Topic 2(a): Teva's Relationships with Distributors, Pharmacies, and other Manufacturers, including The Teva Defendants' agreements with distributors, pharmacies and other manufacturers, for the time period from 1999 to the date when the Teva Defendant was added to the State's Complaint, related specifically to the sale of opioids, sales reimbursements, purchasing, marketing, distribution, anti-diversion and dispensing, including, but not limited to agreements with distributors of opioids and pharmacies related to the pricing, marketing, provision of data, or other services related to the sale of opioids.

Agreements with Manufacturers

Teva Defendants have entered historical Distribution and Supply Agreements with Purdue that permit Teva Defendants to manufacture generic oxycodone

- 2009 Settlement Agreement among Purdue and Actavis (TEVA_MDL_A_06770141), 2013 Distribution and Supply Agreement between Actavis and Purdue (TEVA_MDL_A_06788775), 2014 Distribution and Supply Agreement between Purdue and Teva USA (TEVA_MDL_A_06787627), 2016 Distribution and Supply Agreement between Purdue and Teva USA, which is still in force (TEVA_MDL_A_12619201)
- Permit Teva Defendants to manufacture and sell generic oxycodone
- Stem from patent litigation with Purdue re disputed ANDAs

Mayne: Actavis entities divested interest in generic Fentora to Mayne Pharma in 2016. Teva USA assumed contract after acquisition. Teva USA is currently selling branded Fentora to Mayne for resale because generic ANDA not yet approved.

Watson: In 2006, Cephalon and Watson Pharma, Inc. entered agreement that established Watson as sales agent for generic Actiq, allowing Watson to solicit orders for generic Actiq on behalf of Cephalon.

Mallinckrdodt: In 2012, Watson Pharma, Inc., Watson Pharmaceuticals, Inc., Watson Laboratories, Inc. and affiliates, after a dispute about a patent, entered into a settlement and license agreement with Mallinckrodt that permitted them to sell hydrocodone HCL ER tablets.

Alpharma: Pursuant to a 2008 Development and Manufacturing Services Agreement between Actavis Elizabeth LLC and Alpharma, and subsequent amendments, Actavis agreed to manufacture Embeda (morphine sulfate; naltrexone hydrochloride) for Alpharma. Embeda is sold by Pfizer.

Teva USA, Cephalon, and the Actavis Entities have entered into agreements with other manufacturers over time for those manufacturers to supply active pharmaceutical ingredients (API):

- Mallinckrodt: Supplied the Teva Defendants (including Actavis after the 2016 acquisition) with fentanyl citrate (Fentora and Actiq), acetaminophen & codeine, hydrocan syrup, morphine sulfate, MS-contin, oxycodone hydrochloride, and hydrocodone bitartrate
- JMI:
    - Supplied the Teva Defendants (including Actavis after the 2016 acquisition) with fentanyl citrate, oxycodone hydrochloride, buprenorphine and naloxone, buprenorphine.
    - Supplied the Actavis Defendants prior to the acquisition with oxycodone hydrochloride, buprenorphine, naloxone

Highly Confidential

- Noramco:
  - Supplied the Teva Defendants (including Actavis after the 2016 acquisition) with morphine sulfate, oxycodone hydrochloride, buprenorphine.
  - Supplied the Actavis Defendants prior to the acquisition with oxycodone hydrochloride, hydrocodone bitartrate, hydromorphone hydrochloride, morphine sulfate, oxymorphone.

Agreements with Distributors

- None of the Teva Defendants have agreements pertaining to opioids only. Opioids that are sold by the Teva Defendants are included within larger portfolios of generic or branded opioids.
- The Teva Defendants enter agreements with wholesalers to supply products that the wholesalers sell to their customers.
- Relationships with distributors are generally controlled by Terms and Conditions contracts that set the terms of the commitment and rebates, and separate agreements over the course of the agreement that identify products and pricing.
- Agreements have been styled differently over time and depending on the wholesaler. They are commonly referred to as Distribution Service Agreements, Generic Wholesale Service Agreements, Purchase Agreements, and the like.

Typical terms of agreements:

- Provisions outlining the operation of the wholesaler arrangement
- Covenant for data exchange (e.g. 844, 852, 867)
- Requirements for inventory management (some contracts incentivize)
- Return procedures
- Pricing terms (rebates, DSA service fees, etc.)
- Covenants to adhere to legal, compliance, and regulatory requirements, including as they relate to controlled substances and products that may have RMPs, RiskMAPS, or REMS and commitment to safe and secure distribution of controlled substances.
- Chargeback processes

Agreements with Pharmacies

Two primary types of agreements with pharmacies:

- The Teva Defendants do not supply opioids to local pharmacies. The Teva Defendants provide a variety of products, which sometimes include opioids, to pharmacy chains (for example, CVS) or health systems (e.g., Kaiser Permanente), as well as distributors/wholesalers. Those entities then distribute the opioids to pharmacy dispensers. When agreement is reached with pharmacy chain, the contract resembles a wholesale contract and typically includes a distribution fee to compensate the chain pharmacy customer. These agreements sometimes allow the chain pharmacy to purchase products from the Teva Defendants or a distributor if the Teva Defendants do not have the products available, and the Teva Defendants will reimburse the customer for any difference.

- Pricing agreements with pharmacies that set a typically discounted price at which the pharmacy can purchase Teva Defendant products from an authorized wholesaler. Savings are attained by the pharmacy through rebates or cash discounts provided by the Teva Defendant to the pharmacy.

Comarketing Agreements: The Teva Defendants have not identified any co-marketing agreements with manufacturers, distributors, or pharmacies.

New Topic 3(a): Inter-Company transactions, general ledgers, and intra-company sales of Opioids and/or Opioid related services shared among the Teva Defendants or to their parent company, including the determination of prices for inter-company sale. To the extent Defendants do not maintain information specific to Opioids, the term Opioids is to be replaced with the phrase "Class II Controlled Substances." The term services shall include but is not limited to marketing, transportation, and compliance.

Transaction Recording and Access • Intracompany transactions are recorded in the Teva Defendants' Oracle system • The Teva Defendants use the same accounting practices and processes as other Teva affiliates to ensure that the accounting data maintained by each business is uniform and meets applicable accounting standards. • Each transaction is recorded at the ledger level for each entity (transaction between entity A and entity B is recorded at the entity level on both ends of the transaction) • The transactions underlie virtually all inter-company interaction, including transfers of products between the entities, services provided between each entity, tangible asset purchases (real estate, machinery), and intangible asset purchases (IP rights owned by one entity that may be transferred to another entity) • While data is available in the Oracle system, the Teva Defendants do not generate ledger reports in the normal course of business because they have extremely limited utility. • Due to limited functionality, the Teva Defendants are unable to run ledger reports as a matter of course, searches of them for specific information must be performed on a customized basis, and search results may be both under- and over-inclusive. • Due to the volume of intercompany transactions, which measures in the millions, conducting these custom searches for specific transactions may take weeks. Types of Intercompany Transactions • Transfer of API and finished products, including opioids, between entities (e.g., if a product is manufactured by one entity and shipped to another before being provided to a distributor) o Every product is recorded as a sale by one Teva Defendant entity and a purchase by another, though the transaction may not be recorded in Oracle contemporaneously o Each of these transactions is recorded on a net zero basis – the value of the product(s) being transferred is recorded in the transaction, but neither the "seller" nor "purchaser" entity books a profit or loss as a result of the transaction o Some of these transfers may be of opioids, but whether they are identifiable as such depends on the level of invoice detail in the transaction, which is not uniform • Transactions accounting for the provision of services between Teva entities. o Provision of services are recorded at the value of the service provided, plus a mark-up for the entity that provided the service. o The Teva Defendants may not be unable to distinguish opioid-related transactions from non-opioid related transactions because the product associated with the service may not be identified. • Recharges/reimbursements: When entity A makes an external payment on behalf of entity B, it will charge entity B so that the payment is correctly recorded on entity B's ledger • Transfer pricing – once per quarter, the Teva Defendants conduct transfer-pricing to properly assign profits associated with IP or product rights from distributor entities to the entity that owns the IP or product rights o In those instances, the profit associated with the external sale of the product is transferred to the ledger of the entity that owns the IP/product rights to the product. o The distributing Teva entity retains a 2% margin on its ledger for acting as a distributor, which is based on similar transactions with external parties. o Maintains integrity of ledger data	Shanna Clark

New Topic 3(b): To the extent the Teva Defendants maintain such information, revenue from opioids nationally and in RI by year, including through drug sales, related services (including but not limited, software, marketing), and distribution fees. Should Teva only maintain data as to Class II Controlled Substances, Teva will provide testimony concerning the same matters as to Class II Controlled Substances.

Source

- Data for revenue calculations come from the Hyperion database, which houses the Teva Defendants' financial data.
- As reflected in the documents containing the data, some of the historic revenue data provided to the State has come from legacy Cephalon systems.

Limitations on the data:

- The Teva Defendants do not maintain revenue information for opioids or controlled substances related distribution fees or related services such as software or marketing. The Teva Defendants have not identified any such data.
- The Teva Defendants do not maintain information geographically.
- The Teva Defendants do not maintain revenue information for opioids sold by the Actavis entities prior to the 2016 acquisition, with limited exceptions:
    - Revenue from 2014 was provided to Teva USA during the course of the acquisition of the Actavis entities, and that information has been produced as described below.
    - The information retained by the Actavis entities and/or provided to Teva USA for sales before 2014 included only accounts receivable transaction data, and not any other data needed to make a revenue calculation.
        - Actavis systems that information came from:
            - QAD: Direct sales and transactional data
            - Revitas: Indirect sales data/chargeback data (data relating to sales by Actavis wholesaler customers)
            - Model N: Contract data
            - SAP: Actavis's system of record, which had various data
    - The Teva Defendants have produced all of the Actavis sales data available to it, but are unable to determine the accuracy of that data.
    - To the extent the Teva Defendants do maintain information regarding pre-acquisition revenues, it is included in TEVA_MDL_A_02416208.

Revenue:

Data, by year, has been produced to the State in three spreadsheets:

- TEVA_MDL_A_02416208:
    - Generic opioid sales from 2011-2017 (includes all Teva Defendants)
    - Revenue for each product is "Total Net Sales"
    - "Legacy" indicates whether the product is a legacy product of an Actavis Defendants ("Actavis") OR Cephalon or Teva USA ("Teva")
    - "Total Unit Sales" is the total number of units sold
    - "Sales_Doses" is the total number of doses sold.
    - Does not list Sales Returns and Allowances, but they are incorporated.
    - "0" means that the data for this time reflects no sales
    - Blanks mean that the data is unavailable
    - Teva Defendants have produced all sales data available that identifies what generic opioids were sold by the Actavis Entities.
    - Includes Generic Actiq (NDCS: 00093-7865-65, 00093-7866-65, 00093-7867-65, 00093-7868-65, 00093-7869-65, 00093-7870-65

- TEVA_MDL_A_02419958:
  - Actiq and Fentora from 2006-2012
  - Revenue for each product is “Net Sales”
  - Additional detail provided in Notes on Topic 3(c)
  - Created by Teva Finance
  - Generic Actiq was sold by Watson as selling agent beginning in 2006
  - Rebates are dispersed among various entries in the SR&A section, depending on type (e.g., distributor rebates are listed in that line)

- TEVA_MDL_A_02401117:
  - Actiq and Fentora from 2012-2018
  - Revenue for each product is “Amount”

- Each of these spreadsheets is independent. To determine total revenue, each entry must be added (i.e., none of them are cumulative).

New Topic 3(c): **To the extent the Teva Defendants maintain such information, how they track, calculate, and project their revenue and whether Defendants track revenue from opioids. Should the Teva Defendants only maintain data as to Class II Controlled Substances, Teva will provide testimony concerning the same matters as to Class II Controlled Substances.**

Tracking
• Teva Defendant sales data is originally sent to a system called BI. Hyperion is another system that pulls sales information from BI so that it can be used by Finance for various purposes, including tracking revenue.
• Revenue is tracked for various purposes, including annual operating plans, long range plans, projections, and product performance evaluation.
• Tracking is performed by the Finance Department, which is the only group with access to the Hyperion database.
 	
Calculating
• For all products, basic calculation is (average list price x volume) – (sales returns and allowances)
• Sales returns and allowances (SR&A) includes various expenses that are recognized at the time of sale, including:
  o Cash and wholesaler discounts
  o Rebates (direct to wholesalers, indirect to wholesalers based on sales to indirect customers, billbacks/differentials)
  ▪ Billbacks/differentials: When Teva Defendant pays a chain pharmacy the difference between Teva's offered price and what the chain pharmacy paid a distributor.
  ▪ For branded products, there are also utilization-based rebates paid to managed care organizations, MCOs administering Medical Part D, and Tricare
  o Medicaid rebates: (paid to states based on Federal program and supplemental contracts with certain states. Calculated monthly base on expected payments to states and the federal program to reimburse pharmacies that have dispensed or will dispense the company's products to Medicaid patients.)
  o Chargebacks
  o Redeemed coupons (branded only)
  o Reserves: Set asides from the period to cover reductions in value or expenses in the future.
• Because of the high number of variables that factor into SR&A calculations, SR&A is not calculated individually. Through the budget process, using standard accounting processes, finance develops a complicated set of assumptions based on the product type to account for expected SR&A, and that is what is used to determine revenues.
• Revenue is not profit. Additional costs not recognized at the time of sale are deducted to determine profit.
 	
Projections
• Different processes for branded and generics
• Consistent set of factors considered, but not a formula
 	
Branded Products
• Projections in budgets and plans include only projections in spaces where the product is indicated and authorized
  o Informal projections are sometimes done on the branded side to for various business purposes, but only formal projections are done for budgeting purposes.
• Projections conducted by Specialty Global Forecasting Group
	Christine Baeder
	Pat McIntosh
	Shanna Clark

- Process for new products:
  - Research: Competitive intelligence and research to understand competition and the target patient population, using IQVIA data and resources to understand prescriber practices
  - Assumptions: Build out market assumptions to form a product profile (e.g., cutting historical data by patient profile to identify population that is eligible for indicated and authorized use, considering marketing strategy)
  - Model: Create model that seeks to determine what portion of the eligible population might use the product
  - Ramp: Use model to ramp how the patient population might change (growth, treatments, changes in profile)
  - Gross to Net: Work with Finance to make their projections gross to net (considering various factors, such as channels in which product is offered)
    - Consider probable discount structure, discount rates, and other impacts on net revenue
  - Review and approval: Final product is projection, which is reviewed by a cross-functional team involved in creating budgets and planning documents that includes commercial, sales, managed care, forecasting, finance, market access, and supply chain to see if there is alignment. If approved, it is included in budget or planning documents

- Existing products:
  - Model built beginning with key indicators (data comes from sources such as IQVIA, Teva's sales, and market research)
    - Number of patients on the product at the time
    - TRx
    - New prescriptions
    - The company's market penetration
    - The company's market share within the patient population
    - Sales volume and mix
    - Historic gross sales
    - Historic net sales
    - Price
  - Depending on product, the model can include additional measures of performances from secondary resources that may impact the projection

- Fentora
  - Fentora "model" was an ad hoc spreadsheet with limited modeling that did not have automated data feeds and often required manual intervention
  - Described contemporaneously as an event based model that used TRx to establish a baseline trend that to which events were manually applied.
  - Factors included:
    - Rapid Onset Opioid Market then share
    - Total prescriptions (annually and monthly)
    - Tablets per prescription (annually and monthly)
    - Total prescriptions of extended units
    - Total non-retail units sold
    - Total demand in units
    - Average price per unit
    - Future price increases (typically increased January 1)

▪ Inventory (what is already in the pipeline at wholesalers and pharmacies and how stocking levels changed over time) ▪ Factory sales o Assumptions included: ▪ Regulatory impact (e.g., TIRF REMS expected to temporarily reduce sales by 20%) ▪ Impact of promotional initiatives (e.g., 2011 initiatives on vouchers and credit cards led to increase in projections) ▪ Expected amount of non-retail sales vs. total demand • Actiq: By the time Fentora was being promoted, Actiq was projected in the same way, but the assumptions did not include projections of promotional initiatives because none existed. o Unable to reconstruct assumptions from Actiq projections. Generics: • Performed by Marketing (Christine Baeder's group) • Same set of considerations for controlled substances and others (driven by supply and demand) • New Products: o Performance of similar products already offered internally or externally o Reimbursement landscape for the product (landscape in place – no effort to expand for generics) o Market at the time ▪ Total demand (all versions of the generic product) ▪ Market competition from other generics) ▪ Timing of market entry (first to market) ▪ Exclusivity, if it exists o Expected price o Actual and target market share • Existing Products o Assumption that volume will remain stable and average price will remain stable with slight erosion, typically 2% price erosion per year (Volume x .98(average price)) o Average price paid by customers, not WAC o The Teva Defendants project revenue for each generic ▪ Prior to 2016, Actavis projected revenue for the entire generic portfolio as a whole (not on a product-by-product basis). o Circumstances where additional tactical analysis is done: ▪ Major market disruptions (large service disruptions, drug shortages, major new competitor enters the market) – Baeder cannot recall any time that this has happened with an opioid product ▪ When a single product is viewed as "material" to the entire portfolio – no opioids have ever been viewed as material	

Topic 3(e): To the extent the Teva Defendants maintain such information, staffing and spending on opioids compliance nationally and in Rhode Island by year. Should the Teva Defendants maintain data as to Class II Controlled Substances, Teva will provide testimony concerning the same matters as to Class II Controlled Substances.

Sample CSA Requirements:
• Know your customer
• Suspicious order monitoring
• Site and supply chain security
• Licensing and registration
• Handling of controlled substances (accounting, reconciliation, proper storage, restricted access, designated observers)
• Documenting transport and provision of controlled substances from one party to another
 	
Structure of Controlled Substance Compliance
• Compliance with the Controlled Substances Act and larger diversion prevention efforts are central to various business units involved in operations that relate to controlled substances.
• The Teva Defendants have a centralized DEA Compliance Department that is ultimately responsible for ensuring compliance with the CSA, but does not carry out every function involved in CSA compliance.
  o Prior to becoming affiliated with Teva USA, the Actavis Entities referred to this group as "DEA Affairs"
• DEA Compliance personnel are directly responsible for a number of the functions required to ensure compliance with the CSA, including:
  o Suspicious order monitoring
  o Quota applications
  o Evaluating customers through the Know Your Customer Program
  o Conducting internal audits and diligence of Controlled Substances Compliance
  o Reporting theft or loss to the DEA
  o Responds to DEA inspections
  o Documents transfers and receipt of controlled substances
• In addition to the functions for which DEA Compliance is directly responsible, numerous other business units outside of DEA Compliance perform functions that facilitate the Teva Defendants' compliance with the CSA and larger anti-diversion efforts.
  o A non-exhaustive list of the business units involved in the Teva Defendants' anti-diversion efforts is included as Appendix C.
 	
Central DEA Compliance and DEA Affairs Department Staffing (**Not exhaustive of all employees involved in CSA compliance)**:
The Teva Defendants have produced organizational charts reflecting the staffing of central DEA Compliance group to the extent reasonably available. Where charts are not available, they have conducted document reviews to reconstruct the staffing
• Since the acquisition of the Actavis Entities: central DEA Compliance has generally had a a headcount of approximately 20 people. (23 in 2017 and 19 in 2018).
• Teva USA/Cephalon from 2012-2016
  o 2016: 16 employees
  o 2015: 17 employees
  o 2014: 16 employees
	Mike Edwards
	
	Appendix D

- 2013: 14 employees
- 2012: 17 employees

- Teva USA: Prior to the acquisition of Cephalon in 2011, central DEA Compliance appears to have consisted of approximately 5-6 employees, based on a review of available files.
- Cephalon: The Teva Defendants have located historical organizational charts from Cephalon reflecting headcount for DEA Compliance at various points.
  - 2011: 5 employees
  - 2007: 7 employees
  - 2006: 7 employees
- Immediately prior to its acquisition, central Actavis DEA Affairs consisted of <u>at least</u> 5 employees
  - The Teva Defendants have limited visibility into DEA Affairs and compliance staffing at Actavis prior to 2016
  - The Teva Defendants understand that CSA compliance activities involved at least the DEA Affairs, Global Corporate Security, Customer Relations, and Master Data Administration groups.

<u>Spending on Controlled Substance Compliance</u>

- The Teva Defendants do not maintain and cannot locate data reflecting total spend on Controlled Substance Compliance in any given year because those efforts and the spending are spread across business units and not accounted for separately.
- Beginning in 2017, central DEA Compliance had its own cost center created in the Teva Defendants' system for the first time.
  - This data only accounts for spending that is tracked to the central DEA Compliance group. It does not include all expenses.
  - Includes, among other things, salary and benefits, travel expenses, meals, material disposal, licensing fees, and some software and site costs. **Other costs associated with CSA compliance are dispersed throughout other business units but are not trackable.**
  - Totals spend only for central DEA Compliance cost center, per Mike Edwards:
    - 2017: $3,726,930
    - 2018: $4,255,526
    - 2019: $2,883,724

Topic 3(f): The methodology(ies) the Teva Defendants currently use and have previously used to determine the price at which to sell opioids.

Branded Products

- Since 2014, pricing has been consolidated in Strategic & Contracting Operations under Jay Simpson, Senior Director of Contract Pricing
- Prior to that point, pricing was done by individual brand groups before being submitted for approval
- Typically an annual price increase implemented on January 1 of each new year, to coincide with the needs of third party payers such as Medicaid.
    - Price increases occasionally occur mid year, but they are typically planned unless there is a major shift in market
- Pricing is determined during the budgeting process
    - Strategic & Contracting Operations works with brand teams to gather information to apply to pricing considerations
    - Strategic & Contracting Operations makes recommendations that it discusses with brand team to come up with proposal for Pricing Committee:
    - Pricing decisions are considered and approved by Pricing Committee, which considers the same factors as Strategic & Contracting Operations and coordinates pricing proposals of each branded group. It includes:
        - Head of North America Commercial
        - Head of Strategic Pricing & Contracting Operations
        - Head of Market Access, Reimbursement, and Government Affairs
        - General Counsel
        - CFO, NA Finance
        - Head of NA Trade Sales
        - Head of Commercial Brand Marketing
        - Head of NA Compliance
        - Head of NA Commercial Brand Sales
        - Head of Government Affairs
- Considerations
    - No formula for determining price of new or existing products, but there is a consistent set of considerations employed by the pricing group
    - Pricing group considers a number of factors, including:
        - Existence and performance of competition in the market
        - Teva USA price vs. competition pricing
        - Differentiation factors of the product being priced that might lead to a premium
        - Payer access and cost coverage
        - Impact on company
        - Pricing sensitivity
        - Contracting strategies/considerations
        - Discount forecasts
        - Rebate forecasts
        - Market channels

- Fentora
  - Launch pricing was a product of a review of various data points:
    - Market research focusing on surveys of stakeholders (physicians, payors, and patients) demonstrating concerns regarding pricing, counseling against a higher price
    - Third party payor treatment of Actiq, which Cephalon expected to be similar to Fentora, including requirements for prior authorizations
    - Generic competition
    - Distribution of doses of Actiq vs. Fentora
    - Product differentiation (faster onset than competitors, better bioavailability, delivery system)
    - The fact that Fentora is a later-line therapy for patients with breakthrough cancer pain
  - Prices generally increased annually, based on a combination of factors
    - Product demand (continued to improve)
    - Status of prior authorizations
    - Third party payer profiles
    - Stakeholder views/pricing sensitivity
    - Impact on volume of sales
    - Product differentiation (Fentora continued to have strong price differentiation)
    - Market competition and market events
- Actiq
  - There was no formula
  - Unable to reconstruct model, but documents indicate that the pricing considerations were the same for Actiq and Fentora
  - Initial price was inherited from Anesta, which had already launched the product
  - Actiq RMP required proportionality between the dosage strengths to minimize risk of tablets being reused.

Generic Products:

- Since 2016, pricing for generics has been in the purview of the Generic Drug Pricing Committee
  - Approves all price increases or decreases, including changes in WAC and contract pricing
  - Has six members
    - US Generics Sales and Marketing Department
    - Generics Customer Administration
    - Generics Pricing Team
    - Generics Finance Committee
- Actavis entities prior to acquisition: Prices were managed by the Contracts and Pricing team, led by Director of Contracts and Pricing Ara Aprahamian. Approvals for pricing decisions were periodically approved by members of Pricing & Business Analytics at Actavis, Inc. Unable to determine the precise approval processes for pricing changes, though considerations were the same.
- WAC price increases rarely occur, are on a product-by-product basis, and are triggered by significant changes in the market. None identified for opioids.
  - Price changes may occur over time, but they are off-invoice and depend on customer and circumstances
- Prices paid by customers vary by customer contract.

- Price is a combination of the prices paid across the customer base. Those prices depend on a wide variety of considerations that may or may not factor into a particular pricing decision, including:
    - Market considerations such as competition with branded or generic products; competition entering or exiting the market; competitor pricing; competitor supply issues
    - Exclusivity
    - Patient and medical necessity
    - Public policy
    - Legal considerations (e.g., rules and regulations relating to sales to government and institutional purchasers, Medicaid inflation penalties, and others)
    - Profitability and sustainability
    - Purchasing arrangements with customers already in place
    - Class of trade, distribution channel, and payer
    - Price sensitivity
    - Cost and cost changes (API, manufacturing, shipping, packaging, overhead, regulatory compliance, acquisition, labor, marketing, and others)
    - Supply chain

APPENDIX C

Business units and activities conducted that contribute to diversion prevention and Compliance with the Controlled Substances Act (Non-Exhaustive)

Business Unit	**Activities**
DEA Compliance	• Oversees and works with various groups listed below to ensure compliance with the Controlled Substances Act ("CSA") • Operates SOM program (Customer diligence, calibrating DEF Ops, investigating pended orders, reporting suspicious orders) • Conducts internal audits to assess CSA compliance • Applies for obtains, and maintains manufacturing and procurement quota • Responds to DEA inspections • Reports thefts/losses to the DEA • Applies for and obtains appropriate licenses and registrations • Documents receipt and transfer of controlled substances
Procurement	• Manages sourcing from API supply partners • Selects DEA Reverse Distributors (handle returns and disposal of unused controlled substances)
Information Technology (central functions and on-site)	• Assists with development and maintenance of electronic systems used to assist with SOM • Inventory management • Facilitating customer & vendor registration and license validation verification checks
Security (central functions and on-site)	• Physical site security (physical security, cameras, etc.) • Access control (vault access) • Security systems • Investigation support • Transportation security • Security inspections
Manufacturing & Packaging site groups	• Designated observer program (employees designated in writing as responsible for areas of surveillance during manufacturing) • Performing material accountability operations (e.g., accounting for API during manufacturing) • Scale/balance calibration (ensuring that devices used to measure API are accurately calibrated) • Manages of DEA regulated machines (machines that create finished products)
Global & site warehousing	• Manages material receipts from controlled substance sales • Manages inventory • Distribution
Site Quality Assurance	• Batch record review and reconciliation • Label accountability • Training support

Supply Chain (central functions and on site)	• Manages closed supply chain
Customer Service	• Manages customer orders • Interacts with customers at direction of DEA Compliance to investigate orders and assists with conducting customer diligence
Commercial Operations	• Provides information regarding availability of Controlled Substances, customer contracts, sales forecasts, and other operations • Negotiates contracts requiring strict compliance and provision of data
Master Data Management	• Manages material data records • Assists in monitoring and investigating customer orders for controlled substances
Customs Compliance	• Supports import & export transactions
R&D and Manufacturing Science and Technology groups	• Project management • Inventory control during development • Material accountability during development
Site Quality Control	• Inventory control • Material accountability
Legal counsel	• Compliance issues, customer investigations, customer engagements (customer visits)
Human Resources	• Employee screening

Appendix D

Identified Members of Cephalon's and Teva USA's Central DEA Compliance Group

CEPHALON 2006	
Kathy Callison	Director, GLP Quality Assurance and DEA Compliance
Colleen Gant	Manager Control Substances
R. Buot	European GLP/QA Manager
Deborah Ratte	DEA Compliance Specialist II (CIMA)
Nancy Radford	Controlled Substance Professional (SLC)

CEPHALON - 2011	
Kathleen Callison	Senior Director, GLP and DEA
Colleen McGinn	Associate Director Controlled Substance
Jason Gardner	DEA Compliance Manager
Gail Martin	Controlled Substance Specialist
Patrick Shields	Controlled Substances Manager

TEVA – 2009-2011	
Chris Lowery	Chief Security Officer
Dennis Ferrell	Senior Director, DEA Affairs
Mike Edwards	Manager, Security
William Spruill	Associate Director, DEA Affairs
Matt Benkert	Diversion Investigator
Edwin Kinkler	Supply Chain & Product Security

TEVA USA/CEPHALON - 2012	
Dennis Ferrell	Senior Director, DEA Affairs
Michael A. Edwards	Manager, Security
Edwin G. Kinkler	Manager, Supply Chain
Colleen McGinn	Associate Director, Controlled Substance
William Spruill	Associate Director, DEA Affairs

Timothy J. Aleman	Diversion Investigator
Peter D. Cirianni	Diversion Investigator
Eric W. Schmidt	Diversion Investigator
Christopher A. Altieri	Diversion Investigator
Timothy J. Hilden	Diversion Investigator
Jason Gardner	DEA Compliance Manager
Gail Martin	Controlled Substance Specialist
Patrick D. Shields	Controlled Substances Manager
Darnell D. Horsley	Supervisor, Diversion Control
Mark Branch	Diversion Investigator
Lee A. Powers	Diversion Investigator
Susan G. Woodard	Diversion Investigator

TEVA USA/CEPHALON - 2013	
Colleen McGinn	Director DEA Compliance
Michael A. Edwards	Manager, Diversion Ops
Kenneth Ferrantello	Manager, Diversion Ops
Jason Gardner	Manager, Diversion Ops
Darnell D. Horsley	Supervisor, Diversion Control
Mark Branch	Diversion Investigator II
Gail Martin	Controlled Substance Specialist
Patrick D. Shields	Manager, Diversion Ops
David E. Penrod	Diversion Investigator II
Timothy J. Aleman	Diversion Investigator II
Peter D. Cirianni	Diversion Investigator II
Eric W. Schmidt	Diversion Investigator II
Matthew Benkert	Diversion Investigator II
Timothy J. Hilden	Diversion Investigator II

TEVA USA/CEPHALON - 2014	
Colleen McGinn	Dir, DEA Compliance
Michael Edwards	Mgr, Diversion Ops
Kenneth Ferrantello	Mgr, Diversion Ops
Jason Gardner	Sr Mgr Quota & DEA Rel Mgmt
Gail Martin	Controlled Substance Specialis
Patrick Shields	Mgr, Diversion Ops
Joseph Tomkiewicz	Mgr, Diversion SOM
Timothy Aleman	Diversion Investigator II
Peter Cirianni	Diversion Investigator II
Timothy Hilden	Diversion Investigator II
Eric Schmidt	Diversion Investigator II
Darnell Horsley	Supvr, Diversion Control
David Penrod	Diversion Investigator II
Matthew Benkert	DEA Compliance Auditor
Mark Branch	Diversion Investigator II
Clyde Mayberry	Diversion Investigator II

TEVA USA/CEPHALON - 2015	
Collen McGinn	Dir, DEA Compliance
Michael Edwards	Assoc Dir, DEA Compliance
Christopher Farris	Diversion Investigator II
Jenny Gallo	Mgr, DEA Compliance
Jason Gardner	Sr Mgr Quota & DEA Rel Mgmt
Clyde Mayberry	Diversion Investigator II
Karen O'Brien	DEA Compliance Investigator
Patrick Shields	Sr Mgr, DEA Compliance
Joseph Tomkiewicz	Mgr, Diversion SOM
Timothy Aleman	Diversion Investigator II
Peter Cirianni	Diversion Investigator II
Timothy Hilden	Diversion Investigator II
Gail Martin	Controlled Substance Specialis
Kelley Shaw	DEA Compliance Specialist
David Penrod	Diversion Investigator II
Eric Schmidt	DEA Compliance Specialist
Matthew Benkert	DEA Compliance Auditor

TEVA USA/CEPHALON - 2016	
Colleen McGinn	Sr. Dir, DEA Compliance
Matthew Benkert	Mgr DEA Compliance, Int Audits
Michael Edwards	Assoc Dir DEA Compliance
Jenny Gallo	Mgr DEA Compliance
Jason Gardner	Sr Mgr DEA Compliance
Patrick Shields	Sr Mgr DEA Compliance
Joseph Tomkiewicz	Mgr DEA Compliance
Timothy Aleman	DEA Compliance Specialist
Peter Cirianni	DEA Compliance Auditor
Timothy Hilden	DEA Compliance Specialist
Gail Martin	DEA Compliance Specialist
Christopher Farris	DEA Compliance Coordinator
Karen O'Brien	DEA Compliance Investigator
Kelley Shaw	DEA Compliance Auditor
David (Dave) Penrod	DEA Compliance Specialist
Eric Schmidt	DEA Compliance Auditor

TEVA DEFENDANTS – 2017 (AFTER ACTAVIS ACQUISITION)	
Colleen McGinn	Sr. Dir DEA Compliance
Matthew Benkert	Mgr DEA Compliance
Michael Edwards	Assoc Dir DEA Compliance
Jason Gardner	Assoc Dir DEA Compliance
Patrick Shields	SR Mgr DEA Compliance
Joseph Tomkiewicz	Mgr DEA Compliance
Timothy Aleman	DEA Compliance Specialist
Peter Cirianni	DEA Compliance Auditor
Timothy Hilden	DEA Compliance Specialist
Clara (Amber) Khatkhate	DEA Compliance Auditor
Gail Martin	DEA Compliance Specialist
Madeline Ocasio Sanchez	Mgr DEA Compliance
Jenny Gallo	Manager, DEA Compliance

William (Bill) Hepworth	Mgr DEA Compliance
Kelley Shaw	DEA Compliance Auditor
Sandy Daly	DEA Compliance Auditor
Christopher Farris	DEA Compliance Coordinator
Karen O'Brien	DEA Compliance Investigator
David (Dave) Penrod	DEA Compliance Auditor
Eric Schmidt	DEA Compliance Auditor
Cassie Whitehead	DEA Compliance Analyst
Sarah Everingham	DEA Compliance Auditor – Suspi
Mary Moskello	DEA Compliance Investigator

TEVA DEFENDANTS – 2018	
Colleen McGinn	Sr. Dir., DEA Compliance
Matthew Benkert	Mgr. DEA Compliance
Michael Edwards	Assoc Dir DEA Compliance
Jason Gardner	Assoc Dir DEA Compliance
Kelley Shaw	DEA Compliance Auditor
Patrick Shields	Sr Mgr DEA Compliance
Joseph Tomkiewicz	Mgr DEA Compliance
Timothy Aleman	DEA Compliance Specialist
Peter Cirianni	DEA Compliance Auditor
Timothy Hilden	DEA Compliance Specialist
Clara (Amber) Khatkhate	DEA Compliance Auditor
Tammara (Tami) O'Connor	DEA Compliance Analyst
Jenny Gallo	Manager, DEA Compliance
Sandy Daly	DEA Compliance Auditor
Christopher Farris	DEA Compliance Coordinator
Karen O'Brien	DEA Compliance Investigator
David (Dave) Penrod	DEA Compliance Auditor
Cassie Whitehead	DEA Compliance Analyst
Sarah Everingham	DEA Compliance Auditor

ACTAVIS, INC. – 2016	
Tom Napoli	Associate Director of CS Compliance
Bill Hepworth	CS Specialist
William Simmons	Compliance Auditor
Lynn DaCunha	Compliance Analyst
Mary-Lou Schoonover	Compliance Analyst

ADDITIONAL ACTAVIS EMPLOYEES INVOLVED IN DEA AFFAIRS ACTIVITIES OVER TIME	
Tracey Hernandez	Director, Controlled Substance Compliance (Watson)
Mary Woods	Customer Relations Operations (Watson)
Ione Graziosi	Manager of Controlled Substance Compliance (Watson)
Jim Dougherty	Auditor, Controlled Substance Compliance (Watson)
Sarah Blankenship	Associate Auditor, Controlled Substance Compliance (Watson)
Lisa Scott	Controlled Substance Auditor (Watson)
Nancy Baran	Director Customer Service (Actavis)
Jinping McCormick	Director, Marketing (Actavis)
Rachelle Galant	Senior Product Manager (Actavis)
Weldon Chin	Director Supply Chain (Actavis)
Jason Chun	DEA Compliance Manager (Actavis)
Omar Plaza	Senior Analyst, DEA (Actavis)
Judy Callahan	Director of Customer Relations (Actavis)
Victoria Lepore	Master Data Administration/Suspicious Order Monitoring Specialist (Actavis)
Sandra Simmons	Manager Support Services (Actavis)
Ella David	Distribution Specialist (Actavis)
Bettina Dwor	Master Data Administrator (Actavis)