined several of his colleagues requesting a study by the Government Accountability Office (GAO) into the issues behind the problem as well as the FDA response and communication with industry. During the debate over the user fee bill last Congress, Senator Casey successfully advocated for the inclusion of language addressing drug shortages. The language closely resembles legislation introduced by Senator Casey called the Preserving Access to Life-Savings Medications Act. Like the original legislation, the bill requires drug companies to notify the FDA about any discontinuance or interruption that could lead to a disruption in supply. Teva GA worked with Senator Casey on this legislation.

DISCUSSION RECOMMENDATIONS

(1) Provide a general overview of Teva:

- Use Key Messaging Points

(2) Reinforce Teva's presence in Pennsylvania:

- Teva's North American headquarters are located in North Wales.
- Teva employs 2,356 Pennsylvanians in 8 different locations – North Wales, Sellersville, Frazer, Horsham, West Chester, Chalfont, Malvern, and Kutztown.
- These facilities make up an intricate network of Teva's manufacturing, warehousing and distribution facilities for finished dose medicines.

Note: *It is important to note that Teva recently announced that the facility in Sellersville will be closing by 2017. The facility currently employs approximately 400 people.

(3) Recognize Senator Casey's support of patients suffering from Multiple Sclerosis:

- Redaction - Other Teva Product Copaxone.
- Copaxone Redaction - Other Teva Product Redaction - Other Teva Product
- Teva's Shared Solutions helps patients secure reimbursement, ensure timely arrival and administration of medicines and assists with adherence.

(4) Propose generic drug savings for deficit reduction:

- Ideas that would constrain costs rather than shifting them include: REMS, Donut Hole, and LIS.
- Increased generic utilization in Medicare would result in true savings and efficiencies in the system.

(5) Raise the issue of Teva's efforts to secure a scientific meeting with FDA regarding Copaxone:

- In his capacity as Co-chair of the Congressional MS Caucus, Senator Casey is interested in ensuring that patients have access to treatments that are safe and effective.
- Redaction - Other Teva Product Redaction - Other Teva Product Copaxone **Redaction - Other Teva Product**
- Use this opportunity to inform Senator Casey about the specifics regarding patient safety and Teva's new data supporting our position.
- Solicit Senator Casey's opinion on how to best influence the agency in support of the scientific meeting request.

SENATOR SCHUMER

OVERVIEW

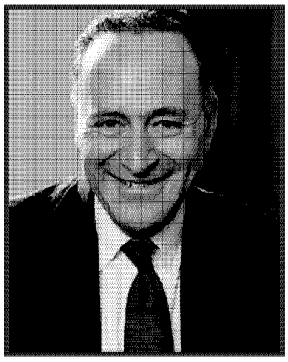
Currently serving in his third term, Senator Charles "Chuck" Schumer is New York's senior Senator first elected in 1998. As a well-respected, outspoken, and influential leader in the Democratic Party, Schumer's support is critical for moving issues forward. He is known for being boisterous, a committed advocate, and a formidable foe. Sen. Schumer is a key member for Teva to maintain a close relationship with, particularly with his seats on both the Senate Committees on Finance and the Judiciary.

An important point to note is that Debra Barrett served on his legislative staff from 1999 - 2001 as his Health Care Policy Aide and the company currently has an excellent working relationship with the Senator and his staff. Most recently, Teva's work with Schumer is in the areas of prescription drug abuse, biosimilars and generic medicines.

The objective of the meeting is to further our relationship with the Senator at the highest levels of Teva, offer to work as a partner in his efforts to find savings in government spending and inform him of Teva's commitment to helping reduce the abuse of prescription medicines.

BIOGRAPHY

Sen. Charles "Chuck" Ellis Schumer is the senior Senator for New York. He was elected to the Senate in 1998 and has served in public office for the past three decades. He is both the Vice Chair of the Democratic Conference, the number three position on the Democratic leadership team, and Chairman of the Democratic Policy and Communications Center (DPCC). Sen. Schumer is a member of the Banking, Judiciary, and Finance Committees, and Chairman of the Rules Committee.



CHARLES SCHUMER
U.S. Senator for New York (D-NY)

After graduating from Harvard College and Harvard Law School in 1974, Chuck returned home and ran for the New York State Assembly, becoming, at 23, the youngest member of the State Legislature since Theodore Roosevelt. In 1980, at 29, Chuck ran for and won the seat in the 9th Congressional District, a district that he represented for eighteen years. Schumer was born in Brooklyn, NY where he still resides along with his wife, Iris Weinshall, and two daughters, Jessica and Alison.

BACKGROUND

Healthcare/Generic Drugs: Sen. Schumer was a strong supporter of the health reform law, and supported the creation of a pathway for biosimilars in the law. He is a longtime champion for access to generic drugs, but has reached out more broadly across the industry as he has become more senior in Senate leadership. During his time in the Senate, he has fought to ease the approval of generic drugs and limit the ability of brand pharmaceuticals to block generics.

Deficit Reduction *(also see backgrounder included in the briefing book)*: Faced with enormous fiscal pressures and national debt, Congress is struggling to find ideas for deficit reduction. Unfortunately, some of the "solutions" being considered would be harmful to the industry. For example, a proposal to increase rebates for beneficiaries who are eligible for Medicare and Medicaid would cost Teva $500-$600 million annually. It would shift costs in the system rather than reducing or restraining costs.

Teva has identified the following areas to generate savings:

REMS (Risk Evaluation and Mitigation Strategies): REMS is a program used by the FDA to ensure a restricted distribution of products with serious side-effects or a higher probability of misuse. Some brand companies are using these programs to deny generic manufacturers product samples for testing, a barrier to market competition.

Donut Hole: The current federal subsidy for brand drugs in the Medicare Part D donut hole should apply only to single source products. If patients begin treatment using a brand and then the federal government subsidizes the payment for that brand, needless government spending is occurring if a generic is available for the brand product.

LIS: The Low Income Subsidies population within Medicare is using less generic drugs than the general population. Cost sharing modifications, or differential co-pays, could be used to ensure LIS beneficiaries use generic drugs more. Currently, only the government pays more when the brand is selected and not the patient.

Patent Settlements: Sen. Schumer voted in support of an amendment by Sen. Bingaman last year (commonly referred to as "Bingaman Vitter"). The amendment would restrict patent settlements between brand and generic pharmaceutical manufacturers.

Importation: Senator Schumer has often cited concerns over the availability of lower cost medicines in foreign countries, believing that the United States is subsidizing the cost of medication for the rest of the world. On several occasions, Senator Schumer has voted to allow for the importation of prescription drugs from foreign countries.

Prescription Drug Abuse: Sen. Schumer has been very involved in issues related to prescription drug abuse. Teva most recently worked with him to help redraft legislation so it aligns with Teva's position. The bill encourages FDA to require generic versions of abuse-deterrent opioid products to be formulated with technology *comparable* to the brand reference product. An early version of this resolution called for deterrence that was *identical* to the brand product.

DISCUSSION RECOMMENDATIONS

(1) General overview of Teva:

- Use Key Messaging Points

(2) Teva's presence in the state:

- Teva employs 434 New Yorkers in two locations – Pomona and North Tonawanda.
- Redaction - Other Teva Product
  ParaGard® Redaction - Other Teva Product
  Redaction - Other Teva Product
- The Pomona facility is undergoing a planned conversion from manufacturing to research and development.

(3) Garner support for NTE program and increased exclusivity:

- Teva believes the current legislative landscape does not adequately reward the continued examination of existing molecules for new uses or for use in new products.
- This is an important area where the U.S. could be a leader.
- More work can and should be done to develop combinations, innovative uses and other improvements to existing molecules that enhance patient benefits.
- Additional exclusivities are needed to protect these products, as it is unlikely that patent protection for these products will be adequate.

(4) Prescription drug abuse:

- Teva is committed to reducing the abuse of prescription medications.
- Teva is participating with a coalition of companies representing different aspects of the supply chain in order to develop a comprehensive solution to address the problem.

(5) Generic savings for deficit reduction:

- Generic drugs have saved U.S. consumers and payors $1 trillion in ten years, with nearly $300 billion in savings to the federal government.
- Increased generic utilization in Medicare would result in true savings and efficiencies in the system.

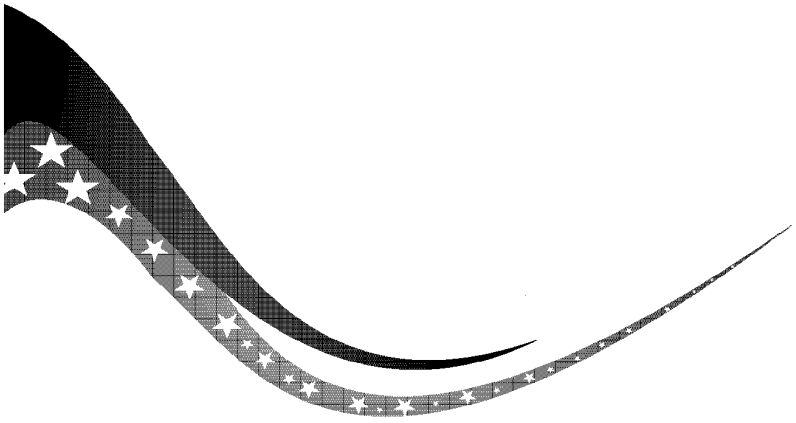
(6) Redaction - Other Teva Product **Granix** Redaction - Other Teva Product

- Granix Redaction - Other Teva Product
- **Redaction - Other Teva Product**

(7) Generic Drug Labeling:

- While the current focus is on the expected FDA draft regulations, the issue, particularly with its implications for product liability, has become politicized on Capitol Hill. Many Democrats feel strongly about providing remedies for injured patients and are especially close, including Schumer, with trial lawyers. Senator Schumer does see himself as a deal maker with some expertise in pharmaceutical issues though, as we may to appeal to him and make sure he understands, the potential downsides for patients and the generic industry if generics are allowed to unilaterally change their labels.

ISSUE BRIEFS



HEALTHCARE REFORM

BACKGROUND

The Affordable Care Act (ACA) of 2010 includes a number of new policies intended to reduce the number of uninsured. Key provisions to be implemented in 2014 include: (1) an individual mandate to purchase health insurance, (2) new insurance exchanges, or mini marketplaces, to purchase insurance, (3) subsidies for coverage in those exchanges, and (4) insurance market reforms. The ACA also includes an expansion of Medicaid, the primary public health insurance program for low-income Americans. However, the Medicaid expansion became a choice for states to make following the Supreme Court ruling in 2012. The ACA was enacted into law on a straight-line partisan basis, and remains a contentious issue between Democrats and Republicans.

The key goal of the ACA is to reduce the number of uninsured Americans. Beginning in 2014, the law requires most U.S. citizens and legal residents to have health insurance. On October 1, open enrollment begins in the exchanges. Premium and cost-sharing credits are available for low-income individuals and families, and states have the option to expand Medicaid eligibility. The law also requires most employers to provide insurance, or pay a fine, but the Obama administration recently delayed enforcing that provision for a year.

RELEVANCE TO TEVA

Several provisions of the ACA directly impact Teva:

- **Biosimilars**—The FDA is now authorized to approve biosimilars. Brand biologic manufacturers are awarded 12 years of market exclusivity.
- **"Donut Hole"**—The ACA closes the Medicare Part D "donut hole," the gap in Medicare drug coverage where beneficiaries must pay for the full cost of prescription drugs out of pocket. The law gradually decreases the beneficiary's share of drug costs by requiring manufacturer discounts and providing government subsidies. The estimated annual cost to Teva is $40 million.
- **Medicaid Rebates**—All manufacturers that participate in Medicaid are required to pay a rebate – essentially a tax – on all drugs offered in the program. The ACA increased this rebate for both brand and generic drugs, from 15% to 23.1% for brands, and 11% to 13% for generics. It also expands the rebate to all insurance plans participating in Medicaid. The annual cost for Teva related to the rebates is $200 million.
- **PhRMA fees**—Beginning in 2012, all brand pharmaceutical manufacturers are subject to an annual fee, based on market share. The estimated impact on Teva is $5-$6 million annually.

NEXT STEPS

On October 1, open enrollment begins in the exchanges, although a few states have said their online sites will not be fully operational. Approximately half of the states have decided to expand their Medicaid programs. Republicans continue to oppose the ACA, and support efforts to repeal the law. Teva has made public statements supporting the effort to expand coverage, and is a member of Enroll America, a non-profit leading the effort to increase enrollment in health insurance.

BACKGROUND

U.S. government spending for biologics is increasing at a faster pace than any other health care-related expense, with the exception of diagnostic imaging tests. In 2011, spending for biologics in the U.S. accounted for more than a quarter of the country's total drug bill.

The Affordable Care Act (ACA) establishes a regulatory pathway in the U.S. for the approval of biosimilars. Teva has been at the forefront of the biosimilars debate in the U.S. and we were heavily involved in the legislative drafting process and continue to be asked for our position on key issues. The key provisions of the biosimilar pathway in the U.S. are as follows:

- 12 years of data exclusivity awarded to the brand biological product;
- Biosimilar applications cannot be filed until four years after the brand product is approved;
- One year of marketing exclusivity for the first biosimilar approved as interchangeable
- Relevant patents for litigation will be identified by the parties, not unilaterally listed by the brand; and
- No automatic stay of FDA approval pending the outcome of patent litigation.

The U.S. approval pathway differs from that of the EU and other countries in several significant ways. Most notably, the U.S. law separates the approval of biosimilars into two categories, and the regulatory agency does not issue guidance to the industry on product classes before accepting applications. A product can be approved as a biosimilar or as an interchangeable biosimilar, to the brand reference product. The first interchangeable product receives one year of exclusivity. Biosimilar products do not receive any period of exclusivity.

To date, the Food and Drug Administration (FDA) has issued draft guidances, held workshops, and has the authority to collect user fees to fund biosimilar approval activities, but a single biosimilar application has yet to be filed.

RELEVANCE TO TEVA

Many details surrounding biosimilars still need to be worked out. While the FDA has given the industry general draft guidance for biosimilar applications, it is still unknown what scientific evidence the agency will find acceptable in terms of: clinical data to prove biosimilarity, how foreign clinical studies will be viewed by the agency, if the agency will allow for the extrapolation of indications, how the products will be named, and what additional work will be required for a product to be deemed interchangeable. Many applicants have begun having meetings with FDA to discuss application packages but the regulatory pathway is still untested.

Redaction - Other Teva Product		
Redaction - Other Teva Product	Granix	Redaction - Other Teva Product
Redaction - Other Teva Product		
Redaction - Other Teva Product	Granix	Redaction - Other Teva Product
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SUPPLY CHAIN (TRACK & TRACE)

BACKGROUND

Counterfeit drugs are responsible for an estimated 2,000 deaths daily worldwide and represent a grey industry anticipated to be worth up to $205 billion touching Europe, America, Japan and emerging markets. According to reports by regulatory authorities, the problem is worsening. Dangerous substances have been substituted for the active ingredient in dozens of drugs in the United States, such as anti-HIV medicines, cancer treatments, cholesterol-lowering agents, and anti-arthritis medications. In May 2012, the FDA had to warn consumers that a fake version of Teva's Adderall was being sold over the internet and did not contain the correct active ingredients.

Congress has been contemplating federal legislation for several years that would provide a single standard by which to track drugs throughout the U.S. supply chain. U.S. lawmakers are currently considering new identification requirements often referred to as "pedigree" or "track and trace." While congressional efforts over the past three years to pass legislation have stalled, the current U.S. Congress is intent on passing new legislation introduced in April.

The proposed legislation would preempt state efforts to establish their own standards and impose lot-level tracking requirements over a period of years for drug manufacturers, re-packagers, distributors and pharmacies. Many states have introduced legislation with their own standards over the years, but California and Florida are the only ones to date to pass significant legislation. Specific product transaction information would be passed down the supply chain when there is a change in ownership and this information would be verified in each instance. If there is a determination that there may be a counterfeit or adulterated product, it would be reported within specific timelines according to a specified notification process.

RELEVANCE TO TEVA

Teva U.S. GA is working alongside several of our colleagues in the supply chain, including Cardinal Health, Pfizer, and the National Association of Chain Drug Stores, to advance a principled approach to drug security and distribution. Teva has already invested approximately $20 million (in the U.S.) on serialization implementation and technology to date and expects to serialize more than 100 of our pharmaceutical lines.

Teva supports a multi-faceted, phased-in approach involving business practices, legislation/regulation, enforcement, and technology to address issues that improve patient safety. Any prescription drug anti-counterfeiting legislative/regulatory initiatives should include the following key principles which we believe will give us the ability to successfully implement a track and trace policy without undue burden or cost to the company:

- Lot-level aggregation—a mechanism by which trading partners may infer what is inside a case or pallet without scanning each individual unit;
- E-labeling—moving to a system where there is no longer a paper label associated with each bottle;
- Error correction—it is imperative that members of the supply chain be allowed to address errors in a timely and efficient manner in order to minimize supply disruptions; and
- A uniform standard—a national policy that applies to all states.

NEXT STEPS

There will be a significant push to have the Senate pass their version of the track and trace bill in the next few weeks so that it can be reconciled with the House version and have a compromise bill signed into law. However, the Senate version contains a very controversial section that would enhance regulation of compounding pharmacies that is not included in the House bill. This issue will have to be resolved before the underlying track and trace bill can move ahead in the process. Teva GA will continue our efforts to influence the track and trace debate and provide lawmakers with solutions that will create uniformity in the U.S. with achievable standards and timelines.

BACKGROUND

U.S. law established almost thirty years ago now requires brand and generic medicines to carry the same labels, containing the same warnings, and prohibits a generic manufacturer from unilaterally changing its label under Federal law. In fact, generic manufacturers were required to wait until a change was approved for the reference listed drug before being able to add it to their label. As a result, when a medication is dispensed by a pharmacy with a medication guide or patient insert, consumers will receive the same information, regardless of how many generic products are on the market.

This process forms the argument for why State tort claims against generics should be preempted by Federal law. This issue has been the subject of significant litigation leading up to two Supreme Court cases this past year. In both cases, the Court affirmed that generics do not have the authority to unilaterally make changes and, therefore, are not liable for claims relating to the label. The practical result has been that patients who were hurt and took a generic cannot pursue compensation based on a claim that the label failed to warn while patients who took a brand medication could. Arguing inequities and patient safety, the trial lawyers have been lobbying for changes that would result in additional responsibility for the generics and the corresponding liability.

This summer, the FDA announced that it is considering changes to its labeling rules aimed at allowing generics to have more control over their labeling. The changes being considered would entail allowing NDA, BLA and ANDA holders to submit Changes Being Effected (CBE) supplements to their applications when they learn of new adverse reactions or have reasons to doubt the adequacy of their warning labels. This proposed regulation change is due out in September.

RELEVANCE TO TEVA

The FDA proposal could allow generic manufacturers to change their labeling immediately while FDA is considering their proposed changes. In addition, both brand name and generic versions of the drug would have to change their labeling in the event that FDA approves any change emanating from either the brand or generics. FDA has publicly cautioned that it is too soon to speculate what exactly the rule will say, but for purposes of assessing Teva's liability, the question of greatest importance in this new regulation is – will the generics be able to make changes and then seek FDA approval or will the FDA have to pre-approve any change beforehand for all products in the field?

If Teva must assume the responsibility of initiating labeling changes for our generic products and continuously conform to any label changes made for multisource products, our regulatory and pharmacovigilance efforts and staff will have to increase significantly. Although we significantly enhanced safety information management for U.S. generic products this year, our communications with FDA regarding safety signals of generic products are minimal. By the time a product becomes generic, most of the adverse events for the product have been reported and are in the labeling. But, the vast majority of "failure to warn" cases involve warnings that are already on the label and the litigation revolves around issues about whether the warning as it existed at the time, such as: font, location, exact wording, etc., was adequate.

Any change to the existing regulation will result in new litigation to interpret what the new duties are for a company to sufficiently warn. If this new rule is enacted with generics able to make label changes without FDA first approving them, it would expose the company to a significant risk of additional product liability litigation over its generic products. Based on our current litigation experience, at least approximately a $10 – 15 million increase in legal fees should be anticipated each year following a rule change. While difficult to fully asess, it is also possible that the company could incur additional costs in the hundreds of millions of dollars for jury verdicts and/or settlements associated with new litigation, as a result of a rule change.

NEXT STEPS

Following the Supreme Court decision in March, legislation was introduced that would give generics equal footing to a brand company to make labeling changes. Congress was unable to pass legislation in 2012, and influential Senators began writing to the FDA demanding regulatory changes. Following the second Supreme Court decision this June, efforts were once again underway to introduce a bill. The FDA announcement that draft regulations would be coming out in September has stalled the legislative effort for the time being. Consumer groups and trial lawyers are conducting a concerted campaign to reinstate failure to warn liability for all generics. They have significant presence in D.C. and contribute generously to many key legislators. An ad hoc policy group within Teva is working to 1) assess the risk to the company, 2) develop a response to the impending FDA draft guidance, 3) work with allies on positioning, and 4) develop policies that would give patients alternatives to state tort litigation – such as a public compensation fund.

DRUG SHORTAGES

BACKGROUND

The number of drug shortages on the FDA's published list nearly tripled from 2005 to 2010. In 2011, the number increased to 250. Over 80% of the drugs on the list are generic injectables. This has become a topic of constant media coverage, FDA scrutiny, and Congressional action. In 2011, Congressional offices began hearing from constituents who were unable to receive the medicines they need and began holding hearings.

The FDA has held stakeholder meetings, asked for stakeholder input on ideas to encourage the manufacturing of sterile products, and published a journal article outlining the causes of shortages and Dr. Woodcock's view that the market does not reward quality manufacturing. The article echoed what the industry has been saying: extremely low reimbursement rates are a major driver of shortages and do not reflect the importance of the therapies to patients or the cost of manufacturing. There was some negative reaction, to the article, from generic manufacturers who felt FDA was criticizing the quality standards of the industry.

RELEVANCE TO TEVA

As the largest generic drug manufacturer, with several products on the drug shortage list due to manufacturing issues at our Irvine plant, the industry and Congress looked to our company for solutions. Teva has been a key player in ongoing efforts to address the problem and the company, led by Fran Zipp's efforts, has worked closely with FDA to resolve the short supply of many products. Although challenges persist, our government affairs and regulatory efforts have created meaningful improvements in our supply of products and relationships with regulators and legislators. Of the 14 products that Teva is currently monitoring for shortages, we have restored supply to patients for 6 of them.

Teva also led the development of an idea called the **Accelerated Recovery Initiative (ARI)**, which was formally proposed to FDA and Congress by a group of generic manufacturers, including both members of the GPhA and non-members, representing about 80% of the generic sterile injectable products sold in the U.S. today. Th goal is to provide a more accurate, timely and comprehensive view of the current drug shortage situation, provide greater visibility to shortages, and establish practices that allow for potential, voluntary production adjustments to lessen or eliminate the impact of a current shortage. An independent third party (IMS Health Incorporated) was hired to collect and transmit the data to the FDA in a manner that safeguards competitively sensitive information. FDA is currently pursuing this idea although the absence of enough companies with manufacturing capabilities in the space, let alone being able to step in and fill the gap, has made this program difficult to implement.

NEXT STEPS

The 2012 User Fee bill included additional FDA notification requirements for manufacturers. A meaningful disruption in supply now requires a company to send notice to FDA. Provisions that would have required pharmaceutical companies to pay fees if their products fell into short supply were opposed by Teva and were not included in the final bill.

Congress is currently considering a bill that would regulate compounding pharmacies and manufacturers and that would allow them to manufacture products during a time of drug shortage. This portion of the bill has been very controversial for the industry, as the manufacturing sites of compounders are not held to the same standards as a typical drug manufacturer. Also, compounding manufacturers would not have the same obligations to pay government rebates or meet government pricing obligations. Teva has taken the position that low reimbursement rates are driving shortages and that the proposed compounding legislation will do nothing to address the root cause of the shortages problem.

DEFICIT REDUCTION

BACKGROUND

One of the main issues being debated in Washington is how to deal with the increasing financial deficit and reduce projected government spending, an issue often referred to as "bending the cost curve." The curve, of course, shows government spending outpacing revenue in the coming years.

This year there were significant spending cuts to the federal budget, known as sequestration, which came about as a penalty for Congress' inability to come to a compromise on raising the U.S. debt ceiling. Sequestration created a mandatory cut of approximately 8% across all federal spending with the exception of Social Security and Medicaid.

- The pharmaceutical industry is concerned that these cuts, which lowered the FDA's budget by approximately 8%, could lead to drug approval delays.

- The user fee agreements signed into law in July 2012 were intended to go into effect in Fiscal Year 2013, but, because an annual budget was not passed, the agency was held to FY 2012 spending levels. The new agreements were not accounted for until Teva successfully advocated for passage of the FDA User Fee Corrections Act, which authorized the FDA to collect and use fees for generic drug applications.

For the past few years, Congress has been unable to come to an agreement on the annual appropriations bills and instead has relied upon Continuing Resolutions, measures that fund the federal government at the prior year's level.

Once the federal government reaches the statutory limit on spending, known as the debt ceiling, action must be taken to increase it in order to not default on financial obligations. The two parties in control of Congress differ greatly on how to approach this issue. Republicans insist on dollar for dollar spending cuts corresponding to any increase in the debt ceiling. Democrats have resisted this approach and instead are focused on targeted tax increases as a means to increase federal revenue.

RELEVANCE TO TEVA

This is of interest to Teva because budget discussions are always a vulnerable time for the pharmaceutical industry. As Congress looks for funding sources to off-set government spending, solutions often include greater contributions from industry.

- One often discussed funding source is an extension of the rebates that are currently paid by pharmaceutical companies to the Medicaid program to those individuals who are also receiving Medicare services. This policy change is estimated to save close to $112 billion over 10 years, which makes it irresistable to policymakers. The estimated cost of this extension to Teva is $500 - $600 million annually. We have argued, along with our colleagues in the industry, that this policy would result in cost shifting rather than cost savings and there are better policy ideas that could actually constrain costs.

- The Congressional Budget Office has also estimated that a ban on patent settlements would result in over $4 billion in savings to the federal government over ten years. It is unclear if this estimate will change in light of the Supreme Court ruling on patent settlements, which allows for greater judicial discretion in evaluating the competitiveness of these agreements.

NEXT STEPS

Federal government spending will remain at the forefront in the upcoming weeks as Congress must pass appropriations bills funding the federal government for Fiscal Year 2014 and legislation to allow for the debt ceiling to be increased once again. These issues have been controversial and complicated and there is little consensus on how to best resolve the problem.

PRESCRIPTION DRUG ABUSE

BACKGROUND

Prescription drug abuse is a growing health concern in the United States and inappropriate use of opioid products is a significant part of the problem. The 2012 *National Survey on Drug Use and Health* conducted by the Substance Abuse and Mental Health Services Administration reported that "Among persons aged 12 or older in 2011-2012 who used pain relievers non-medically in the past 12 months, 54 percent got the drug they used most recently from a friend or relative for free, and 10.9 percent bought the drug from a friend or relative. An annual average of 4.3 percent got pain relievers from a drug dealer or other stranger, and 0.2 percent bought them on the Internet."

Lawmakers and regulators have taken notice. In the U.S. Congress, there have been several hearings and numerous bills introduced to address various aspects of the issue, including the approval of abuse deterrent formulations, such as Teva's AD Hydrocodone. Other bills would: restrict the number of prescriptions a physician could write for an individual patient; limit the prescribing of pain medication for severe-only pain and preclude it for moderate-to-severe pain; limit the number of pharmacies from which a patient may get their pain medications. Additionally, the FDA has issued draft "abuse deterrence" guidance for industry, convened a two-day public meeting to get reaction from interested stakeholders, actively promoted responsible prescribing education programs for physicians and established an internal opioid task force. Most recently, the FDA has made label change requirements for opioids intended to limit prescribing, as well as requiring product sponsors to conduct post market studies to gather more information about the risks of opioid abuse. The Drug Enforcement Agency has also publicly advocated for the rescheduling of hydrocodone products from Schedule III to the more restrictive Schedule II.

In the absence of better ideas, policymakers have offered a variety of legislative and regulatory initiatives that target the individual links in the supply chain that will, at best, have a minimal impact in truly addressing, in a comprehensive manner, the problem. Furthermore, this approach has resulted in a fear among physicians of intensified scrutiny by law enforcement and has caused many to stop or greatly reduce the number of prescriptions they write for "pain patients." Pharmacies are also proactively questioning both physicians about their prescribing practices and patients on their need for these medicines. The bottom line is that legitimate access for those patients who truly need these medicines is being reduced.

RELEVANCE TO TEVA

Recognizing that this hostile environment could hinder the ability of Teva to properly market our current pain products, as well as our pipeline AD Hydrocodone product and the pain related NTE drugs that are being internally reviewed at this time, Teva conceived and worked behind the scenes to establish the "Alliance to Prevent the Abuse of Medicines" (Alliance). The Alliance is led by Teva, CVS-Caremark (the nation's largest pharmacy health provider in the U.S.), Cardinal Health (the second largest wholesaler in the country) and the American Medical Association (the largest representative of the nation's doctors). This coalition will help to get Teva a "seat" at the policymaking table which may ultimately be critical for our business.

The Alliance brings together representatives from across the domestic supply chain in the United States. The goal of the Alliance is to partner with policymakers to craft systemic, workable and effective solutions that target the misuse and diversion while preserving access. Policy solutions under consideration include: strengthening Prescription Drug Monitoring Programs; incentivizing physician and patient education initiatives, positioning the problem as a public health issue and not a law enforcement one; regulating pill mills; and improving patient-focused drug take back programs.

NEXT STEPS

The Alliance is scheduled to go public this month. Next immediate steps include: additional member recruitment, determination of agreed upon policy alternatives, development of strategic programming/tactical calendar, and development of a full website.