No. 11-204

IN THE

Supreme Court of the United States

MICHAEL SHANE CHRISTOPHER, *et al.*,

Petitioners,

v.

SMITHKLINE BEECHAM CORPORATION
dba GLAZOSMITHKLINE,

Respondent.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

BRIEF OF PHARMACEUTICAL REPRESENTATIVES AS *AMICI CURIAE* IN SUPPORT OF PETITIONERS

STEPHEN A. WEISS
JAMES A. O'BRIEN III
SEEGER WEISS LLP
77 Water Street
26th Floor
New York, NY 10005

MICHAEL R. DICHIARA
Counsel of Record
DICHIARA LAW FIRM LLC
77 Market Street
Suite 2
Park Ridge, NJ 07656
(201) 746-0303
michael@dichiarallc.com

Counsel for Amici Curiae

240363

COUNSEL PRESS

(800) 274-3321 • (800) 359-6859

TABLE OF CONTENTS

Page

TABLE OF CONTENTS i

TABLE OF CITED AUTHORITIES iii

I. STATEMENT OF INTEREST OF *AMICI CURIAE* 1

II. SUMMARY OF THE ARGUMENT 2

III. ARGUMENT 5

A. The Job Duties of a PSR Have Changed Materially Over the Past Century 5

1. The PSR of Long Ago..... 6

a. The PSR's Job Duties and Responsibilities 6

b. Educational and Job Requirements of Earlier PSRs 10

2. Modern Era PSRs..... 11

a. Dana Higgs..... 11

b. Eugene Kuzinski 13

B. Legislative and Regulatory Actions Compelled Changes in PSRs' Job Duties... 14

Table of Contents

Page

C. The Pharmaceutical Industry Has Changed The Role of PSRs 22

1. PhRMA's Description of the Role of Today's PSRs 22

2. The PhRMA Code Has Changed The Role Of PSRs 23

3. Other Industry Publications Reflect the Changed Job Duties of Today's PSRs 25

4. In SEC Filings, Many Drug Companies Have Reported That PSRs Don't Sell Pharmaceutical Drugs; They Only Promote Them 26

5. Other Industries Have True Sales Positions 30

D. Employees in Other Industries With Similar Promotional Duties Will Be Adversely Impacted if the Pharmaceutical Industry's Arguments Are Upheld 31

CONCLUSION 34

TABLE OF CITED AUTHORITIES

Page

CASES

Adams v. Upjohn Co.,
142 Ga. App. 264, 235 S.E.2d 584
(Ga. Ct. App. 1977) 8

Brock v. Superior Care,
840 F.2d 1054 (2d Cir. 1988). 9

Burling v. Real Stone Source, LLC,
2009 WL 1812785 (D. Idaho June 24, 2009). 32

Christopher v. SmithKline Beecham Corp.,
635 F.3d 383 (9th Cir. 2011), *cert. granted*,
132 S. Ct. 760 (2011) 2, 5, 6

Clements v. Serco, Inc.,
530 F.3d 1224 (10th Cir. 2008) 32

Coultrip et al. v. Pfizer, Inc.,
06-cv-9952 (S.D.N.Y.) 1, 11, 30

Evavold v. Sanofi-Aventis, U.S. LLC et al.,
09-cv-5529 (D.N.J.) 1

Frank v. McQuigg,
950 F.2d 590 (9th Cir. 1991) 9

IMS Health Inc. v. Ayotte,
No. 06-CV-280-PB, 2006 WL 4507573
(D. N.H. filed July 28, 2006). 26

Cited Authorities

Page

In re Novartis Wage and Hour Litigation,
611 F.3d 141 (2d Cir. 2010), *cert. denied*,
131 S. Ct. 1568 (2011) 5, 21

Ironworkers Local Union 68 v. Astrazeneca Pharma., LP,
634 F.3d 1352 (11th Cir. 2011) 26

Kuzinski et al. v. Schering Corp.,
Civil Action No. 07-cv-233 (D. Conn.)..... 1

Kuzinski v. Schering Corp,
604 F. Supp. 2d 385 (D. Conn. 2009), *aff'd*,
384 F. App'x 17 (2d Cir. 2010), *cert. denied*,
131 S. Ct. 1567 (2011) 1, 13, 26, 31

Parke, Davis & Co. v. Fifth Judicial Dist. Ct. in and for Beaver County,
93 Utah 217, 72 P.2d 466 (1937) 8

Proctor & Gamble Pharma., Inc. v. Hoffman-LaRoche, Inc.,
2006 WL 2588002 (S.D.N.Y. Sept. 6, 2006) 21-22

Seymour v. Parke, Davis & Co.,
423 F.2d 584 (1st Cir. 1970) 8

Slow v. Prestige Merchandising Co., Inc.,
2011 WL 4373516 (E.D.N.Y. Sept. 19, 2011)..... 32

Cited Authorities

Page

Smith Co. v. American Pharma. Co.,
270 N.Y. 184 (1936) 8

State ex rel. Ciba Pharmaceutical Products, Inc. v. State Tax Commission,
382 S.W.2d 645 (Mo. 1964) 8

Wirtz v. Keystone Readers Services, Inc.,
418 F.2d 249 (5th Cir. 1969) 32

Zeneca v. Eli Lilly & Co.,
1999 WL 509471 (S.D.N.Y. July 19, 1999). 22

Zirin v. Charles Pfizer & Co.,
121 So.2d 694 (Fla. Dist. App. 1960), *aff'd*,
128 So. 2d 594 (1961) 8

STATUTES

29 U.S.C. § 259(a). 9

21 C.F.R. § 201.128 19

21 C.F.R. § 202. 21

21 C.F.R. § 202.1(e)(6) 19

21 C.F.R. § 203. 21

29 C.F.R. § 790.14 9

29 C.F.R. § 790.15 9

Page

29 C.F.R. § 790.17 9

Durham-Humphrey Amendment of 1951 (codified as amended at 21 U.S.C. § 353 (2004)) 3, 17

Fair Labor Standards Act of 1938 ..... 1, 6, 9

False Claims Act (codified as amended 31 U.S.C. § 3729 (1986))... 3, 21

The Federal Food, Drug and Cosmetic Act of 1938 (amended 1994) 3, 17, 18, 21

Kefauver-Harris Amendments of 1962 (codified as amended at 21 U.S.C. § § 321, 331-32, 348, 351-53, 355, 357-60, 372, 374, 376, 381 (1970)) (Drug Efficacy Amendments) 3, 19

Pure Food and Drug Act of 1906. 14

OTHER MATERIALS

75 Fed. Reg. 28404 (May 20, 2010) 33

Arthur F. Peterson, *Pharmaceutical Selling, "Detailing" and Sales Training* (2d ed. Heathcote-Woodbridge, Inc. 1959), *available at* http://babel.hathitrust.org/cgi/pt?u=1&num=0&seq=23&view=image&size=100&id=uc1.%24b332738 ..... 7, 10

Cited Authorities

Page

Benjamin Falit, *The Path to Cheaper and Safer Drugs; Revamping the Pharmaceutical Industry in Light of GlaxoSmithKline's Settlement*, 33 J.L. Med. & Ethics 174 (2005) . . . 10-11

Charles J. Walsh, Alissa Pvrich, *FDA Efforts to Control the Flow of Information at Pharmaceutical Industry-Sponsored Medical Education Programs: A Regulatory Overdose*, 24 Seton Hall L. Rev. 1325 (1994) 19, 20

Code on Interactions with Healthcare Professionals, www.phrma.org/about/principles-guidelines/code-interactions-healthcare-professionals 22, 23, 24, 25

Eli Lilly and Company, 2010 Annual Report, Form 10-K, http://files.shareholder.com/downloads/LLY/1642776639x0x447905/6281D413-C258-488B-ADBE-B35289495F26/English.pdf 28

George R. Cain, *The Detail Man – What the Pharmaceutical Industry Expects of Him*, 38 Bull. N.Y. Acad. Med., No. 2, Feb. 1962, *available at* http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1804767/?page=4. 6-7

Jennifer E. Spreng, *Pharmacists and the "Duty" to Dispense Emergency Contraceptives*, 23 Issues L. & Med. 215 (2008) 15, 18, 19

Cited Authorities

Page

Jesse M. Boodoo, Note and Comment, *Compounding Problems and Compounding Confusion: Federal Regulation of Compounded Drug Products and the FDAMA Circuit Split*, 36 Am. J.L. & Med. 220 (2010) 15

Katherine A. Helm, *Protecting Public Health From Outside The Physician's Office: A Century of FDA Regulation From Drug Safety Labeling to Off-Label Drug Promotion,* 18 Fordham Intell. Prop Media and Ent. L.J. 117 (2007) . . . . . *passim*

Lars Noah, Esq., *Death of a Salesman: To What Extent Can the FDA Regulate the Promotional Statements of Pharmaceutical Sales Representatives*, 47 Food & Drug L.J. 309 (1992). 11, 16, 19

Merck and Co., Inc.; Form 10-K filed with SEC on 2/28/11; http://www.merck.com/investors/financials/form-10-k-2011.pdf. 28

Michelle M. Mello, *Shifting Terrain in the Regulation of Off-Label Promotion of Pharmaceuticals*, 360 N. Engl. J. Med 1557 (2009) 19, 20, 21

Nancy L. Shore, Note, *Advanced Nursing Practice and Prescriptive Authority: A Victory for New Jersey Nurses*, 17 Seton Hall Legis. J. 576 (1993). 14, 15, 17

Page

Novartis SEC Filing 29

Opinion Letter from Wage and Hour Div., U.S. Dep't of Labor, 1994 DOLWH LEXIS 65 (Aug. 19, 1994) 33

Opinion Letter from Wage and Hour Div., U.S. Dep't of Labor, 1998 DOLWH LEXIS 17 (Feb. 19, 1998) 32

Opinion Letter from Wage and Hour Div., U.S. Dep't of Labor, FLSA 2006-16, 2006 WL 1698305 (May 22, 2006) 32

Peter Temin, *The Evolution of the Modern Pharmaceutical Industry*, Working Paper of Department of Economics, Massachusetts Institute of Technology, No. 223 (1978), *available at* http://dspace.mit.edu/bitstream/handle/1721.1/63589/evolutionofmoder00temi.pdf?sequence=1 15

Pharmaceutical Manufacturers Association (now known as Pharmaceutical Research and Manufacturers of America), www.pharma.org/about/phrma. 3

Pharmaceutical Marketing in Perspective: Its Value and Role as One of Many Factors Informing Prescribing, PhRMA July 2008, www.phrma.org/sites/default/files/187/phrmamarketingbrochureinfluencesonprescribingfinal.pdf . . 23, 25, 26

Page

Rufus L. McQuillan, *Is the Doctor In? The Story of a Drug Detail Man's Fifty Years of Public Relations with Doctors and Druggists* (Exposition Press, New York, 1963), *available at* http://babel.hathitrust.org/cgi/pt?id=mdp.39015072117149 . . 7

Susan Kopp Keyack, Note, *The Drug Price Competition and Patent Term Restoration Act of 1984: Is it a Healthy Long Term Solution?*, 21 Rutgers L.J. 147 (1989) 18

The Facts About Pharmaceutical Marketing & Promotion, PhRMA July 2008, www.phrma.org/research/publications/profiles-reports 23, 25

The Pharmaceutical Century, Ten Decades of Drug Discovery (ACS Publications), *available at* http://www2.uah.es/farmamol/The%20Pharmaceutical%20Century/Ch2.html 16

Tom Jones, *Detailing the Physician, Sales Promotion by Personal Contact with the Medical and Allied Professions* (New York, Romaine Pierson Publishers, Inc. 1940), *available at* http://babel.hathitrust.org/cgi/pt?id=mdp.39015072276374 7

I. STATEMENT OF INTEREST OF *AMICI CURIAE*[1]

Eugene Kuzinski ("Kuzinski") is a former pharmaceutical sales representative ("PSR" or "detailer") of Schering Corporation, and is a named plaintiff in *Kuzinski et al. v. Schering Corp.*, Civil Action No. 07-cv-233 (D. Conn.), a Fair Labor Standards Act of 1938 ("FLSA") overtime action pending in the United States District Court for the District of Connecticut.[2] Kuzinski worked in the pharmaceutical industry as a PSR from 1973 until 2006. Dana Higgs ("Higgs") is a former PSR for Pfizer, Inc., and is a named plaintiff in *Coultrip et al. v. Pfizer, Inc.*, 06-cv-9952 (S.D.N.Y.), a wage and hour action pending in the United States District Court for the Southern District of New York. Higgs worked as a PSR for Pfizer from 1984 until 2006. Dede Evavold ("Evavold") is former PSR for Sanofi and is the named plaintiff in a FLSA action pending in the United States District Court for the District of New Jersey, *Evavold v. Sanofi-Aventis, U.S. LLC et al.*, 09-cv5529 (D.N.J.). Evavold worked in the pharmaceutical industry as a PSR from 2003 to 2008.

---

1. No counsel for a party authored this brief in whole or in part, and no such counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than the *amici*, or its counsel, made a monetary contribution intended to fund its preparation or submission. The Petitioners have filed a blanket waiver with the Court consenting to the submission of all *amicus* briefs. The consent of the Respondent is submitted herewith.

2. *Kuzinski v. Schering Corp*, 604 F. Supp. 2d 385 (D. Conn. 2009), *aff'd*, 384 F. App'x 17 (2d Cir. 2010), *cert. denied*, 131 S. Ct. 1567 (2011).

II. SUMMARY OF THE ARGUMENT

Amici submit this brief in support of the appeal of Petitioners — Michael Shane Christopher and Frank Buchanan, who were formerly employed as PSRs by respondent, GlaxoSmithKline ("GSK") — to address the change in the job duties and responsibilities of PSRs during the past century. This change is materially relevant to the decision below in *Christopher v. SmithKline Beecham Corp.*, 635 F.3d 383 (9th Cir. 2011), *cert. granted*, 132 S.Ct. 760 (2011). The Ninth Circuit determined that the Petitioner-PSRs are exempt from overtime pay under the FLSA's outside salesman exemption, and declined to grant deference to the interpretation of the Secretary of Labor that the outside sales exemption does not apply to PSRs. In reaching this result, the Ninth Circuit assumed that the job duties of a PSR have not changed since the 1930s; that PSRs generally have been considered "salespeople" since 1938; that "the conventional wisdom [is] that detailing" is the "functional equivalent" of making a sale in the pharmaceutical industry; and that until recently the Secretary has "not challenge[d]" that view. *Id.* at 387-88, 396, 399.

Because of external and internal regulation of the pharmaceutical industry, the job duties of a PSR, and the manner in which pharmaceutical prescription drugs are sold by the pharmaceutical industry, have changed dramatically since the 1938 enactment of the FLSA. The PSR *amici* submitting this brief have 60 years of combined detailing experience. Drawing on that decades-deep reservoir of knowledge, they refute two fundamental rationales of the Ninth Circuit's holding: that a) the job duties of a pharmaceutical detailer have remained static

over time; and b) the pharmaceutical industry accordingly has been unfairly surprised by the Secretary of Labor's *amicus curiae* position that PSRs are not exempt under the FLSA as outside salesmen.

In reality, numerous Acts of Congress[3] and regulations have significantly changed the duties and responsibilities of PSR's. The Secretary's *amici* briefs analyzed these changed duties, not the PSRs of long ago. Based on the primary duty of contemporary PSRs, the Secretary properly concluded that PSRs are not exempt outside salesmen.

In addition, the pharmaceutical industry itself has established self-imposed regulations that have substantially altered the duties and responsibilities of PSRs. The Pharmaceutical Manufacturers Association was founded in 1958 — now known as Pharmaceutical Research and Manufacturers of America ("PhRMA")[4]— consists of a consortium of pharmaceutical companies,[5]

---

3. *See* The Federal Food, Drug and Cosmetic Act ("FDCA") of 1938 (amended 1994); the Durham-Humphrey Amendment of 1951 (codified as amended at 21 U.S.C. § 353 (2004)); the Kefauver-Harris Amendments of 1962 (codified as amended at 21 U.S.C. § § 321, 331-32, 348, 351-53, 355, 357-60, 372, 274, 376, 381 (1970)); and the False Claims Act (codified as amended 31 U.S.C. § 3729 (1986)).

4. *See* www.pharma.org/about/phrma

5. *See* www.pharma.org/about/principles-guidelines/code-interactions-healthcare-professionals. The signatory members of PhRMA that have announced they intend to abide by the Code are as follows: Abbott; Allergan, Inc.; Amgen Inc.; Amylin Pharmaceuticals, Inc.; Astellas US LLC; AstraZeneca LP; Bayer HealthCare Pharmaceuticals; Biogen Idec; Boehringer Ingelheim

including respondent Respondent SmithKline Beecham Corp. ("GSK"), and it has established a strict code governing interactions between PSRs and healthcare professionals with which its members must abide. PhRMA has issued numerous reports and articles about pharmaceutical marketing and promotion, in which it classifies the role of PSRs as marketing and promotion. Critically, PhRMA does *not* characterize the interaction between PSRs and healthcare professionals as one involving "sales."

These dramatic changes in the duties of a PSR and the manner in which pharmaceutical drugs are sold over the past century are relevant to the Ninth Circuit's conclusion that, until recently, the DOL has long acquiesced in the practice of the pharmaceutical industry to consider detailers to be salespeople.

Pharmaceuticals, Inc.; Bristol-Myers Squibb Company; Celgene Corporation; Caphalon, Inc.; Covidien; Cubist Pharmaceuticals, Inc.; Cumberland Pharmaceuticals Inc.; CV Therapeutics, Inc., Daiichi Sankyo, Inc., Eisai Inc.; EMD Sorono; Endo Pharmaceuticals Inc.; Enzon Pharmaceuticals, Inc.; Forest Laboratories, Inc.; Genzyme Corporation; GlaxoSmithKline; Hoffman-LaRoche Inc.; Johnson & Johnson; Eli Lilly and Company; Lundbeck Inc.; Merck & Co, Inc.; Millennium Pharmaceuticals, Inc.; Novartis Pharmaceuticals Corporation; Novo Nordisk Inc.; OSI Pharmaceuticals; Otsuka America, Inc.; Pfizer Inc; Procter & Gamble Pharmaceuticals; Purdue Pharma L.P.; Regeneron Pharmaceuticals, Inc.; sanofi-aventis U.S.; Schering-Plough Corporation; Sepracor Inc.; Shire Pharmaceuticals, Inc.; Sigma-Tau Pharmaceuticals, Inc.; Solstice Neurosciences, Inc.; Solvay Pharmaceuticals, Inc.; Takeda Pharmaceuticals North America, Inc.; Talecris Biotherapeutics; and Wyeth.

III. ARGUMENT

A. The Job Duties of a PSR Have Changed Materially Over the Past Century

The Ninth Circuit panel gave "no deference" to the DOL's interpretation in the agency's *amicus* brief below that PSRs are not exempt outside salespersons. The lower court justified its decision not to grant deference based in part on the following reasons:

(a) The job of "detailing" has changed little over the last 60 years. *Christopher v. SmithKline Beecham Corp.*, 635 F.3d 383, 387 (9th Cir. 2011);

(b) The outside sales exemption has existed since 1938 and "[PSRs] have generally been considered salespeople" (*Id.* at 399); and

(c) Given points (a) and (b) above, the DOL has historically accepted the "conventional wisdom" that detailing is the functional equivalent of selling pharmaceutical products –until, suddenly, the agency changed course in its *amicus* briefs in the *Novartis*[6] appeal and this appeal. *Id.*

The brief of the Respondent in support of the *certiorari* petition, and the *amicus curiae* briefs of the Chamber of Commerce of the United States of America and the Pharmaceutical Research and Manufacturers of America in support of the Respondent, likewise suggest, imply, or

6. *In re Novartis Wage and Hour Litigation*, 611 F.3d 141 (2d Cir. 2010), *cert. denied*, 131 S. Ct. 1568 (2011).

argue that the job duties of PSRs have changed little over time, that for over 70 years PSRs been considered exempt by the industry based on those job duties, and that to hold otherwise would unfairly upset this settled understanding. 2011 WL 5007892, at **i, 2, 24-29; 2011 WL 4941011, at *5; 2011 WL 5007893, at **2, 6, 19, 21, 23-24.

1. The PSR of Long Ago

a. The PSR's Job Duties and Responsibilities

Contrary to the beliefs of the Ninth Circuit in *Christopher* and the Respondent and its *amici*, the job duties and responsibilities of modern PSRs differ materially from those of the pharmaceutical detailers of the distant past. These facts are relevant to — and substantially undermine — the *Christopher* panel's belief that PSRs have always done the same work since the FLSA's enactment and that therefore the DOL's *amicus* position that PSRs do not make sales for purposes of the outside salesman exemption is somehow an unfair surprise to the industry and an abrupt and improper change.

Notably, both prior to the FLSA's 1938 enactment and for several decades following its enactment, the job duties of PSRs included not only promotional work but also the actual selling of pharmaceutical products — specifically, the soliciting and taking of purchase orders for such products. *See* George R. Cain, *The Detail Man – What the Pharmaceutical Industry Expects of Him*, 38 Bull. N.Y. Acad. Med., No. 2, Feb. 1962, at 129 (noting that "[m]ost [PSRs] have . . . also a 'sales assignment' where they call upon buying accounts such as drugstores and hospitals"); *available at* http://www.ncbi.nlm.nih.gov/

pmc/articles/PMC1804767/?page=4; *id.* at 131 ("Many years ago the pharmaceutical sales representative sold many 'competitive' products to the pharmacist who could then compound prescriptions written by the doctor. Today most prescriptions are for products that have already been compounded by the manufacturer. Thus the role of the detail man has changed to a considerable extent from 'competitive product' selling in the drug store to detailing the physician on the specialties of his company."); Arthur F. Peterson, *Pharmaceutical Selling, "Detailing" and Sales Training*, at 33, 83, 132, 139-40, 157, 166-69, 181, 188-89, 241-44 (2nd ed. Heathcote-Woodbridge, Inc. 1959) (PSR's job duties included soliciting and taking actual orders for prescription drugs from physicians, wholesale druggists, retail pharmacies, and physician supply houses, taking inventories of drug retailers' stock, discussing pricing, and carrying and filling out order forms), *available at* http://babel.hathitrust.org/cgi/pt?u=1&num=0&seq=23&view=image&size=100&id=uc1.%24b332738; Tom Jones, *Detailing the Physician, Sales Promotion by Personal Contact with the Medical and Allied Professions*, at 158-64 (New York, Romaine Pierson Publishers, Inc. 1940) (PSRs performed both detailing and selling duties and part of their duties included taking of orders from physicians), *available at* http://babel.hathitrust.org/cgi/pt?id=mdp.39015072276374; *see also* Rufus L. McQuillan, *Is the Doctor In? The Story of a Drug Detail Man's Fifty Years of Public Relations with Doctors and Druggists*, at 37 (Exposition Press, New York, 1963) (noting that *some* PSRs could be "a good detail man in their work with doctors, and yet poor in selling to drugstores and hospitals. And, of course, the reverse was true – good as a salesman but poor as a detail man"), *available at* http://babel.hathitrust.org/cgi/pt?id=mdp.39015072117149.

The fact that PSRs of long ago — contrary to modern PSRs — actually sold drugs is further confirmed by case law. *See*, *e.g.*, *Seymour v. Parke, Davis & Co.*, 423 F.2d 584, 587 (1st Cir. 1970) (salesmen for drug company Parke, Davis & Co. (which later became subsidiary of Pfizer, Inc.) visit physicians, hospitals and retail pharmacies to disseminate product information and to solicit and take orders, which are forwarded to Massachusetts office for acceptance and filling from warehouse); *Adams v. Upjohn Co.,* 142 Ga. App. 264, 264, 235 S.E.2d 584, 584 (Ga. Ct. App. 1977) (sales representative employed by pharmaceutical company, whose job duties included disseminating information to physicians and hospitals, was authorized to request and receive orders for products in hospitals); *State ex rel. Ciba Pharmaceutical Products, Inc. v. State Tax Commission*, 382 S.W.2d 645, 648 (Mo. 1964) (professional service representatives employed by Ciba Pharmaceutical Products, Inc. (which later became part of Novartis) not only called upon physicians, but also solicited orders for drugs from retail druggists and hospital pharmacies, and filled out orders and sent them to home office for approval); *Zirin v. Charles Pfizer & Co.*, 121 So.2d 694, 697 (Fla. Dist. App. 1960) (activities of Pfizer, Inc. detail men included not only calling on doctors to persuade them to prescribe company's products, but also soliciting and receiving orders from retailers for products, relaying orders to local wholesalers for execution, and forwarding substantial number of orders to regional or home office), *aff'd*, 128 So.2d 594 (1961); *Parke, Davis & Co. v. Fifth Judicial Dist. Ct. in and for Beaver County*, 93 Utah 217, 72 P.2d 466, 466 (1937) (traveling salesman for Parke, Davis & Co. solicited and took orders from purchasers which he forwarded to company's branch office for acceptance); *Smith Co. v. American Pharma. Co.*, 270 N.Y. 184, 187 (1936) (noting that defendant pharmaceutical

company's salesman in 278 visits to drug stores delivered in forty-two instances company's products to druggist).

Moreover, in contrast to today's PSRs who do not receive commissions, the PSRs of long ago received commissions for sales that they made, *see* Peterson, *Pharmaceutical Selling*, at 119, 184, 198 — an important factor indicating that they actually sold pharmaceutical products.

Thus, unlike the pharmaceutical detailers of today who merely promote drugs, earlier medical detailers performed job duties that arguably could be classified as exempt under the FLSA's outside salesman exemption. Thus, it is not surprising that, until recently, the DOL had not rendered an interpretation that affirmatively and expressly stated that PSRs are not exempt as outside salesmen because they perform purely promotional work.[7]

---

7. It is also not surprising that the DOL did not until recently articulate a position on whether PSRs are exempt outside salesmen because no pharmaceutical company has ever requested an interpretation on that issue from DOL, despite the risk of being held to have acted in reckless disregard of the law or less than good faith for FLSA liability purposes in the absence of such a request. *See* 29 U.S.C. § 259(a) (reliance on written administrative interpretation by DOL suffices to show good faith by employer); 29 C.F.R. §§ 790.14, 790.15, 790.17; *Frank v. McQuigg*, 950 F.2d 590, 599 (9th Cir. 1991) ("The regulations and relevant precedent also indicate that any duty of inquiry owed by the employer is satisfied by an inquiry *to the Administrator*.") (emphasis in original) (citing authorities); *Brock v. Superior Care*, 840 F.2d 1054, 1062 (2d Cir. 1988) ("Failure to obtain a [DOL] ruling, even when one has not been suggested, has resulted in a determination of willful violation under the reckless disregard standard") (citation omitted).

b. Educational and Job Requirements of Earlier PSRs

The background and job requirements of PSRs of the past were also fundamentally different. They reflected an aptitude and a level of sophistication necessary for the ability to work with physicians *and* the retail pharmacy industry in an environment that had only recently begun to experience tightening oversight by the federal government and the requirement of written prescriptions of physicians for most types of drugs. In this regard, a PSR was "a scientifically trained graduate in pharmacy, pharmaceutical chemistry, pharmacology, or biology. He usually ha[d] a bachelor of science or higher degree. He [wa]s well versed in chemistry, bacteriology, physiology, and pharmacology and obviously th[ought] as a scientist." Peterson, *Pharmaceutical Selling*, at 26. Indeed, individuals who were not pharmacy college graduates were discouraged from seeking a detailer position, because they would be at a competitive disadvantage with those who had trained in pharmaceutical sciences and "who are thus ideally suited" to work as PSRs. *Id.* at 33. In addition, PSRs of the past needed to read current literature on pharmacology and therapeutics and to study the relevant scientific material. To "enable [the PSR] to utilize fully and to the greatest advantage in his work, [he or she] require[d] the scientific training afforded in the 5- or 6-year pharmaceutical course baccalaureate or higher degree." *Id.* at 2-3, 26-27, 31-32.

In contrast, the educational background considered acceptable for today's PSR is simply a college degree. *See* Benjamin Falit, *The Path to Cheaper and Safer Drugs; Revamping the Pharmaceutical Industry in*

Light of GlaxoSmithKline's Settlement, 33 J.L. Med. & Ethics 174, 176 (2005) ("Typically, pharmaceutical sales representatives are college graduates who spend approximately six to eight weeks in training before entering the field.").

2. Modern Era PSRs

Unlike the PSR of long ago, PSRs of today "do not 'sell' prescription drugs, but they do encourage health professionals to utilize pharmaceutical products when treating patients." Lars Noah, Esq., *Death of a Salesman: To What Extent Can the FDA Regulate the Promotional Statements of Pharmaceutical Sales Representatives*, 47 Food & Drug L.J. 309, 310 (1992). As described below by modern day PSRs, the job of a PSR today is materially different from that of the PSR of long ago.

a. Dana Higgs

Higgs worked for Pfizer from 1984 to 2006. During her tenure with Pfizer, she witnessed the evolution of the PSR position. *See* Supplemental Declaration of Higgs, document No. 94-19 and submitted in the *Pfizer* action on May 7, 2008, at ¶ 8 (describing how when she first started with Pfizer in 1984, PSRs "had direct accounts with pharmacies and physicians and sales were tracked by pharmacy and direct account orders. However, over the years, the tracking of 'sales' changed, as pharmaceutical reps stopped selling directly to physicians or taking orders from pharmacies. Pharmaceutical reps at Pfizer have not had any direct accounts with physicians or pharmacies for well over ten years…Reps stopped selling products to pharmacies and physicians with direct accounts over

ten years ago.") *See also* transcript from the June 15, 2007 deposition of Dana Higgs, at 214:10-215:16. Higgs testified: "When we first started the job, pharmacists used to purchase products directly from us. And it's changed over the years. Now, they only buy through wholesalers. And we can't take direct orders from pharmacists." *See id.* at 262:2-8.

At her deposition in the Pfizer action, Higgs also noted that the job qualifications for PSRs had changed radically – no longer were most PSRs scientifically trained – and that PSRs' primary duty when they made detailing visits to doctors was to announce a memorized script prepared by the drug company:

> When I first started, I was one of the few reps that weren't pharmacists. There were a lot of reps who were pharmacists. And I had a business degree. Now, the reps don't have business degrees, don't have pharmacy degrees. Most of them, you know, they can have anything. They can have a degree in physical education and the doctors don't feel, in general, rely upon the expertise of a drug rep. We aren't considered someone that they value for information so much, you know, because the way that we present is not the way we used to before…
>
> But it's not that way anymore. Now its, this is the paragraph you're going to read. You're going to go in and your going to tell him this paragraph. And it's going to be the same paragraph the rep before you read, and the

> rep before him. (See also Higgs Depo. Tr. 156, Lines 4-24, where Ms. Higgs relates that Pfizer PSRs were instructed how to hold their pens when pointing to promotional materials and to recite a "memorized presentation" to doctors. (*Id* at p. 161:11)).

b. Eugene Kuzinski

The testimony Kuzinski provided in the *Schering* action is consistent with that of Higgs in that he described the evolution of the duties of a PSR. *See* Reply Declaration of Kuzinski submitted in the *Schering* action on March 4, 2011, at ¶ 6 ("When I started as a pharmaceutical representative for Cooper Laboratories in 1973, unlike my tenure with Schering, I had the authority to do my own research to find clinical studies to use on calls with physicians. I could make my own visual aids, and I could decide which doctors to call on and how often. I also worked for Fleming & Co. from 1976-1980, and I had the authority to call on any doctor I wanted. I could even call on doctors in different states.") Kuzinksi further provided that when he worked for Key Pharmaceuticals, prior to working for Schering, he actually sold products to pharmacies. *See* Declaration of Kuzinski submitted in the *Schering* action on June 16, 2008 (Doc No. 194-2) at ¶ 4.

The testimony of these PSRs reflects the material change in job duties that occurred in the last century. Whereas PSRs of the past could actually sell drugs to purchasers and their focus concentrated on pharmacies, the PSR of today cannot sell any drugs but may only promote them, and physicians are the primary focus of these promotional efforts.

B. Legislative and Regulatory Actions Compelled Changes in PSRs' Job Duties

During the last century, the duties of a PSR materially changed in at least two respects: (1) a PSR could no longer actually sell drugs, but could only promote pharmaceutical drugs, and (2) PSRs no longer targeted wholesalers or retail pharmacies but strictly focused on physicians. This change in the PSR's duties resulted from the fact that the pharmaceutical industry and the manner in which it did business changed dramatically during the twentieth century as a result of laws enacted by the federal government.

In the late 1800's, there were few restrictions on drugs. Katherine A. Helm, *Protecting Public Health From Outside The Physician's Office: A Century of FDA Regulation From Drug Safety Labeling to Off-Label Drug Promotion,* 18 Fordham Intell. Prop Media and Ent. L.J. 117, 125 (2007). Drugs were branded as cure-alls, snake oils and elixirs that claimed to relieve all ailments. *Id.*

Prior to the 1900s, the public could obtain medications without a prescription. Nancy L. Shore, Note, *Advanced Nursing Practice and Prescriptive Authority: A Victory for New Jersey Nurses*, 17 Seton Hall Legis. J. 576, 587 (1993). Not until the early 1900s did physicians become responsible for drug prescription. *Id.* Subsequently, the Pure Food and Drug Act of 1906 limited the authority to prescribe narcotic drugs only to physicians, yet all other drugs were free to be purchased without a prescription. *Id.* That act prohibited interstate commerce in 'adulterated' or 'misbranded' drugs," Helm, 18 Fordham Intell. Prop Media and Ent. L.J. at 125, but there was no distinction

made between prescription and proprietary, or over-the-counter, drug products under the 1906 Act, *id.* The original act remained viable for thirty-two years. Shore, 17 Seton Hall. Legis. J. at 587.

Moreover, as late as the mid-1920s, more than 80 percent of prescriptions required "compounding" by a pharmacist while two decades later, only about a quarter required such work. Jennifer E. Spreng, *Pharmacists and the "Duty" to Dispense Emergency Contraceptives*, 23 Issues L. & Med. 215, 230 (2008). "Indeed, up until the dawn of modern pharmaceutical manufacturing in the 1950s, the majority of prescriptions were still compounded [by pharmacies]." Jesse M. Boodoo, Note and Comment, *Compounding Problems and Compounding Confusion: Federal Regulation of Compounded Drug Products and the FDAMA Circuit Split*, 36, Am. J.L. & Med. 220, 222 (2010). "The number of compounded prescriptions dropped precipitously in the 1950s and 1960s, as mass pharmaceutical production supplanted labor-intensive compounding. *Id.*

In the 1930s, drug companies did not advertise to doctors because any non-narcotic drug could be purchased without a prescription before 1938. Peter Temin, *The Evolution of the Modern Pharmaceutical Industry*, Working Paper of Department of Economics, Massachusetts Institute of Technology, No. 223, at 2 (1978), *available at* http://dspace.mit.edu/bitstream/handle/1721.1/63589/evolutionofmoder00temi.pdf?sequence=1. In addition, the range of products sold in the 1930s was extremely limited. *See id.* ("You could count the basic medicines on the fingers of your two hands.") (quoting president of Merck); *see also id.* 3 ("Most of our products were sold

without a prescription" and "43 percent of the prescription medicines were compounded by the pharmacist") (quoting president of Merck). During the 1930s, there were only a small number of basic medicines, and many of these were compounded by pharmacists and sold without prescriptions. Noah, *Death of a Salesman*, 47 Food & Drug L.J. at 311. Marketing efforts by PSRs therefore focused almost exclusively on retail pharmacies. *Id.*

Into the 1930s, moreover, dangerous drugs were still sold legally, because safety testing was not required before marketing. *The Pharmaceutical Century, Ten Decades of Drug Discovery* (ACS Publications), *available at* http://www2.uah.es/farmamol/The%20Pharmaceutical%20Century/Ch2.html. Pharmaceutical companies still manufactured many 19th and early 20th century drugs that were sold in bulk to pharmacists, who then compounded them into physicians' prescriptions. *Id.*

Also, newer drugs, such as many biological and sulfa drugs (after 1935), were packaged for sale directly to consumers and seemed to represent the future of drug manufacturing. *Id.*.

This led to the next major change in U.S. drug regulation, which occurred after a healthcare crisis in 1937. Helm, 18 Fordham Intell. Prop Media and Ent. L.J. at 126. In that year, many children died after ingesting a liquid formulation of a publicly distributed drug that had been tested for flavor, but not safety, before marketing. *Id.* The public outcry galvanized Congress to action — a disaster-based call repeated in the context of drug regulation a number of times over the following years. *Id.* Congress recognized that the United States Food

and Drug Administration's ("FDA's") authoritative reach needed to extend beyond labeling standards. *Id.* "It needed to provide a substantive pre-marketing review of drugs." Id. Shortly thereafter, the Federal Food, Drug and Cosmetic Act of 1938 ("FDCA") was enacted. *Id.* at 126-27. It required for the first time that drugs be proved "safe" and that manufacturers submit New Drug Applications before marketing. *Id.* at 127. Under the FDCA, the FDA tightly controlled all aspects of drug marketing, mandating that the drug product be labeled with extensive safety warnings and directions for use. *Id.*

Drug manufacturers initially retained discretion over the classification of drugs as prescription or non-prescription. *Id.* But a 1945 amendment to the drug labeling regulations initially defined the types of drugs that would require a physician prescription. Shore, 17 Seton Hall. Legis. J. at 587. And in 1951, after several episodes of consumer misuse, the Durham-Humphrey Amendment created a distinct separation of prescription drugs and over-the-counter drugs. *Id*; Helm, 18 Fordham Intell. Prop Media and Ent. L.J. at 127. This amendment distinguished between drugs that could be marketed with adequate directions for use by laymen and those that were not considered safe for untrained use even with directions. The former class of drugs was categorized as non-prescription drugs that could be dispensed over-the-counter, while the latter were categorized as prescription drugs that could only be dispensed by a prescription licensed medical practitioner. *See id.* at 127-28 (citing the Durham-Humphrey Amendment of 1951 (codified as amended at 21 U.S.C. § 353 (2004)). Accordingly, the public's reliance on physician pharmaceutical expertise grew. Shore, 17 Seton Hall. Legis. J. at 587.

The FDCA created a new healthcare landscape and, effectively, architected the FDA's role as guardian of public safety in the drug industry. Helm, 18 Fordham Intell. Prop Media and Ent. L.J. at 128. The FDCA also encouraged physician dependence, by establishing new privileges for licensed physicians to become the arbiters of the FDA's growing system of regulations for prescription drugs. *Id.* As a result, the medical profession enjoyed an institutionalized and legitimized increase in status throughout the 1950's, when patients relied heavily on their physicians to determine the proper treatments. *Id.*

Before the enactment of the FDCA, all nonnarcotic drugs were available without a prescription from a pharmacist and, as a result, consumers chose their own drugs on the basis of self-diagnosis, drug advertisements or labels. Susan Kopp Keyack, Note, *The Drug Price Competition and Patent Term Restoration Act of 1984: Is it a Healthy Long Term Solution?*, 21 Rutgers L.J. 147, 151 (1989). Thus, one major effect of the FDCA and its amendments was to create a distinction between prescription and over-the-counter drugs. *Id.* Another major effect was increased FDA control, whereby the FDA dictated which drugs could be placed on the market, and individual discretion shifted from consumers to prescribing physicians. *Id.* With the emergence of prescription drugs, a new and prosperous drug industry evolved "characterized by large firms selling new, patented drugs . . . ." *Id.*

"These regulatory changes had a profound effect on the practice of pharmacy." Jennifer E. Spreng, Pharmacists and the "Duty" to Dispense Emergency Contraceptives, 23 Issues L. & Med. 215, 230 (2008) "[I]n

the wake of 'prescription-only' regulations, the 'product,' not the 'process,' became central to pharmacy practice, and the pharmacist's role evolved from compounder to society's prescription drug distributors. *Id.*

As the modern drug industry came into being after World War II, pharmaceutical companies began promoting their products directly to prescribers. Noah, *Death of a Salesman*, 47 Food & Drug L.J. at 311. In the years following World War II, the prescription drug industry experienced enormous growth. Charles J. Walsh, Alissa Pvrich, *FDA Efforts to Control the Flow of Information at Pharmaceutical Industry-Sponsored Medical Education Programs: A Regulatory Overdose*, 24 Seton Hall L. Rev. 1325, 1339 (1994). New drug products were introduced at a greater pace than in the past. *Id.* Drug company profits also rose substantially, and with increased profits came an increase in the promotion of prescription drug products. *Id.*

The 1962 Kefauver-Harris Amendments to the FDCA, also known as the Drug Efficacy Amendments, established the protectionist system of drug regulation exists today. *Id.* (citing 21 U.S.C. §§ 321, 331-32, 348, 351-53, 355, 357-60, 372, 274, 376, 381 (1970)). The amendments precluded the shipment in interstate commerce of any new drug that the FDA had not formally approved for use. With the advancement of these amendments, pharmaceutical companies were precluded from promoting drugs for off-label uses, or any uses that that not been approved by the FDA. *See* Michelle M. Mello, *Shifting Terrain in the Regulation of Off-Label Promotion of Pharmaceuticals*, 360 N. Engl. J. Med 1557, 1558 (2009); *see* 21 C.F.R. §§ 201.128, 202.1(e)(6). Consequently, the FDA must approve

all marketing materials and placed restrictions on information PSRs could convey to physicians. Mello, 360 N. Engl. J. Med. at 1558. Now, if a PSR is the recipient of an unsolicited question concerning the off-label use of a drug, such inquiries, according to the FDA, must be handled by a pharmaceutical company's medical affairs office, *not* its sales force. *Id.* (emphasis added).

"By 1968, drug manufacturers employed approximately 20,000 persons in their sales forces." Walsh, Pvrich, 24 Seton Hall L. Rev. at 1339. "FDA Commissioner Alexander Schmidt observed in 1973 that the detail man 'really has been the major source of continuing education about therapeutics for the practicing physician.'" *Id.*

Prior to 1980, the FDA had imposed few restrictions concerning off-label promotion of drugs, particularly concerning the promotional mechanisms of disseminating scientific reprints and sponsorship of continuing medical education programs. *Id.* During the 1980's, Congressional concerns about off-label promotion grew, and hearings were held in 1990. *Id.* The hearings in 1990 resulted in the FDA publishing regulatory guidance concerning when continuing medical education ("CME") programs would be deemed to be improper off-label promotion, and it also issued warning letters to pharmaceutical companies concerning off-label promotion and the dissemination of clinical reprints. *Id.* at 1558-59.

In addition, in 1997, the FDA initiated a policy change to allow pharmaceutical companies to engage in direct-to-consumer ("DTC") advertising through newspapers, magazines, televisions, and the internet. Helm, 18 Fordham Intell. Prop. Media & Ent. L.J. at 148.

As pharmaceutical manufacturers have engaged in more assertive marketing tactics, the FDA has responded by exercising its regulatory authority over drug marketing and advertising. *Id.* at 151. The FDA's current authority to regulate the manufacture, sale and distribution of drugs includes extensive oversight over the promotional labeling and advertising claims made by pharmaceutical companies on behalf of approved drugs. *Id.* According to the FDA, a pharmaceutical company may promote a drug only for its approved purposes. *Id.* Any claim made in a promotional advertisement must be wholly consistent with the approved product labeling. *Id.*

Currently, the FDA regulates all dissemination of information about a pharmaceutical product. *Id.* at 151-52. It has established a regulatory system in which drug products cannot be promoted to anyone (including physicians), for any use, in the absence of labeling for the FDA-approved use. *Id.* at 151; 21 C.F.R. §§ 202, 203. This regulatory system has had a major impact on the job duties of PSRs, as anything that they convey to a healthcare provider must be pre-approved by the FDA, or else pharmaceutical companies risk civil and criminal exposure for the off-label promotion of products. Enforcement actions concerning off-label promotion may be brought pursuant to the FDCA or the False Claims Act. Mello, 360 N. Engl. J. Med. at 1561. Indeed, several companies, including GSK, have settled for millions of dollars with the FDA for the off-label promotion of products. *Id.* at 1562-63 (chart of companies that have settled cases concerning off-label promotion). Due to such pervasive regulation and liability risks, many companies require that PSRs of today adhere to scripted presentations. *See Novartis*, 611 F.3d at 145, 157; *Proctor & Gamble Pharma., Inc. v. Hoffman-*

LaRoche, Inc., 2006 WL 2588002, at *31 (S.D.N.Y. Sept. 6, 2006) (case in which GSK and other companies agreed that "sales representatives are trained to tell doctors only what is previously authorized. In other words, sales calls are not spontaneous, but are carefully scripted presentations"); *Zeneca v. Eli Lilly & Co.*, 1999 WL 509471, at *8 (S.D.N.Y. July 19, 1999) ("Eli Lilly provides its sales representatives with selling scripts or 'verbatims' that tell them what to say to doctors").

Accordingly, the substantial governmental regulatory changes during the past century have resulted in significant and material changes in the job duties of a PSR. The role of the PSR changed from one that involved wide latitude and actually selling drugs to purchasers (such as pharmacies) to a highly restricted one involving purely promotional efforts directed at physicians.

C. The Pharmaceutical Industry Has Changed The Role of PSRs

1. PhRMA's Description of the Role of Today's PSRs

By arguing that PSRs are exempt pursuant to the outside sales exemption, the pharmaceutical industry takes a position that is in direct contradiction to its description of PSRs in the *Code on Interactions with Healthcare Professionals*[8] ("PhRMA Code") and other publications by PhRMA. The members of PhRMA consistently refer to the role of PSRs and their interaction with healthcare providers as "marketing and promotion."

8. www.phrma.org/about/principles-guidelines/code-interactions-healthcare-professionals

S*ee Pharmaceutical Marketing in Perspective: Its Value and Role as One of Many Factors Informing Prescribing*[9] ("Perspective Publication"), PhRMA July 2008 at p. 1; *The Facts About Pharmaceutical Marketing & Promotion*[10] ("Facts Publication"), PhRMA July 2008 at p. 17 (describing PSR's sales and training as part the pharmaceutical industry's DTC budget). Notably, *not once* does the PhRMA Code refer to the interaction between PSRs and healthcare providers as "sales". *See* PhRMA Code at p. 2 ("this document focuses on the interactions with healthcare professionals that relate to the *marketing* of our products (emphasis added)"; p. 4 ("Interactions should be focused on *informing* healthcare professionals about products, providing scientific and educational *information*, and supporting medical education (emphasis added)."). As set forth below, the PhRMA Code has changed the duties of PSRs as they fulfill their informational role for the pharmaceutical industry.

2. The PhRMA Code Has Changed The Role Of PSRs

The PhRMA Code was established by the pharmaceutical industry to:

> [R]einforce our intention that our interactions with healthcare professionals are professional exchanges designed to benefit patients and to enhance the practice of medicine. The Code is based on the principle that a healthcare

9. www.phrma.org/sites/default/files/187/phrmamarketingbrochureinfluencesonprescribingfinal.pdf

10. www.phrma.org/research/publications/profiles-reports

> professional's care of patients should be based, and should be perceived as being based, solely on each patient's medical needs and the healthcare professional's medical knowledge and experience.

PhRMA Code at p. 2. To satisfy its goal, the current PhRMA code, which took effect in 2009 and built upon the Code that took effect on July 1, 2002, establishes strict policies to which all PSRs must adhere, which include:

1. When providing meals to healthcare providers during an informational interaction, meals must be modest in cost and accompanied by a presentation of educational or scientific value. PhRMA Code at p. 4.

2. To ensure the appropriate focus on education and informational exchange and to avoid the appearance of impropriety, PSRs cannot provide entertainment or recreational items to any healthcare professional who is not a salaried employee of the company. *Id.* at p. 5.

3. PSRs are precluded from providing non-educational and non-practice related items to healthcare professionals. *Id.* at 11.

4. As PSRs play an important role in *delivering accurate, up to date information* to healthcare providers about approved indications, companies should ensure that all representatives receive training about applicable laws, regulations and industry codes, including the PhRMA Code. *Id.* at 14.

As discussed above, it is evident that the pharmaceutical industry itself has implemented its own voluntary restrictions on the duties of PSRs that have transformed the nature of their jobs. By doing so, the pharmaceutical industry has implicitly recognized the change in the role of PSRs from that of making "sales" to a strictly promotional and informational role, and the PhRMA Code was enacted to reflect that change and provide guidance on how companies should utilize PSRs to properly convey information to healthcare professionals.

3. Other Industry Publications Reflect the Changed Job Duties of Today's PSRs

The Facts Publication and Perspective Publication — which were published by the *pharmaceutical industry* — are additional evidence that the pharmaceutical industry acknowledges that PSRs do not sell and that PSRs in fact have limited, if any, influence on the prescribing habits of physicians. As the Perspective Publication provides, the pharmaceutical industry acknowledges that while PSRs add value to pharmaceutical *marketing and promotion by disseminating information*, other factors—such as formulary position on managed care plans and clinical studies—play a larger role than PSRs in determining which drug a patient ultimately receives. *See* Perspective Publication, at 4. Indeed, in a physician survey, in identifying sources that influenced prescribing habits, five-times as many physicians (55%) identified peer-reviewed literature, and three-times (35%) as many identified the patient's formulary, than those who identified information from pharmaceutical representatives (11%). *Id.* at 6.

Other sources further demonstrate that there are multiple factors that may influence a physician's

decision to prescribe a drug, only one of which might be a PSR's presentation. *See Ironworkers Local Union 68 v. Astrazeneca Pharma., LP*, 634 F.3d 1352, 1362-63 (11th Cir. 2011); Declaration of Randolph V. Frankel ¶ 31, *IMS Health Inc. v. Ayotte*, No. 06-CV-280-PB, 2006 WL 4507573 (D. N.H. filed July 28, 2006).

In addition, the Perspective Publication concludes by noting that the interaction between PSR's and physicians — which it again characterizes as "marketing and promotion" — "plays an important role *in providing information*" to physicians about pharmaceutical products. *Id.* at 9 (emphasis added). Significantly, as indicated above, the Perspective Publication never refers to the interaction between a PSR and a health care provider as "selling" or "sales."

4. In SEC Filings, Many Drug Companies Have Reported That PSRs Don't Sell Pharmaceutical Drugs; They Only Promote Them

In the *Kuzinksi v. Schering* action, plaintiffs submitted excerpts from Schering's Form 10-K document that the Company filed with the United States Securities and Exchange Commission ("SEC") for the fiscal year that ended December 31, 2007. These publicly-filed excerpts further reflect the pharmaceutical industry's understanding that PSRs do not make sales of pharmaceutical drugs. The excerpts provided, under the header of *Marketing Activities and Competition* in the Form 10-K, the following:

> Schering-Plough, through its trained professional sales representatives, introduces

> and makes known its prescription drugs to physicians, pharmacists, hospitals, managed care organizations and buying groups. Schering-Plough sells prescription drugs to hospitals, certain managed care organizations, wholesale distributors and retail pharmacists. Schering-Plough also introduces and makes known its prescription products through advertising, direct mail advertising, the distribution of samples to physicians, and through television, radio, Internet, print and other advertising media.

(*See* Excerpts from Schering's 10-K filing with the SEC (Doc. No. 97-1), at Exhibit 1 at p. 18 of 230.)

This 10-K filing — a document that requires accurate and precise language — indicates that Schering's PSRs promote its products while other employees at Schering actually sell them. Indeed, in the very same 10-K filing, Schering states that, as a company, it sells its prescription drugs to hospitals, managed care organizations, wholesalers, and retail pharmacists — entities that Schering classifies as direct purchasers and with whom its PSRs do not interact. Schering utilizes the same language to describe the role of its PSRs as it uses to describe the role of its direct-to-consumer advertising — "introduces and makes known its prescription products." These excerpts from Schering's 10-K filing are yet another example of the pharmaceutical industry itself characterizing the role of PSRs as not involving the selling of drugs.

Other pharmaceutical manufacturers have similarly submitted SEC filings that distinguish between the

manufacturer's sales of drugs to wholesalers, and the entirely different promotional duties of PSRs.[11]

---

11. Eli Lilly and Company, 2010 Annual Report, Form 10-K, p. 3 http://files.shareholder.com/downloads/LLY/1642776639x0x447905/6281D413-C258-488B-ADBE-B35289495F26/English.PDF

> Marketing: We sell most of our products worldwide. We adapt our marketing methods and product emphasis in various countries to meet local needs.
>
> Pharmaceuticals—United States
>
> In the United States, we distribute pharmaceutical products principally through independent wholesale distributors, with some sales directly to pharmacies. In 2010, 2009, and 2008, three wholesale distributors in the United States— AmerisourceBergen Corporation, McKesson Corporation, and Cardinal Health, Inc.— each accounted for between 12 percent and 17 percent of our worldwide consolidated net sales. No other distributor accounted for more than 10 percent of consolidated net sales in any of those years. We also sell pharmaceutical products directly to the United States government, but those sales are not material.
>
> We promote our major pharmaceutical products in the United States through sales representatives who call upon physicians and other health care professionals. We advertise in medical journals, distribute literature and samples of certain products to physicians, and exhibit at medical meetings. In addition, we advertise certain products directly to consumers in the United States and we maintain web sites with information about all our major products.
>
> ***

Merck and Co., Inc.; Form 10-K filed with SEC on 2/28/11; p. 13 http://www.merck.com/investors/financials/form-10-k-2011.pdf

Distribution

The Company sells its human health pharmaceutical products primarily to drug wholesalers and retailers, hospitals, government agencies and managed health care providers such as health maintenance organizations, pharmacy benefit managers and other institutions. Human health vaccines are sold primarily to physicians, wholesalers, physician distributors and government entities. The Company's professional representatives communicate the effectiveness, safety and value of the Company's pharmaceutical and vaccine products to health care professionals in private practice, group practices, hospitals and managed care organizations.

***

Novartis Pharmaceutical Corporation also draws a sharp difference between PSRs' marketing duties and the company's actual sales of its drugs.

Marketing and Sales: The Pharmaceutical Division serves customers with approximately 5,700 field force representatives in the US (including supervisors), and an additional 15,300 in the rest of the world. These trained representatives, where permitted by law, present the therapeutic and economic benefits of our products to physicians, pharmacists, hospitals, insurance groups and managed care organizations. *Although specific distribution patterns vary by country, Novartis generally sells its prescription drugs primarily to wholesale and retail drug distributors, hospitals, clinics, government agencies and managed healthcare providers. See* Novartis SEC Filing, "AG Form 20-F," at 43 (2009), http://access.edgar-online.com/DisplayFilingInfo.aspx?TabIndex=2&FilingID=6364690&companyid=85434&ppu=%252fE

5. Other Industries Have True Sales Positions

Industries other than the pharmaceutical business have employees called "sales representatives" who do what their job title suggests — they actually sell products. These non-drug industries believe that PSRs do not have a primary duty of "making sales." In a declaration submitted in support of her motion for summary judgment, Evavold stated in paragraph 21: "Other industries recognize that what Reps do is not 'sales.' For example, attached as Exhibit A are job postings for medical device sales that I found on www.medreps.com and www.directsalesrecruiting.com. On the job postings, the companies seeking medical device sales representatives specifically indicate that they will only accept applications from pharmaceutical representatives who have limited experience with pharmaceutical 'sales' because what Reps do is not selling."

Other PSRs who are currently litigants against pharmaceutical companies have remarked on the difference between their role as a PSR and other non-pharmaceutical-related sales jobs. For example, Anthony Coultrip, a named Plaintiff in the *Pfizer* action, submitted a supplemental declaration, document number 94-17 dated May 7, 2008, in which he described the difference between

---

xpandedSearch.aspx%253fsite%253d0acade95-c20b-4c47-bebb-1dca89fl5ab1%2526amp%253bsearchTypeID%253d1%253bname%253dNovartis*%2526amp%253bFormGroupID%253d4%2526amp%253bReceivedDate%253dLAST_12_MONTHS%253bfrom%253dquicksearch&type=convpdf.

(emphasis added).

a sales position at Cutera Incorporated and Pfizer at ¶ 4: "Unlike my job at Pfizer, I sell directly to physicians and hospitals. Also unlike my job at Pfizer, I have the ability to take orders for my product, enter into contracts with health care providers, negotiate prices and accept money for the purchase of the product I sell. My commission is directly related to the products that physicians purchase or lease from me."

Another PSR, who is a named Plaintiff in the *Schering* action, Shawn Jones, submitted at ¶ 4 of his declaration, June 16, 2008 (Doc. No. 95): "After I left Schering, I worked for Masimo Corporation selling medical equipment. Unlike the bonus I received at Schering, when I was at Masimo Corporation, I received a true commission. The commission was based on the number of devices I sold. The more I devices I sold, the more money I made. I would receive that commission regardless of the financial status of the company or how many devices other salespeople sold. Unlike my position with Schering, the harder I worked, the more commissions I would receive. Also, unlike my position with Schering, when I made a sales call for Masimo Corporation, customers would be able to purchase the product directly through me."

D. Employees in Other Industries With Similar Promotional Duties Will Be Adversely Impacted if the Pharmaceutical Industry's Arguments Are Upheld

Other industries in which nonexempt employees who, like PSRs, merely promote products that are sold by others will be adversely affected by a ruling that PSRs are exempt as outside salesmen. The arguments

of Respondent and its *amici curiae* fail to acknowledge the possibility of this substantial prejudicial effect on thousands of nonexempt employees in other industries.

In this regard, the primary duty of today's PSR is essentially no different from that of the nonexempt promotional employee in other industries (*i.e.*, those who promote products or matters for which the sales are consummated by others). These include, for example, the college recruiter; the army recruiter; the charity solicitor; the organ donation promoter; the canvasser; the student promoter of magazine subscriptions, and the street-corner sandwich board bearer. *See Clements v. Serco, Inc.*, 530 F.3d 1224, 1227-28 (10th Cir. 2008) (civilian military recruiters who merely promoted military not within the outside salesperson exemption); *Wirtz v. Keystone Readers Services, Inc.*, 418 F.2d 249, 261 (5th Cir. 1969) (student magazine subscription promoter not exempt as outside salesmen because they promoted products sold by others); *Slow v. Prestige Merchandising Co., Inc.*, 2011 WL 4373516, at *1 (E.D.N.Y. Sept. 19, 2011) (worker employed as canvasser and canvass manager not exempt where she promoted products sold by others); *Burling v. Real Stone Source, LLC*, 2009 WL 1812785, at **3-7 (D. Idaho June 24, 2009) (sales representative for stone production company not exempt outside salesman where he promoted products sold by others); Opinion Letter from Wage and Hour Div., U.S. Dep't of Labor, 1998 DOLWH LEXIS 17, at **3, 7 (Feb. 19, 1998) (college recruiters who promoted school not exempt as outside salesmen where others that decided whether to make contractual offers were ones that made actual sales); Opinion Letter from Wage and Hour Div., U.S. Dep't of Labor, FLSA 2006-16, 2006 WL 1698305 (May 22, 2006) (solicitor of

future charitable donations not exempt because "'selling the concept' of donating to a charity does not constitute 'sales' for the purposes of the outside sales exemption . . . the solicitors do not obtain orders or contracts for services or for use of . . . facilities for which a consideration will be paid"); Opinion Letter from Wage and Hour Div., U.S. Dep't of Labor, 1994 DOLWH LEXIS 65, at *3 (Aug. 19, 1994) (organ donation promoter not exempt because "[t]he selling of a concept does not constitute 'sales' within the meaning of the regulations"); 75 Fed. Reg. 28404, 28414 (May 20, 2010) ("exemption . . . for outside salespeople does not apply to individuals employed solely to wave signs or wear placards, sandwich boards, or costumes to attract potential customers as such promotion work is not performed in conjunction with sales actually made by those individuals").

CONCLUSION

For the foregoing reasons, the judgment of the Court of Appeals should be reversed.

Respectfully submitted,

Stephen A. Weiss
James A. O'Brien III
Seeger Weiss LLP
77 Water Street
26th Floor
New York, NY 10005

Michael R. DiChiara
Counsel of Record
DiChiara Law Firm LLC
77 Market Street
Suite 2
Park Ridge, NJ 07656
(201) 746-0303
michael@dichiarallc.com

Counsel for Amici Curiae