

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

_____	X	
MARY K. JONES, Individually and on Behalf	:	Civil Action No. 1:10-cv-03864-AKH
of All Others Similarly Situated,	:	
	:	<u>CLASS ACTION</u>
Plaintiff	:	
vs.	:	DECLARATION OF RYAN A. LLORENS
	:	IN FURTHER SUPPORT OF PLAINTIFFS'
	:	MOTION TO EXCLUDE CERTAIN
PFIZER INC., et al.,	:	TESTIMONY OF DEFENDANTS'
	:	EXPERTS SUNIL PANCHAL, WILLIAM W.
Defendants.	:	HOLDER, JACK T. TANSALLE AND JOHN
_____	X	C. COATES IV

I, RYAN A. LLORENS, declare as follow:

1. I am a partner in the law firm of Robbins Geller Rudman & Dowd LLP and counsel to plaintiffs. I am duly licensed to practice before all courts of the State of California and admitted *pro hac vice* in this case. I have personal knowledge of the matters stated herein and, if called upon, I could and would competently testify thereto.

2. Attached hereto are true and correct copies of the following exhibits:

Exhibit 19: Excerpts to the November 11, 2013 Deposition Transcript of Henry McKinnell;

Exhibit 20: Excerpts to the December 6, 2013 Deposition Transcript of Jeffrey Kindler; and

Exhibit 21: Excerpts to the May 2, 2013 Deposition Transcript of Gail Cawkwell.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed December 30, 2014, at San Diego, California.

s/ RYAN A. LLORENS

RYAN A. LLORENS

CERTIFICATE OF SERVICE

I hereby certify that on December 30, 2014, I authorized the electronic filing of the foregoing with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the e-mail addresses denoted on the attached Electronic Mail Notice List, and I hereby certify that I caused to be mailed the foregoing document or paper via the United States Postal Service to the non-CM/ECF participants indicated on the attached Manual Notice List.

I certify under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on December 30, 2014.

s/ RYAN A. LLORENS

RYAN A. LLORENS

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EXHIBIT 19

1 UNITED STATES DISTRICT COURT
2 SOUTHERN DISTRICT OF NEW YORK

3 MARY K. JONES, Individually and on
4 Behalf of All Others Similarly
5 Situated,

6 Plaintiffs, No. 10-cv-
7 -against- 3864(AKH)

8 PFIZER, INC., HENRY A. McKINNELL,
9 JEFFREY B. KINDLER, FRANK D'AMELIO,
10 DAVID L. SHEDLARZ, ALAN G. LEVIN,
11 IAN C. READ, JOSEPH FECZKO, KAREN
12 KATEN, J. PATRICK KELLY and ALLEN
13 WAXMAN,

14 Defendants.

15
16 CONFIDENTIAL - PURSUANT TO PROTECTIVE ORDER

17
18 DEPOSITION OF
19 HENRY McKINNELL
20 November 11, 2013

21 Reported by:
22 Lisa Rosenfeld
23 Job No. 1741328

24
25 PAGES 1 - 344

1 benefit, where they saw a favorable risk return
2 tradeoff for individual patients.

3 So that even though a drug may not
4 have been approved for a certain indication, if
5 physicians were finding it useful, cancer
6 compounds in the eye would be a good example,
7 that's a clue that maybe we should do some
8 exploratory research and see what the mechanism
9 of action is and see if it's worth spending the
10 hundred million dollars or whatever it takes to
11 develop the indication for FDA approval.

12 Q. And looking at the off-label
13 prescription data by indication, would you be
14 able to observe any trends regarding the
15 prescription of Pfizer's drugs by indication?

16 MR. FARINA: Objection to form.

17 A. I saw that data so rarely, I would
18 not see trends, no.

19 Q. Do you ever recall seeing that data
20 with respect to Bextra?

21 A. No, I do not.

22 Q. What about with respect to Geodon?

23 A. Geodon, no.

24 Q. What about respect to Lyrica?

25 A. Are you speaking of trends or

1 individual points in time?

2 Q. Let's talk with trends first.

3 A. Certainly no trends, no.

4 Q. What about individual points of time?

5 A. May have seen Lyrica but I can't
6 recall. Certainly not routinely.

7 Q. Do you recall the context which you
8 might have seen this data regarding Lyrica?

9 A. I think it was raised in respect to
10 the off-label promotion, which is wrong, that we
11 saw in Warner-Lambert before the acquisition by
12 Pfizer, but I can't recall the specifics.

13 Q. What do you mean with respect to the
14 off-label promotion, what are you referring to?

15 A. Well, off-label prescribing is fine,
16 physicians do this all the time, they prescribe
17 drugs that in their independent medical judgment
18 is an appropriate risk benefit tradeoff for an
19 individual patient. Cancer drugs are routinely
20 used off-label by physicians. What the
21 pharmaceutical company cannot do is promote for
22 those indications, that was and is a violation of
23 Pfizer's policy.

24 We found that practice in one
25 district in Warner-Lambert and ended it, and in

1 the meantime we investigated it, remediated it
2 and reported it to Government.

3 And your question is did I see the
4 off-label promotion data, I think in the context
5 of that investigation I saw the off-label data.

6 Q. And just to be clear, we're referring
7 to the investigation related to Warner-Lambert,
8 is that right?

9 A. Shortly after the acquisition,
10 correct.

11 Q. And we had been talking about Lyrica,
12 now I just want the record clear, are you sure
13 that that investigation related to Lyrica or did
14 it relate to Neurontin?

15 A. You're correct, it related to
16 Neurontin. I did not see Lyrica off-label data.
17 In fact I think Lyrica may have been launched
18 while I was CEO but it was very early. It may
19 have even been after I retired.

20 Q. And so during the acquisition process
21 of Warner-Lambert, it's your recollection that
22 you may have seen data reflecting off-label
23 prescriptions by indication for Neurontin?

24 A. No, that's not quite correct, our
25 acquisition of Warner-Lambert was hostile. We

EXHIBIT 20

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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

-----)
MARY K. JONES, Individually)
and on Behalf of all others) No. 10-cv-3864
similarly situated,) (AKH)
Plaintiff,)
vs)
PFIZER, INC., HENRY A.)
MCKINNELL, JEFFREY B.)
KINDLER, FRANK D'AMELIO,)
DAVID L. SHEDLARZ, ALAN G.)
LEVIN, IAN C. READ, JOSEPH)
FECZKO, KAREN KATEN, J.)
PATRICK KELLY and ALLEN)
WAXMAN,)
Defendants.)
-----)

CONFIDENTIAL- SUBJECT TO PROTECTIVE ORDER

VIDEOTAPED DEPOSITION of JEFFREY KINDLER,
in the above-captioned matter, held at 1251
Avenue of the Americas, New York, New York,
before Eileen Mulvenna, CSR/RMR/CRR, Certified
Shorthand Reporter, Registered Merit Reporter,
Certified Realtime Reporter and Notary Public of
the State of New York, December 6, 2013, at 9:05
a.m.

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1 MR. FARINA: September. 11:40:40

2 BY MR. ROSEN: 11:40:40

3 Q. As of September -- 11:40:41

4 Thank you. 11:40:41

5 As of September 2002, what did you 11:40:42

6 and Mr. Lankler do to investigate and ensure that 11:40:44

7 the sales reps were not off-label marketing? 11:40:47

8 A. I can't tell you exactly what we did 11:40:50

9 at any pinpoint in time. And I might point out, 11:40:54

10 if I may, that this is 80 pages worth of legal 11:40:57

11 matters that I'm responsible for at that time. 11:41:00

12 We had a lot on our plate. I just arrived at the 11:41:03

13 company. We had a very small compliance 11:41:06

14 department at that time. 11:41:08

15 We were building it out. We were 11:41:09

16 managing a lot of challenges and issues, and we 11:41:10

17 were doing our best to make all of these systems 11:41:13

18 more compliant -- excuse me -- more robust. And 11:41:16

19 we worked very hard to do that. 11:41:20

20 Q. So as of September of 2002, did your 11:41:21

21 compliance activities or function allow you to 11:41:28

22 examine, say, the percentage of Bextra sales that 11:41:31

23 were written for off-label purposes as of that 11:41:36

24 time? 11:41:38

25 A. I believe that data existed. 11:41:39

1 Q. But my question was, as part of your 11:41:42
2 compliance function, as part of Mr. Lankler's 11:41:45
3 compliance function, did you guys examine that? 11:41:47
4 A. I don't remember. Mr. Lankler would 11:41:51
5 remember -- or would know. 11:41:53
6 Q. Do you recall examining Bextra 11:41:55
7 off-label sales data -- 11:41:57
8 A. At some point -- 11:41:58
9 Q. I'm sorry. 11:42:00
10 -- in September of 2002? 11:42:00
11 A. Certainly that happened at some 11:42:01
12 point. I can't remember whether it was at this 11:42:03
13 particular point in time. 11:42:06
14 Q. And as part of your compliance 11:42:07
15 function, did you guys examine in 2002 call notes 11:42:09
16 relating to Bextra's detailing by sales reps? 11:42:14
17 A. Well, first of all, I didn't 11:42:19
18 personally examine those at any time. Whether 11:42:20
19 they were examined at this precise point in time 11:42:24
20 or not I couldn't tell you. 11:42:27
21 Q. So my question is, as part of the 11:42:34
22 compliance -- 11:42:36
23 A. Go ahead. 11:42:40
24 Q. As part of the compliance function 11:42:40
25 in 2002, did your and Mr. Lankler's 11:42:42

1 responsibilities include examining what percent 11:42:45
2 of a drug's sales were on- and off-label? 11:42:49
3 A. I couldn't answer the question the 11:42:54
4 way you characterize it. Let me try to answer it 11:42:55
5 this way: Let me start by saying drugs can be 11:42:57
6 prescribed off-label in a perfectly legal and 11:43:03
7 appropriate way by physicians. There's nothing 11:43:06
8 inappropriate or illegal with drugs being 11:43:09
9 prescribed off-label. 11:43:12
10 Physicians have every right to do 11:43:13
11 that, and there are many drugs in the world that 11:43:14
12 are prescribed off-label in substantial amounts. 11:43:17
13 We were talking earlier about Geodon, which is an 11:43:22
14 antipsychotic. Many antipsychotics have 11:43:24
15 substantial off-label sales precisely because 11:43:29
16 there are limited options for patients, 11:43:32
17 particularly pediatric patients. 11:43:34
18 So the mere fact that a drug is 11:43:36
19 prescribed off-label in and of itself doesn't 11:43:38
20 prove or suggest any improper activity. 11:43:42
21 That said, a drug that has 11:43:46
22 substantial off-label uses is certainly one that 11:43:48
23 is -- presents a potentially greater risk of 11:43:51
24 off-label promotion than one that doesn't. And, 11:43:57
25 therefore, it is appropriate for the compliance 11:44:01

1 function to pay more attention to those kinds of 11:44:04
2 drugs than others. 11:44:07
3 And in the course of enhancing our 11:44:08
4 compliance systems, Mr. Lankler and his team 11:44:13
5 certainly over time paid attention to those drugs 11:44:17
6 that presented different kinds of risks. Some 11:44:22
7 drugs presented other types of risks besides 11:44:25
8 off-label promotion. Some drugs presented the 11:44:28
9 risk of different kinds of claims that may or may 11:44:31
10 not have been appropriate. Some drugs presented 11:44:33
11 the risk of off-label claims. 11:44:35
12 And one point of data that they may 11:44:37
13 have looked at in that connection might have been 11:44:41
14 the amount of off-label sales. 11:44:43
15 Q. My question is, as of September of 11:44:46
16 2002, as part of your role in the compliance 11:44:49
17 function to ensure that sales reps were not 11:44:54
18 off-label marketing Bextra, did you or 11:44:58
19 Mr. Lankler examine the amount of sales that were 11:45:00
20 achieved that were off-label? 11:45:04
21 A. I think I've -- 11:45:06
22 MR. FARINA: Objection to form. 11:45:07
23 THE WITNESS: -- answered that, but 11:45:08
24 I'll answer it one more time. 11:45:08
25 Number 1, I don't think I ever did 11:45:10

EXHIBIT 21

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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

MARY K. JONES,)
Plaintiff,)
-vs-) Civil Action No.
PFIZER INC., et al.,) 1:10-cv-03864-AKH
Defendants.)

CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER

Videotaped Deposition of GAIL CAWKWELL,
M.D., Ph.D., taken at 1251 Avenue Of The
Americas, New York, New York, commencing
at 9:15 a.m., Thursday, May 2, 2013, before
Debra Sapio Lyons, RDR, CRR, CCR, CPE.

JOB No. 1640982
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1 Gail Cawkwell, M.D., Ph.D. - Confidential
2 label? 17:12:32
3 MR. PETROSINELLI: Object to the 17:12:32
4 form. 17:12:33
5 A. I don't recall at the time seeing 17:12:34
6 this information, although I may have, but I 17:12:43
7 would note that I don't find it particularly 17:12:46
8 surprising considering how doctors use NSAIDs. 17:12:48
9 Q. And why don't you find it 17:12:52
10 surprising? 17:12:55
11 A. NSAIDs, some medicines like 17:12:55
12 ibuprofen or Naprosyn have been on the market 17:12:59
13 for many, many years. Most doctors regardless 17:13:01
14 of their specialty feel very comfortable using 17:13:04
15 NSAIDs and have -- and use them almost every 17:13:07
16 day in their practice. They're among the most 17:13:10
17 common drugs prescribed in the United States. 17:13:12
18 And most doctors perceive that all NSAIDs are 17:13:14
19 about the same. So when a new NSAID comes on 17:13:17
20 the market, it's not unusual for doctors to -- 17:13:22
21 to feel that it's an NSAID, it can be used in 17:13:25
22 any way. And -- and you're also describing 17:13:30
23 the first four months after approval where I 17:13:32
24 would think for the most part doctors are 17:13:37
25 writing their first few prescriptions and are 17:13:39

1 Gail Cawkwell, M.D., Ph.D. - Confidential
2 probably seeing it as an NSAID and writing it 17:13:41
3 like they would any other NSAID. 17:13:44
4 Q. Assuming that the other 17:13:45
5 indications there, "Other Chronic Pain" and 17:13:48
6 "All Other" don't relate to the 15 percent 17:13:52
7 that's listed there for dysmenorrhea, 17:13:56
8 osteoarthritis and rheumatoid arthritis, would 17:13:59
9 that surprise you that only 15 percent of the 17:14:02
10 prescriptions written in the first four months 17:14:05
11 were for the on-label uses of the drug? 17:14:08
12 MR. PETROSINELLI: Object to the 17:14:11
13 form. 17:14:12
14 A. It's hard for me to say if I'm 17:14:12
15 surprised or not without seeing how, for 17:14:17
16 example, Naprosyn or Lodine or Arthrotec, what 17:14:21
17 their distribution is because as a 17:14:27
18 rheumatologist, as a person who prescribes a 17:14:29
19 lot of NSAIDs, again, it's my impression that 17:14:31
20 doctors hear about an NSAID and immediately 17:14:35
21 believe it's appropriate to use it in a manner 17:14:40
22 like they use other NSAIDs regardless of the 17:14:43
23 indications or the label or -- and regardless 17:14:46
24 of promotional activities. This doesn't seem 17:14:49
25 surprising to me, but it would be hard to know 17:14:53

1 Gail Cawkwell, M.D., Ph.D. - Confidential
2 if this is surprising without seeing how other 17:14:56
3 NSAIDs are prescribed. 17:14:59
4 Q. Is -- is 85 percent off-label 17:15:00
5 sales consistent with what you expected Bextra 17:15:06
6 to achieve after launch based on your position 17:15:08
7 as Medical Director for Bextra? 17:15:12
8 MR. PETROSINELLI: Object to the 17:15:14
9 form. 17:15:15
10 A. I don't believe anybody, as 17:15:15
11 somebody in a medical function would have 17:15:20
12 asked me what I believe our sales figures 17:15:21
13 would look like as it's not part of my normal 17:15:23
14 role. 17:15:26
15 Q. But I'm not talking about the 17:15:26
16 sales figures necessarily as the breakdown 17:15:27
17 of -- of uses. As -- as Medical Director for 17:15:30
18 Bextra, did you have expectations for what the 17:15:32
19 sales spread would be over uses after launch? 17:15:36
20 A. I don't remember now if I had 17:15:42
21 expectations at that time. All I can comment 17:15:44
22 is on what I'm thinking now as I look at these 17:15:47
23 numbers. 17:15:50
24 Q. So you don't recall any 17:15:50
25 expectations that you developed as Medical 17:15:53

1 Gail Cawkwell, M.D., Ph.D. - Confidential

2 Director for Bextra about the launch and where 17:15:55

3 you thought the sales would be generated from? 17:15:58

4 A. I don't recall any expectations. 17:16:00

5 Q. Did the sales data in the first 17:16:02

6 four months of Bextra raise any red flags in 17:16:07

7 your mind as to the marketing methods the 17:16:11

8 company was using to achieve Bextra sales? 17:16:14

9 MR. PETROSINELLI: Object to the 17:16:17

10 form. 17:16:18

11 A. I'm clearly not a marketing 17:16:18

12 expert and so I'm not sure that I'm qualified 17:16:24

13 to -- to make a comment, but it does seem to 17:16:29

14 me that in the first four months it's not 17:16:32

15 giving the sales organization much time to do 17:16:35

16 anything or have an impact. I would assume a 17:16:37

17 lot of what happens in the first few months is 17:16:40

18 based more on spontaneous actions that a 17:16:44

19 doctor takes, but I don't really have any 17:16:48

20 expertise in that area. 17:16:50

21 Q. So -- so is it your testimony 17:16:51

22 that the sales that Pfizer achieved for Bextra 17:16:52

23 after launch didn't have anything to do with 17:16:56

24 the promotional activities that you were in 17:16:58

25 charge of overseeing? 17:17:00

Regan Karstrand

From: NYSJ_ECF_Pool@nysd.uscourts.gov
Sent: Tuesday, December 30, 2014 1:18 PM
To: CourtMail@nysd.uscourts.gov
Subject: Activity in Case 1:10-cv-03864-AKH Jones et al v. Pfizer, Inc. et al Declaration in Support of Motion

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U.S. District Court

Southern District of New York

Notice of Electronic Filing

The following transaction was entered by Llorens, Ryan on 12/30/2014 at 1:17 PM EST and filed on 12/30/2014

Case Name: Jones et al v. Pfizer, Inc. et al
Case Number: [1:10-cv-03864-AKH](#)
Filer: Mary K. Jones
Stichting Philips Pensioenfond
Document Number: [416](#)

Docket Text:

DECLARATION of Ryan A. Llorens in Support re: [385] MOTION in Limine to Exclude Certain Testimony of Defendants' Experts Sunil Panchal, William W. Holder, Jack Tanselle and John C. Coates IV.. Document filed by Mary K. Jones(Individually), Stichting Philips Pensioenfond. (Attachments: # (1) Exhibit 19, # (2) Exhibit 20, # (3) Exhibit 21)(Llorens, Ryan)

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