

CRIMINAL NO.

VIOLATIONS:

18 U.S.C. § 371

(Conspiracy to Violate the Anti-Kickback Statute)

18 U.S.C. § 982

Defendant.

(Criminal Forfeiture)

The Grand Jury charges:

At all times material to this Indictment, unless otherwise alleged:

1. Warner Chilcott plc, its subsidiaries and affiliates (“Warner Chilcott”), distributed

2. Between 2009 and 2011, defendant CARL REICHEL (“REICHEL”), a resident of

ersey, was the President of Warner Chilcott's pharmaceuticals division. REICHEL

3. At various times between 2009 and 2013, Warner Chilcott sold and marketed

l drugs, including Actonel[®] (used to prevent and treat postmenopausal osteoporosis),

Atelvia[®] (used to treat postmenopausal osteoporosis), Doryx[®] (used to treat acne), Enablex[®]

(used to treat overactive bladder), Loestrin 24 FE[®] (an oral contraceptive), Asacol HD[®] (used to treat ulcerative colitis), and various formulations of these products (the “Warner Chilcott drugs”).

4. The Warner Chilcott drugs were sold throughout the United States. REICHEL, together with Senior Executive 1, formulated the sales strategy. The company’s sales force was divided into several sales divisions. As President, REICHEL communicated the sales strategy to division directors and regional sales directors (“RSDs”). The RSDs communicated the strategy to district managers (“DMs”), who communicated the strategy to sales representatives. The sales representatives executed the strategy by calling on physicians and other health care professionals (collectively, “HCPs”) nationwide.

The Medicare and Medicaid Programs

5. The Medicare Program (“Medicare”) was a federal health insurance program established by the Social Security Act of 1965 to assist qualified aged and disabled individuals, referred to as “Medicare beneficiaries.” Medicare was administered by the Centers for Medicare & Medicaid Services (“CMS”), a federal agency under the United States Department of Health and Human Services. Medicare reimbursed health care providers and suppliers for the costs of health care services and items provided to Medicare beneficiaries. Through its Part D program, Medicare provided for the coverage of certain prescription drugs.

6. The Medicaid program (“Medicaid”) was a federal and state health care program providing benefits to individuals and families who met specified financial and other eligibility requirements, and certain other individuals who lacked adequate resources to pay for medical care. CMS was responsible for overseeing the Medicaid program in participating states, including Massachusetts.

7. Medicare and Medicaid were “health care benefit programs” within the meaning of 18 U.S.C. § 24(b), in that they were public plans affecting commerce, under which medical benefits, items, and services were provided to individuals, and included individuals and entities who were providing medical benefits, items, and services for which payment may be made under the plan.

COUNT ONE
Conspiracy to Violate the Anti-Kickback Law
(18 U.S.C. § 371)

8. The allegations set forth in paragraphs 1 through 7 are re-alleged and herein incorporated in full.

9. Between January 2009 and in or around February 2012, the exact dates being unknown to the Grand Jury, in the District of Massachusetts and elsewhere, the defendant,

W. CARL REICHEL,

did knowingly and willfully combine, conspire, confederate and agree with others, known and unknown to the Grand Jury, to knowingly and willfully offer and pay remuneration, directly and indirectly, overtly and covertly, in cash and in kind, that is, kickbacks and bribes, from Warner Chilcott, to induce physicians and other health care professionals to purchase, order, and arrange for goods, services and items, that is, prescriptions of Warner Chilcott drugs, for which payment was made in whole and in part by the federal health care programs, in violation of Title 42, United States Code, Section 1320a-7b(b)(2)(B).

Object of the Conspiracy

10. The object of the conspiracy was for REICHEL and his co-conspirators to unlawfully enrich themselves and Warner Chilcott by paying remuneration to physicians to induce prescriptions of Warner Chilcott drugs.

Manner and Means of the Conspiracy

11. The manner and means by which REICHEL and others sought to accomplish the object of the conspiracy included, among other things, the following:

- a. It was part of the conspiracy that REICHEL established a sales strategy of providing remuneration to HCPs, in the form of free dinners, “speaker” payments, and

food and drink for HCPs and their staff to induce HCPs to prescribe Warner Chilcott drugs.

b. It was part of the conspiracy that REICHEL provided the sales representatives with virtually unlimited expense accounts to take HCPs out for free dinners, misleadingly referred to as “medical education programs” or “med eds.”

c. It was part of the conspiracy that REICHEL required sales representatives to take out HCPs for free dinners at least twice a week. REICHEL frequently informed the sales force that the most successful sales representatives conducted the most “med eds.”

d. It was a part of the conspiracy that REICHEL communicated that the sales representatives should use the dinners to “build relationships” with the HCPs. REICHEL discouraged the sales representatives from including an educational program with the dinners. Instead, REICHEL encouraged the sales representatives to simply have dinners with the HCPs without any formal agenda, which frequently amounted to nothing more than social dinners. REICHEL referred to these dinners as “roundtables.”

e. It was a part of the conspiracy that the roundtables were frequently held at expensive restaurants, that the sales representatives were allowed to spend up to \$125 per person, and that REICHEL allowed sales representatives to bring their spouse or significant other to the dinners. The HCPs frequently brought a spouse or guest as well, contributing to the social atmosphere of the events.

f. It was a part of the conspiracy that REICHEL intended for the sales force to gain a “commitment” from the HCPs during dinner to prescribe Warner Chilcott drugs. The sales representatives were instructed to subsequently review the HCPs’ prescribing patterns. If the HCPs failed to prescribe the applicable Warner Chilcott drug at a

sufficient level, the sales representatives were taught to follow up with the HCPs in their offices and at subsequent dinners. The sales representatives were directed to remind the HCPs of their promises to prescribe Warner Chilcott drugs, reference the dinner(s) and the food, drinks and snacks that the sales representative had provided to the HCPs and staff, and again ask for prescriptions.

g. It was a part of the conspiracy that REICHEL referred to this aggressive sales technique as a type of “business conversation” where the sales representative “leveraged relationships” with HCPs by “holding them accountable” for their commitments. REICHEL pushed “business conversations” as a primary Warner Chilcott sales tactic.

h. It was part of the conspiracy that REICHEL instructed the sales representatives that, if an HCP did not prescribe Warner Chilcott drugs at a sufficient level after attending free dinners, the sales representative should communicate to the HCP, explicitly or implicitly, that the free dinners would cease if the physician did not increase his or her prescribing habits.

i. It was a part of the conspiracy that REICHEL instructed the sales force to sign up high prescribing physicians as paid “speakers” for Warner Chilcott. The “speakers” were paid between approximately \$600 and \$1,200 for attending the free dinners. Even though these dinners included a “speaker,” unlike speaker events at other pharmaceutical companies, REICHEL communicated that the Warner Chilcott “speaker” events should be roundtables: informal dinners without a clinical lecture.

j. It was a part of the conspiracy that REICHEL emphasized to the sales force the importance of obtaining prescriptions of Warner Chilcott drugs from the paid “speakers.”

k. It was a part of the conspiracy that REICHEL communicated that sales representatives should use paid “speakers” as long as they were prescribing Warner Chilcott drugs. However, REICHEL instructed the sales force that, if a “speaker” was not prescribing Warner Chilcott drugs at a satisfactory level, a DM or sales representative should communicate to the “speaker” that he or she would no longer be used until their prescriptions increased.

l. It was part of the conspiracy that REICHEL, RSDs and DMs tracked the market share of the “speakers” prescriptions of Warner Chilcott drugs, versus other drugs in the market, and instructed the sales representatives to communicate to “speakers” that they would not be used if their prescriptions did not increase above a specified market share threshold.

m. It was a part of the conspiracy that REICHEL instructed the sales force to tell potential “speakers,” as well as “speakers” who were not prescribing at a sufficient level, that they could not be used until they gained more “clinical experience” with Warner Chilcott drugs. “Clinical experience” was understood to be a euphemism for “active ongoing prescribing” of Warner Chilcott products.

n. It was part of the conspiracy that REICHEL also provided the sales representatives with a separate expense account to buy food and drinks for physicians’ employees in their offices.

o. It was a part of the conspiracy that, for Warner Chilcott drugs that had poor insurance coverage, and where insurers would only pay for the drugs if they received prior authorization medical forms from physicians’ offices, REICHEL instructed the sales force to take out, as well as buy food and drink for, physicians’ staff who prepared

the prior authorization forms. The sales representatives were told to “leverage” these “relationships” to ensure that the staff submitted the prior authorizations.

p. It was part of the conspiracy that REICHEL communicated the “med ed” and “speaker” strategy to the RSDs and DMs. The DMs communicated the strategy to the sales representatives during meetings, conference calls, “ride alongs,” and in “field coaching reports.” The sales representatives executed the scheme, taking out high-prescribing HCPs for thousands of free dinners at expensive restaurants, having “business conversations” with HCPs, “leveraging relationships” and “holding them accountable” to prescribe Warner Chilcott products, signing up high-prescribing HCPs as paid “speakers,” informing “speakers” that they were expected to prescribe a substantial amount of Warner Chilcott drugs, and if they did not live up to expectations, telling the “speakers” that they would not be used until their prescribing habits increased, and spending money on physicians’ staff to convince them to prepare prior authorizations of Warner Chilcott products.

q. It was a part of the conspiracy that REICHEL hired young, aggressive sales representatives with little or no experience selling pharmaceuticals to execute the “med ed/speaker” strategy. REICHEL approvingly referred to these young, aggressive, inexperienced sales representatives as “Type A crazy” representatives, while he derided sales representatives who did not follow his sales strategy as “cream puffs.”

r. It was a part of the conspiracy that REICHEL sought to ensure that Warner Chilcott hired aggressive sales representatives by screening candidates with a personality test that sought to identify candidates who were assertive, willing to confront physicians, and who were not cautious about or sensitive to rules;

s. It was a part of the conspiracy that, upon hiring these aggressive sales representatives, REICHEL de-emphasized selling based on clinical data, instructed them to not use clinical studies or visual aids in their interactions with physicians, and belittled employees who raised clinical questions during meetings;

t. It was a part of the conspiracy that REICHEL provided the sales representatives with limited training concerning compliance with health care laws and otherwise de-emphasized the importance of compliance to the sales force.

Overt Acts

12. In furtherance of the conspiracy and in order to effect the objects thereof, REICHEL and his co-conspirators committed or caused the commission of the following overt acts in the District of Massachusetts and elsewhere:

a. In or about December 2009, REICHEL attended a training for the Gastroenterology/Dermatology sales force, which sold Asacol HD and Doryx. During this training, the sales representatives were instructed to “Utilize All Resources” that Warner Chilcott provided, such as (1) “Out of Office Lunches and Dinners (Med Eds)” which “Establish ‘neutral ground’ and venue for pointed business conversation,” (2) “Speakers,” and (3) “Breakfasts, Lunches, Goodies,” because “Competitors cannot do this anymore-sets W.C. apart!”

b. On May 13, 2010, RSD 1 emailed the DMs, with a copy to REICHEL, instructing them that “[t]he keys to success” included “[m]ed eds” and “breakfasts” which “will continue to set our sales force apart.” REICHEL forwarded the email to Senior Executive 1 and noted “Consistent message to the field.”

c. On or about June 6, 2010, REICHEL instructed certain directors and managers to “make sure” that sales representatives “can have business convos during dinners” with HCPs.

d. On November 2, 2010, defendant gathered the Osteoporosis Division RSDs and DMs to communicate the sales strategy and message for Atelvia[®], which was being launched in January 2011. REICHEL informed the RSDs and DMs that they should identify the highest prescribing osteoporosis medication physicians in their districts and meet with them before the official launch. Defendant referred to this as the “early experience program.” REICHEL instructed the RSDs and DMs to tell these physicians that they could become paid speakers for Warner Chilcott if they began prescribing Atelvia[®]. REICHEL instructed the RSDs and DMs to tell these physicians:

I really do need you to get some clinical experience. It is the most important thing. You know we are going to be going through a launch, I have reps that I know already planned dinner meetings, speaker meetings. I know and I need to know that you are going to have that clinical experience so you promise me you are going to start 5-10 between now and January, we got a deal? Okay.

e. On or about December 4, 2010, REICHEL reiterated in a conference call with Osteoporosis Division RSDs and DMs that the physicians who had more “clinical experience” with Atelvia[®] would speak more.

f. On January 28, 2011, RSD 3 emailed a number of DMs, copying REICHEL, instructing them to “continue to call on early experience drs when you are out with the reps. It’s your job to hold these drs accountable because they made the commitment to you to prescribe Atelvia . . . make sure reps are utilizing these doctors in their med eds.”

g. On February 17, 2011, REICHEL held another conference call with directors and managers, during which he communicated that the purpose of the early experience

program was for the selected physicians to get “clinical experience with Atelvia,” and he expressed frustration because these physicians were not prescribing Atelvia® at a high level. REICHEL stated that “med ed programs are everything” but stated that the sales representatives should not take out “early experience” doctors who had not yet prescribed Atelvia®. REICHEL called on DM 2, who stated that DM 2 was canceling dinners for “early experience” physicians who were not prescribing, and DM 2 was having “business conversations” with these physicians expressing to them that they would not be taken out to dinner or paid as a “speaker” unless their prescribing habits increased.

h. That same day, February 17, 2011, RSD 3 emailed a number of DMs a list of the “speakers” in their districts, asking them to review their prescription history and explain why any of their “supporter[s]” have not prescribed Atelvia®. DM 3 responded, “Nobody on this list, but if I did, it would not be a good day for that advocate . . . Doing this same accounting with my district’s advocates and having the talk.”

i. On March 6, 2011, DM 3 instructed a sales representative to “use advocacy as a carrot” for doctors “who are little lower volume [sic] and lack experience with Atelvia at this point.”

j. In September 2011, RSD 1, having been trained by REICHEL that he should not use “speakers” who do not prescribe Warner Chilcott drugs at an acceptable level, instructed DMs to prepare “no speaker lists.” These lists identified “speakers” who should no longer be used because their market share of Atelvia® was not high enough. Sales representatives were instructed to tell the underperforming HCPs that they would not be used at subsequent “speaking” programs until they prescribed more Atelvia®. DM 4, among others, disseminated the list to a number of sales representatives.

k. DM 4 aggressively pushed sales representatives to leverage business from

speakers:

- On or about February 2011, sales representative 1, who reported to DM 4, told a “speaker,” “no writey no speakey.”
- On May 25, 2011, sales representative 2 wrote DM 4 that a new “speaker” “is excited to ‘be on our team’, his words, 3 switches yesterday with no problem and a strong commitment for increased Atelvia business.”
- On August 5, 2011, sales representative 3 told DM 4 that he had “straight talk” with a physician, who “understood and am happy to see that he popped with 2 [prescriptions] this week.”
- On September 6, 2011, DM 4 told a sales representative that DM 4 needed to see a physician’s “prescriptions increase dramatically over the next 4-6 weeks or I cannot justify using him as a speaker any longer.”

l. DM 5, the top DM in the Osteoporosis Division, pressured sales representatives to leverage spending on HCPs with prescriptions. On March 11, 2011, DM 5 wrote to the district, “We’ve all done many Med Ed’s, lunches, coffee breaks, etc with our top physicians, and now is the time that accountability comes in.” On November 18, 2011, DM 5 wrote to the district:

Remember, at a minimum I expect 2 Med Ed dinner programs (with or w/o a speaker (preferably with one of your speakers) each week. THIS IS NON-NEGOTIABLE!! I would also suggest you Med Ed the key staff members in your top practices (Ex. Nurse/tech who preps the patient, staff members that handle the PA’s, call backs, fax renewals, etc). If you’re not performing well you should be thinking about doing more to assist in driving your Atelvia NRx share.

m. On several occasions in 2010 and 2011, sales representative 4, a top Osteoporosis Division sales representative who reported to DM 5, left a Warner Chilcott credit card at restaurants, allowing physicians to have free dinners on their own, and they were

occasionally paid “speaker” fees as well for attending dinners. On November 11, 2011, a physician in sales representative 4’s district went out to dinner at an expensive New York restaurant, without the sales representative present, and spent \$1,778, including alcohol, suckling pig, crab cake platters, and a \$550 gift card. Sales representative 4 expensed the event as a “med ed.”

n. Sales representative 5, another successful sales representative in DM 5’s district, cultivated HCP 1, a high-prescribing physician, to be a “speaker.” Sales representative 5 paid HCP 1 as a “speaker” when the dinners were mere social events. Sales representative 5 also paid for HCP 1’s office holiday party at a restaurant and gave HCP 1 a gift card worth several hundred dollars to an expensive New York restaurant, expensing both items as “med eds.” HCP 1 prescribed Atelvia[®] for numerous patients, in part, in exchange for these payments.

o. On or about May 29, 2011, DM 6 instructed a sales representative, “continue to build your bench with advocates . . . and demand more business from them . . . you must step up the pressure with your advocates. You deserve more business than you are getting. Let them know this. Hold them accountable . . . An advocate should be writing at least 50%. If you are not getting these results let them know the expectation and tell them you will use advocates that get it done for you instead.”

p. On September 16, 2010, sales representative 6, who reported to DM 6, emailed a Massachusetts HCP who prescribed Loestrin[®]. Sales representative 6 wrote:

I hope everyone enjoyed last night. I thought it was a success! I just had a meeting with my boss and he has laid out his expectations for the group. Every provider involved in this group in women’s health has been writing at the minimum 30% Loestrin 24 since that dinner took place, WHICH IS THE MINIMUM EXPECTATION. This is your breakdown . . . [DM 6] doesn’t

understand why you're the only provider who is not on board, and I have to agree I am stumped myself. (the largest provider might i add!!) I told my boss that you were on board, which is why he has given me a couple of months to see what happens, He told me that he will not let me pay for December's event or any for that matter if it doesn't turn around.

q. On or about June 14, 2011, DM 7 praised a sales representative for "the Sushi night monthly that you have created [with two HCPs]. Let's make sure we are growing business. Now with the time you are spending with these docs, they should be at two scripts per week easy now." On or about October 27, 2011, DM 7 praised another sales representative because she "had a crucial conversation" with physicians "and have seen them begin to write. They are beginning to understand the need to get clinical experience with Atelvia."

r. Throughout 2010 and 2011, DM 8 pressured sales representatives in New England to pay remuneration to physicians in exchange for prescriptions. Sales representative 7 cultivated RITA LUTHRA, a high-prescribing physician, to be a "speaker." On numerous occasions, sales representative 7 brought food to LUTHRA's Springfield, MA, office, spent a few minutes with LUTHRA, and paid her "speaker" fees—even though LUTHRA was not "speaking" about anything. Sales representative 7 also paid for a barbecue that LUTHRA was hosting for friends and family, expensing the party as a "med ed."

s. On or about April 1, 2011, sales representative 8 took out a number of physicians to an expensive restaurant at the Foxwoods casino in Connecticut. Sales representative 8 expensed the dinner, which cost approximately \$4,500, as a "med ed." Sales representative 8 also held "med ed" dinners at an expensive steakhouse at the Mohegan Sun casino in Connecticut on several occasions. Sales representative 8 and other sales

representatives in New England also provided gift cards and other gifts to physicians to induce them to prescribe Warner Chilcott products. Sales representative 8 and other sales representatives in New England also provided remuneration to physicians' employees to induce them to prepare prior authorizations for Atelvia®.

t. On or about November 3, 2011, sales representative 9 paid to cater a "game day party" for an HCP's softball team. The event occurred on a Saturday and the HCP's employees' families were included amongst the 30 people who ate at the picnic. Sales representative 9 did not attend the picnic but expensed it as a "med ed." After the HCP's employee thanked sales representative 9 for ordering the food, sales representative 9 instructed the HCP's employee to "keep [the HCP] writing..."

u. In or about September 2010, sales representative 10 signed up HCP 2, a high prescriber of osteoporosis medication, to be a Warner Chilcott "speaker." On September 30, 2010, sales representative 10 reminded HCP 2's spouse, who worked in the office, "the more dinners, the more money! Also, I know that you said that you would make sure that [HCP 2] is prescribing Actonel. [HCP 2] is forgetting to. So please remind [HCP 2]." Sales representative 10 frequently took out HCP 2 and HCP 2's family to expensive dinners at restaurants such as Ruth's Chris steakhouse, and on some occasions sales representative 10 took out HCP 2, along with family members, birthdays and anniversaries, expensing the events as "med eds." Sales representative 10 paid HCP 2 a "speaker" fee in connection with these family dinners. On at least one occasion, HCP 2 accepted a "speaker" payment even though HCP 2 did not attend the event. As a result of these payments, HCP 2 became a high-volume Atelvia® prescriber.

All in violation of Title 18, United States Code, Section 371.

FORFEITURE ALLEGATIONS
(18 U.S.C. §982(a)(7))

The Grand Jury further charges:

13. Upon conviction of the offense set forth in Count One of this Indictment,

W. CARL REICHEL,

defendant herein, shall forfeit to the United States pursuant to 18 U.S.C. § 982(a)(7), any property, real or personal, that constitutes or is derived, directly or indirectly, from gross proceeds traceable to the offense.

14. If any of the property described in paragraph 13 above, as a result of any act or omission of the defendant --

- a. cannot be located upon the exercise of due diligence;
- b. has been transferred or sold to, or deposited with, a third party;
- c. has been placed beyond the jurisdiction of this Court;
- d. has been substantially diminished in value; or
- e. has been commingled with other property which cannot be divided without difficulty;

it is the intention of the United States, pursuant to 18 U.S.C. § 982(b)(1), incorporating 21 U.S.C. § 853(p), to seek forfeiture of any other property of the defendant up to the value of the property described in paragraph 13.

All pursuant to Title 18, United States Code, Section 982.

A TRUE BILL

Eiizabeth L Taylor
FOREPERSON OF THE GRAND JURY

David S. Schumacher
DAVID S. SCHUMACHER
MIRANDA HOOKER
ASSISTANT U.S. ATTORNEYS

DISTRICT OF MASSACHUSETTS; October 28, 2015

Returned into the District by the Grand Jurors and filed

Thomas J. Quinn
DEPUTY CLERK
10/28/2015
@ 12:52pm