Testimony of Walter C. Kalmans
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Good morning! My name is Walter Kalmans, and I am currently employed as Vice President of New Ventures at WhiteGlove Health, a venture-backed company in Austin, TX. This testimony is not related in any way to my current employer. Rather, it is based on work independently developed as a result of 20 years of experience working as a consultant and commercial operations executive in the pharmaceutical industry.

Of particular relevance to this hearing is experience gained while serving as Vice President of Business Development for Oncology Therapeutics Network (OTN) from 2003 to 2008. OTN was the 2nd largest specialty drug distributor in the United States until its acquisition by McKesson Corporation in late 2007.

The popular press as well as recent publications by ASPE, FDA, and IMS Health do a good job characterizing the generic drug shortages and tend to cite manufacturing and supply chain issues as the chief culprits. As citizens, we are led to believe that over time, industry will fix the problem by investing in additional capacity, improving quality control, and identifying more high-quality suppliers for raw materials.

However, there is much more to this issue. Why all of the sudden would the pharmaceutical industry, one of the most sophisticated industries on Earth, be experiencing an unprecedented growth of shortages, and why in particular, shortages of generic injectable drugs? Manufacturing and supply chain issues certainly play a role, but it is my opinion that the Medicare Modernization Act (MMA) of 2003 is the core culprit for why generic injectable drugs are in growing shortage.

To most Americans, MMA is known as the act that expanded prescription drug coverage for Medicare patients; however, another part of the legislation drastically altered how Medicare reimburses community-based oncologists who administer drugs in their offices, under Medicare Part B. Oncologists are one of the few specialists who make a margin on buying a drug for price X and receiving Medicare reimbursement of price X+Y.

Prior to MMA, Medicare reimbursed community-based oncologists based on a price called AWP (average wholesale price). MMA introduced a new price called ASP (average selling price). Calculating ASP required significant pricing transparency from pharmaceutical manufacturers and resulted in lower Medicare reimbursement payments to community-based oncologists and notably, a more rapid price decline for many generic injectable drugs.

In addition, because the legislation set Medicare reimbursement for Part B drugs at ASP+6%, it established thinly veiled price controls making it unpalatable for a pharmaceutical manufacturer to raise price more than 6% a year. For example, if a

manufacturer were to raise price on a $100 drug more than 6% during a year, an oncologist would likely be faced with the scenario of buying the drug for $106 and receiving Medicare reimbursement of $104.

Now fast-forward to today, if you were a generic injectable manufacturer with finite capacity, would you focus your capacity on manufacturing generics for products that have just lost patent protection, reaping high profits for the next few quarters, or would you manufacture lower priced generics, drugs whose patents expired long ago?

Under normal economic circumstances, if there are shortages, prices adjust upward to reach a new equilibrium until additional product comes on-line. However, because MMA limits price increase to 6% annually, prices do not reach an equilibrium; even worse, because the profit potential of these drugs is so low, new entrants decide to stand on the sidelines or focus on more profitable products.

In conclusion, it is my opinion that we will experience shortages of generic injectable drugs until legislation is passed to change the way generic injectable drugs are reimbursed by Medicare. Like any piece of legislation, MMA provided many citizens with benefits, but also like any piece of legislation, it had flaws. Unfortunately, these flaws took several years to be exposed and for a variety of reasons, it may take quite some time to fix them.

Thank you!

WALTER C. KALMANS
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PROFESSIONAL EXPERIENCE

WHITEGLOVE HEALTH – Austin, TX 2011 – present
Vice President, New Ventures

- Lead business development efforts for innovative healthcare provider that lowers health plan costs for primary care, wellness and chronic care while providing consumers with an unparalleled healthcare experience.
- Negotiate agreements with hospital systems to reduce readmissions of patients discharged with acute myocardial infarction, congestive heart failure, and pneumonia.

LONTRA VENTURES, LLC – Austin, TX 2008 – 2011
President

- Delivered consulting services (sales, marketing & business development) to specialty drug manufacturers and to companies selling products or services to specialty divisions of large pharmaceutical firms.
- Led business development efforts for client resulting in more than $1M in annual incremental sales to pharmaceutical manufacturers from a base of $300K.
- Developed marketing materials for a client that provides copay solutions to pharmaceutical manufacturers. Introduced client to more than 10 manufacturers which led to two, million dollar deals and more still pending.
- Negotiated contracts with wholesalers & distributors to help ensure successful launch of a new oncology drug.
- License early-stage healthcare technologies for commercialization.

MCKESSON – San Francisco, CA 2007 – 2008
Largest Publicly Traded Healthcare Company in the World
Vice President, Business Development / Integration Leader, McKesson Specialty

- Led the integration of all manufacturer-facing activities for McKesson Specialty and OTN/Onmark: people, processes, technology and strategy. Completed all deliverables on time and within budget.

ONCOLOGY THERAPEUTICS NETWORK (OTN) – South San Francisco, CA 2005 – 2007
Privately Held, Second Largest Oncology and Rheumatology Drug Distributor and GPO
Vice President, Business Development

- Negotiated and managed more than $1.5B in annual buy/sell agreements with pharmaceutical manufacturers. Grew high-margin, value added services revenue stream from zero to $40M in three years.
- Led OTN's business development group that focuses on pharmaceutical manufacturers who sell oncology, rheumatology, and supportive care drugs.
- Managed a team of high achieving sales and service personnel who delivered complex marketing/promotion and information services to sales, marketing, and market research teams at global pharmaceutical companies.
- Presented to financial syndicate in order to secure $300M revolving credit facility.
- Member of OTN's Operating Committee responsible for company business strategy and operations.

BRISTOL-MYERS SQUIBB – South San Francisco, CA 2003 - 2005
Top 10 Pharmaceutical Firm
Director of Business Development, Onmark, an OTN Company

- Created and launched Onmark, OTN's group purchasing organization (GPO) in late 2004; developed business concept and market positioning and led efforts to secure contracts with global pharmaceutical companies.
- Negotiated multi-million dollar GPO contracts with global pharmaceutical companies who sell oncology and supportive care drugs. In 9 months, Onmark became the 2nd largest GPO servicing office-based oncologists.

Director of Business Development, Oncology Therapeutics Network (OTN)

- Negotiated multi-million dollar agreements with global pharmaceutical companies who sell oncology and supportive care drugs. In 2004 was 140% to quota, representing 35% of $3B division's operating profit.
- Chaired Commercial Strategy and Operations Team responsible for increasing OTN's revenue, gross profit and market share. Coach individuals to develop effective performance metrics and hold them accountable for performance against metrics. Allocate human and financial resources as needed to achieve commercial goals.
- Launched sales and marketing program to increase sales to rheumatologists; increased annual sales from $40M to $250M over a 12 month period, moving OTN from 7th in this market segment to 2nd.

- Developed strategy and implementation plan for OTN's entry into the specialty pharmacy market. Interviewed more than 20 health plan executives, developed business models, company positioning, and customer value propositions. Result: OTN acquired ivpcare, the nation's largest, privately held specialty pharmacy.

VIGNETTE - Austin, TX 2000 - 2002
Market Leader in Web Content Management Software
Director of Product Marketing, Packaged Applications Division

- Led Product Marketing for Vignette's 2 packaged, J2EE applications. Positioned and launched portal application, which became the fastest growing new product in Vignette history with more than 40 customers ($8M revenue) in first 6 months. Developed pricing; wrote product collateral; trained and educated 150 sales personnel and channel partners in the US, Europe, Asia, and Australia; briefed industry analysts and the press.
- Secured #1 ranking in portal functionality and #1 ranking in portal technology from AMR Research, a leading industry analyst firm (March 2002). 15 companies evaluated including Oracle, IBM, and BEA.
- Negotiated stronger partnership with IBM marketing and sales executives. Created joint sales and marketing collateral for portal software resulting in 6 joint sales opportunities ($2.5M) in first 6 weeks.
- Managed $10M sales pipeline for Vignette's commerce application; Presented and demonstrated the application to customers, prospects, and channel partners such as PricewaterhouseCoopers, Accenture, and IBM Global Services. Helped close first 2 customers resulting in more than $1M in bookings.

Corporate Strategist

- Led multidisciplinary (sales, marketing and engineering) initiative to reclaim leadership in web content management software market resulting in10 press articles and 20 new partnering opportunities.
- Developed financial model to measure P&L impact of Vignette's largest channel and technology partners. Recommendations were implemented resulting in smaller, more focused, partner organization.

BECTON DICKINSON & CO. - Franklin Lakes, NJ 1998 - 2000
Market Leader in Medical Devices and Diagnostics
Director of Marketing & Business Development, Healthcare Software Division (BD.id)

- Member of executive management team that formulated strategy and oversaw P&L performance of start-up healthcare software division with budget of $12M and sales of $4.6M. Acquired/integrated a company with 600 customers, 25 employees and 50 SKUs. Grew division from 4 to 70 employees in 2 years.
- Supervised staff of 7 with $1.5M budget to execute all division marketing, product management, and customer training. Launched 2 new product lines in 18 months to reduce life-threatening errors in specimen collection and medication administration. Product lines were composed of hardware, software, disposables, consulting services, and customer support.
- Increased sales pipeline by 300% by developing and launching marketing programs, print and web advertisements, trade articles, trade show activities, sales promotions, and direct marketing campaigns. Negotiated $350K contract with advertising agency to develop creative materials and to execute marketing research and public relations programs. Market research findings generated 12 trade articles.
- Met with executives of Cardinal, McKesson, SMS, Cerner, Sunquest, and start-ups to pursue, sales alliances, partnerships, equity investments, and acquisitions. Helped negotiate agreements with Palm, Symbol Technologies, and Aether Software. Wrote joint case studies and conducted interviews with partners to raise industry awareness of BD's software products.
- Participated as youngest member of BD's Senior Marketing Team (BD's top 10 marketing executives) to develop and implement company-wide initiatives for e-business, customer integrated value propositions, and corporate re-branding. Presented e-business proposal to CEO and received $250K in initial funding.

Q.E.D. INTERNATIONAL - Hawthorne, NY 1997 - 1998
Medical Marketing Communications Firm
Consultant to the CEO

- Led brand strategy and positioning projects for Abbott Labs (Cardiovascular/*Hytrin*), Purdue Pharma (Pain/*Oxycontin*) and Forest Laboratories (Respiratory/*Aerobid*). Sold $75K initial project to Abbott, which led to $300K follow-on project.
- Developed a short list of merger and acquisition candidates. Contacted and met with CEOs to assess interest level. Q.E.D. was acquired by Quintiles Transnational in 1999.

BOOZ·ALLEN & HAMILTON - New York, NY 1995 - 1997
Associate, Pharmaceutical/Biotechnology Clients

- Developed business and marketing strategies for $6B firm's cardiovascular business and $1B firm's oncology business. Analyzed and presented key pharmaceutical industry trends particularly around reimbursement. Interviewed therapeutic area thought leaders to assess current and future competitive landscape. Developed product forecasts, and identified strategic sales and marketing partners.
- Analyzed financial and strategic fit of $500M acquisition candidate. Interviewed medical thought leaders. Modeled various financial scenarios to value business. Recommended against acquisition.

Associate, Medical Device/Equipment Clients

- Evaluated strategic fit of $700M-$800M acquisition candidate for a CEO which resulted in acquisition. Created detailed analytic frameworks and financial models for bundled sales opportunities and cost saving synergies; interviewed customers to identify attractive product bundles; analyzed competitive landscape; presented findings to executive management.
- Increased product profitability by 15% by recommending that $500M European company adopt new manufacturing process using new raw materials. Project projected to generate NPV of $50M.
- Restated a $1B firm's financials to show profitability by product line. Identified which products generated profits and which did not. Reallocated expense and capital dollars to support more profitable products.
- Evaluated R&D projects and new product/market opportunities for a $1B company to fill $150M revenue gap. Recommended higher investment in fewer R&D projects; profiled and proposed 2 acquisitions.

THE WALT DISNEY COMPANY - Orlando, FL 1994
Summer Associate

- Wrote comprehensive business plan for new Disney conference center and hotel. Presented plan to executive management; recommended that Disney proceed with venture. Plan included: customer/market analysis, competitive analysis, market strategy, operations strategy, partnering strategy, financial projections, risk assessment, and implementation plan.
- Benchmarked best practices across multiple industries and created statistical simulation models to enable Disney to reduce annual workers' compensation expenses by $5M, from $37M to $32M.

ACCENTURE - Philadelphia, PA 1989 - 1993
Senior Consultant, Merck: Astra/Merck Joint Venture

- Supervised a project team of 8 and managed a budget of $250K to design and create Astra/Merck's Licensing and Business Development function. The project deliverables were of such high quality that they became the role model for future Accenture projects at Astra/Merck.
- Drove and facilitated meetings of marketing and R&D executives to create initial vision and strategy that enabled Astra/Merck to build sustainable competitive advantage in the GI, cardiovascular, and CNS therapeutic areas. AstraZeneca acquired Merck's 50% stake in 1995 for $800M.
- Helped *Prilosec* become world's most profitable drug, by creating Astra/Merck's first business process model, organizational model, financial model, and information model.

EDUCATION

DUKE UNIVERSITY, Fuqua School of Business
M.B.A. concentrating in Marketing and Entrepreneurship
J.B. Fuqua Scholar (academic top 10%)

UNIVERSITY OF PENNSYLVANIA, The Wharton School/College of Arts & Sciences
B.S. in Finance and **B.A.** in Molecular Biology
Co-Founder, University of Pennsylvania Student Federal Credit Union

Committee on Oversight and Government Reform
Witness Disclosure Requirement – "Truth in Testimony" Required by House Rule XI, Clause 2(g)(5)

Name: Ted A Okon

1. Please list any federal grants or contracts (including subgrants or subcontracts) you have received since October 1, 2008. Include the source and amount of each grant or contract.

None.

2. Please list any entity you are testifying on behalf of and briefly describe your relationship with these entities.

I serve as the Executive Director of the Community Oncology Alliance.

3. Please list any federal grants or contracts (including subgrants or subcontracts) received since October 1, 2008, by the entity(ies) you listed above. Include the source and amount of each grant or contract.

None.

I certify that the above information is true and correct.

Signature: 

Date: 11-22-11