From the SDNY Amended Whistleblower Complaint; filed August 3, 2018

DETAILED COMMENTARY FROM "FMV OF BFSF INDUSTRY CONFERENCE"

452. Dr. Borzilleri obtained definitive confirmation of the "service fee" scheme from his attendance at an industry expert conference focused specifically on the topic. The two-day conference, sponsored by CBI, was entitled "Fair Market Value of Bona Fide Service Fees". The event was held in Philadelphia on October 7-8, 2013.

453. CBI describes itself as "the leading provider of market-driven, unbiased conferences for the pharmaceutical, biotechnology, medical device and healthcare industries."

454. The conference was attended by senior corporate government program staff from the biopharmaceutical and drug distribution industries, as well as representatives from leading consulting and law firms that advise industry regarding BFSFs and FMV. Of particular note was the absence of CMS or any other government agencies at the conference.

455. Key staff from the Defendants were in attendance, including Amgen, AbbVie, Bristol-Myers Squibb, Pfizer, Sanofi and Express Scripts. Also present were representatives from other leading drug manufacturers and service providers, including Johnson and Johnson, Glaxo, Astellas, Gilead, Mylan, Otsuka and Diplomat Specialty Pharmacy.

456. The legal and consulting firms, which gave most of the presentations and led discussions, are the leading firms among a narrow group of pharmaceutical and PBM industry advisors with dedicated BFSF and FMV healthcare practices. As per their corporate websites, these firms advise the majority of top pharmaceutical and biotechnology companies regarding compliance with government regulations.

457. Besides CIS, consultant firm presenters included representatives from Huron Consulting and Navigant Consulting.

458. On the legal front, presenters included representatives from King & Spalding, Reed Smith, Hogan Lovells and Sidley Austin. See **Exhibit 14** for a list of conference presenters and attendees.

Exhibit 14

"First Ever" Fair Market Value of Bona Fide Service Fees Conference

October 7-8, 2013, Philadelphia, PA

Presenter/Attendee List

Name	Title
Presenters (in chronological order)	
Tom Evegan	Senior Director, Commercial Contracting at Compliance Implementation Systems (CIS)
John Shakow	Partner, King & Spalding
Mark Linver [1]	Managing Director, Huron Consulting Group
Stephanie Gilson	Assistant General Counsel, Johnson & Johnson
Christopher Jackson	Corporate Attorney, Otsuka American Pharmaceuticals, Inc.
Donna White	Senior Director, Contracts and Compliance at Cornerstone Therapeutics
Joseph Metro	Partner, Reed Smith LLP
Mark Dewyngaert, Ph.D.	Managing Director, Huron Consulting Group
Michael Hepburn[2]	Senior Director, Government Contract Compliance at Janssen Pharmaceuticals, Inc.
Doris Chern[2]	Senior Manager, Pricing Strategy and FMV at Janssen Pharmaceuticals, Inc.
Jim Abrams	Director, Government Pricing and Reporting at Mylan Pharmaceuticals
Trevor L. Wear	Senior Associate, Sidley Austin, LLP
Julie DeLong, CFA	Director, Valuation and Financial Risk Management at Navigant Consulting, Inc.
Isabel P. Dunst	Partner, Hogan Lovells US LLP
John Moose, MBA, CPA, ABV	Project Leader, Huron Consulting Group
Other Attendees	
Sajid Saeed	Director Fee-for-Service, Glaxo Smithkline

Greg Haverkamp	Senior Manager of Government Contracts and Compliance, Novo Nordisk
Mitzi Cole	Strategic Pharmaceutical/Biotechnology Legal Counsel, Pfizer
Cynthia Bass	Associate General Counsel, Sanofi US
Cheryl Allen	VP Development/Industry Relations, Diplomat Specialty Pharmacy
Allyson Behm	Senior Corporate Attorney - Regulatory, Astellas
Jason Carter	Senior Manager, Government Analytics & Compliance, Roche/Genentech
Josh Parker	Director, Product Marketing, Express Scripts/Accredo Health
Lyndsay Nahf	Director, Central Consultancy Group, AbbVie
Linda Ozark	STAR Project Manager, Marketing Operations Systems, AbbVie
Jill Thompson	Senior Counsel and Assistant Secretary, NPSP Pharmaceuticals
John Walsh	Director Trade Account Management, Pfizer
Christine Morse	Senior Attorney, Novo Nordisk
Jamie Rowe	Senior Category Manager, Amgen

[1] Mark Linver did not attend the conference; his presentation was given by his colleague, Mark Dewyngaert

[2] Janssen Pharmaceuticals is a division of Johnson & Johnson

Source: CBI conference agenda and attendee poster from conference, Corporate websites.

459. At the conference, Dr. Borzilleri directly heard extensive commentary from the "insider" conference presenters, which fully corroborated the "service fee" allegations outlined in this Complaint. Dr. Borzilleri noted considerable trepidation among the presenters and audience regarding legal exposure throughout the two-day conference.

460. All key components of the fraud were verified via presentations, candid discussions and direct quotes at the conference, namely:

a. "Service fees", rather than manufacturer rebates/discounts, have become the primary vehicle for manufacturer compensation of PBMs/specialty pharmacies;

b. The standard contract terms between manufacturers and service vendors utilize "percent of revenue" terms; without adjustment even for severe price increases, despite broad awareness of FMV fraud risk.

c. The experts recognize that the majority of "service fees" should legitimately be valued via the straightforward "Cost Approach" to FMV assessment, but it is rarely being done;

d. The large service vendors, including the PBMs, are using their considerable negotiating leverage to preserve “percent of revenue” service contracts with manufacturers.

461. In the first few minutes of his opening statements, Tom Evegan of CIS, the Chairman of the conference, stated that "fees were the key to government pricing" and the majority of compensation to service providers from manufacturers had "shifted from rebates to fees".

462. On the second day, Mr. Dewyngaert, a senior consultant from Huron Consulting, stated that "service fee agreements" accounted for a "substantial pool of money" and were the "main source of income" for service vendors.

463. A key presenter was John Shakow, from the law firm King & Spalding. Mr. Shakow disclosed that he was a defense lawyer in the Streck Qui Tam case, which included allegations of “service fee” abuse in the Medicaid program.

464. After providing background on the history of BFSFs and potential legal risks, Mr. Shakow stated that he was "not a fan” of “percent of revenue” contracts and that manufacturers need to "consider whether percent of sales can be consistent with FMV as prices rise". He stated it was "a lot easier to have a fixed fee per unit of service", which would make him "less worried regarding the impact of price increases".

465. Mr. Shakow went on to say that “percent of revenue” arrangements "may bear no relation to the value of service unless (the service is) price-based". He expected that "percent of revenue" deals will be "challenged in the future".

466. Mr. Shakow emphasized that the manufacturer’s handling of fees must be able to "withstand review/auditing by an independent party, which can determine the same FMV", as well as "justify the FMV to an outside party brought in by the government". He stated that the government will "look beyond the agreement and evaluate the true nature of the fees, via emails, communications, interviews and sworn testimony", in its search for “intent".

467. In their joint presentation, Isabel P. Dunst, a partner at Hogan Lovells and Julie DeLong, the Director of Valuation and Financial Risk Management at Navigant Consulting, offered somewhat contrasting viewpoints regarding valuation methodologies. Ms. Dunst stated that she "did not recommend percent of sales" contracts to her manufacturer clients, while Ms. DeLong indicated more flexibility.

468. Ms. DeLong stated that she "can value anything" and was comfortable "translating per unit fees to percentage of revenue". Ms. DeLong elaborated, stating that "some want to be paid in different ways" and that she could "translate FMV into a dollar amount per month or year, as well as a percent of revenues". During this discussion, Ms. Dunst stated that she hoped "the conference was not being recorded".

469. Ms. DeLong further stated that the FMV was a "snapshot in time" and "percent of revenue" deals had greater risk when linked to fast-rising “list” prices.

470. An audience member then asked about the proper FMV handling of fees for a $100 versus a $1,000 prescription with the same number of pills. Ms. Dunst, of Hogan and Lovells, replied that a "real problem was developing with percent of revenue" contracts. We view this

commentary as particularly relevant for fast-inflating, extreme-priced oral “specialty” drugs, which may not require significant legitimate support services.

471. Numerous presenters stated the "Cost Approach" is the most legally-justifiable FMV methodology for the vast majority of services provided for manufacturers by service vendors. In the “Cost Approach”, the payment is determined by a straightforward determination based upon the staffing, time and resources required to provide a specific service.

472. In his discussion of contracting processes, John Moose of Huron Consulting stated that the negotiating parties must recognize that "most of the value of services comes from the connection with the patient" and that a "dollar amount per activity is the easiest to justify".

473. Julie DeLong and Isabel P. Dunst specifically discussed the topic of FMV for services provided for “specialty” drugs. Ms. Dunst stated that she "does not view the specialty channel any differently from other channels" regarding the handling of fees and FMV.

474. If a particular “specialty” service is "core" to the business model of the specialty pharmacy and "they are already doing it", the manufacturer "should not be paying for it". Ms. Dunst and Ms. DeLong indicated that virtually all the specialty pharmacy services are patient/unit based and should be valued using the "Cost Approach".

475. Despite the uniform recommendation of the "Cost Approach" for FMV “fee” determinations, conference presenters repeatedly admitted that this methodology is rarely used in practice. Rather, “percent of revenue” contracts, inclusive of all price increases, remain the industry standard.

476. A definitive moment in the two-day conference came during the final presentation of the first day given by Jim Abrams, the former Director of Government Pricing and Reporting at Mylan Pharmaceuticals. Mylan’s leading brand drug, Epipen (epinephrine for severe allergic

reactions) has been a controversial product, with its vast US sales growth over the past decade driven by massive price increases.

477. Mr. Abrams took a simple poll of the audience. He asked attendees to raise their hands "if they were using a rigorous cost-plus approach to qualify fees" - only one person, among the 50-60 conference attendees, raised his hand.

478. John Moose of Huron Consulting specifically discussed the need for contract adjustments for rising drug prices. He stated that unless manufacturers put "adjustments in contracts for price changes", they "run the risk of paying too much". He stated that manufacturers need to "refresh" contracts for price increases and service changes, in order to maintain reasonable FMV determinations. Despite his expert recommendation, Mr. Moose then admitted that "he had not done any refreshes for service contracts".

479. In her presentation, Stephanie Gilson, the Chief Counsel at Johnson & Johnson, admitted that "percent of WAC (Wholesale Acquisition Cost), deals are often not updated by manufacturers".

480. The considerable negotiating leverage of large service vendors, especially the PBM Defendants, pertaining to “service fee” contracts was apparent at the conference.

481. Jim Abrams of Mylan polled the audience of largely manufacturers and consulting/legal advisors, asking for an indication of who had "engaged vendors to assess fee structure". Out of the 50-60 attendees, only 2 raised their hands.

482. Tom Evegan of CIS then commented that "very few vendors were willing to provide the data" and were "worried" about doing so. Mr. Evegan expressed concern since "manufacturers were looking for documentation since manufacturers were responsible if ever challenged".

483. Mr. Shakow further stated that "up to a few years ago few contracts gave specifics regarding fees" and this "could be trouble".

484. Numerous expert presenters emphasized the need for manufacturers to insist on broad "audit rights" in their contracts with large service vendors, while admitting little success with these requests.

485. Mr. Shakow stated that shifting away from "percent of revenue" service contracts was difficult for manufacturers because vendors "all want percent of revenue deals" and change required "getting partners to agree".

486. Mark Dewyngaert from Huron stated that "often partners (i.e. service vendors) will not allow cost plus" fee determinations.

487. Ms. Gilson stated Johnson & Johnson was "trying to work with intermediaries" in order to decrease their reliance on "percent of WAC" contracts, but were getting "strong pushback from service providers". She stated that to change these business practices may require either a "manufacturer industry initiative" or a "CMS mandate".

488. Finally, expert commentary indicated that the federal government has been struggling to address industry “service fee” practices. Ms. Gilson stated that the Office of the Inspector General (OIG) "has been looking at these practices", but really had little knowledge" and the "learning curve takes time". She further stated that the OIG auditors had only just "engaged" with J&J directly on this issue recently in the "second quarter of 2013".

489. An attendee agreed that the OIG was "behind industry" and asked Ms. Gilson when the government would be "dangerous enough to understand how industry works". Ms. Gilson responded that she thought "CMS was getting burned out because a lot of stakeholders were in their ear".