

## **AFFIDAVIT OF EDWARD H. HENSLEY**

I, Edward Harvey Hensley, being over the age of 18 and of sound mind, do swear and hereby state and affirm, pursuant to 18 U.S.C. § 1621, that the following statements are true to the best of my knowledge and recollection:

### **Background**

1. I previously have agreed to answer questions that the United States Attorney's Office for the District of Massachusetts and the Department of Justice have put to me regarding my time at Advanced Care Scripts ("ACS") and The Assistance Fund ("TAF"), as well as my relationship with Teva Neurosciences ("Teva") and other pharmaceutical manufacturers. This includes sitting for multiple voluntary interviews and sworn testimony.
2. I am providing this affidavit in response to the demand by the United States Attorney's Office for the District of Massachusetts and the Department of Justice that I answer under oath additional questions they have put to me regarding my relationship with Teva.

### **Relationship between Teva, ACS and the Chronic Disease Fund ("CDF")**

3. By no later than 2008, I understood that Teva was purposefully utilizing ACS and structuring its donations to CDF in a manner that essentially ensured that such donations would benefit only Copaxone patients, and not patients who had been prescribed competitor MS medications.
4. I arrived at this understanding because, among other things, Teva employee Denise Lynch conveyed this to me. Specifically, in or around 2008, Ms. Lynch told me that she would not authorize donations to Patient Services, Inc. ("PSI") because PSI had "burned" her with respect to a prior donation. When I asked Ms. Lynch what she meant by this, Ms. Lynch explained that a donation that Teva had made to PSI had not been passed through to

Copaxone patients, but rather had been used to cover the co-pays of patients who had been prescribed competitor MS drugs. Ms. Lynch stated to me that she was “tired” of other pharmaceutical manufacturers “riding on [Teva’s] coattails.” Ms. Lynch told me, in sum and substance, that Teva would only authorize a donation to a charity that could provide Teva reasonable assurance that the donation would exclusively (or at least predominantly) benefit Copaxone patients.

5. Ms. Lynch and I identified CDF as a foundation that could provide Teva the assurance for which it was looking. Specifically, Ms. Lynch and I discussed the fact that CDF did not maintain a waitlist of patients who applied to its MS fund when funding was not available and that, when CDF did receive money and “opened” its fund, it accepted patients on a “first come, first serve” basis. Ms. Lynch and I discussed that this would provide a benefit to Teva’s goal that its charitable contributions take care of as many of its patients as possible. In particular, CDF’s patient intake process (*i.e.*, “first come, first serve” without a wait list) was designed to ensure that monies that a pharmaceutical manufacturer donated would flow through to that manufacturer’s patients. In practice, this meant that within minutes (or even seconds) of receiving a Teva donation causing its MS fund to “open,” CDF would accept from ACS, Teva’s preferred specialty pharmacy, a “batch file” containing dozens and sometimes hundreds of Medicare Part D Copaxone patients whose co-pay obligations might otherwise deter them from filling their prescriptions.

#### **Teva’s Coordinated Donations to CDF**

6. While I worked at ACS, Ms. Lynch would regularly ask David Blanc or me how many of ACS’s Copaxone patients were waiting to fill their prescriptions pending enrollment in a co-pay assistance fund. Mr. Blanc and/or I would provide Ms. Lynch that information.

Because the Medicare Part D “donut hole” amount was easily determinable, Ms. Lynch was able to determine the exact amount of money that Teva would need to donate to CDF to have all of the waiting Copaxone patients enrolled into the foundation. The amount was determined through simple multiplication: (number of patients) \* (donut hole + estimated catastrophic coverage co-pay + estimated administrative fee). If Ms. Lynch needed assistance in determining the necessary donation figure, I would, and at times did, provide that assistance.

7. Based on my course of dealing with Ms. Lynch, various discussions I had with Ms. Lynch, statements that Ms. Lynch made to me, and Teva’s donation patterns, it was clear to me that Teva was tailoring its donation amounts so that the donation would be sufficiently large to cover all of ACS’s waiting Copaxone patients but not so large that any significant number of non-Copaxone patients would be benefitted. Although Ms. Lynch never expressly stated that the size of a particular donation was designed to be sufficient but not greater than necessary to cover ACS’s waiting Copaxone patients, her statements that Teva did not want other pharmaceutical companies free-riding on Teva’s charitable donations made it clear that this was a principal factor in Teva’s determination of how large of a donation to give to CDF at any given time. I also understood from my conversations with Ms. Lynch that she needed approval from Teva’s senior management, including potential management in Israel, to make the larger donations and that she might not obtain that approval unless she were able to demonstrate that the donations would substantially go to Copaxone patients.

### ACS's "Batch Files" of Copaxone Patients to CDF

8. Ms. Lynch would provide me and/or Mr. Blanc advance notice that Teva would be making a donation to CDF. This advance notice could range from several days to several weeks. For example, I recall a specific occasion where Ms. Lynch told me that Teva would be sending a wire donation on "Thursday after three o'clock." Based on my course of dealing with Ms. Lynch, various discussions I had with Ms. Lynch, and statements that Ms. Lynch made to me, I knew that Ms. Lynch was providing this advance notice so that ACS would have sufficient time to ready its "batch file" of ACS's waiting Copaxone patients, which it could then send to CDF without delay (sometimes minutes or seconds after CDF received Teva's donation). In addition, when Teva finally wired funds to CDF, Ms. Lynch would immediately inform Mr. Blanc and me of this fact. Ms. Lynch provided us these notifications because they were essential to ensuring that ACS had a significant advantage in its ability to enroll Copaxone patients into CDF's MS Fund, and thereby to ensure that Teva's donations flowed through to Copaxone patients as Teva intended.
9. ACS was a contracted provider for Teva and, therefore, Teva expected ACS to be acting exclusively for Teva's benefit when enrolling ACS patients into CDF. However, Mr. Blanc and I would sometimes "pepper" a batch file with non-Copaxone patients who were in dire need of co-pay assistance (*i.e.*, randomly intersperse a relatively small number of non-Copaxone patients throughout the batch file that ACS and Teva otherwise intended to be filled exclusively with Copaxone patients). ACS never told Teva about the "peppering," at least in part because I had some concerns about whether Teva would consider the "peppering" to be inconsistent with its expectations of ACS's performance under the service contract.

### **Teva's Change of Preferred Co-Pay Assistance Fund to TAF**

10. While on a phone call with Ms. Lynch and possibly Jennifer Clark, another Teva employee, in or around 2009, Ms. Lynch asked me several questions about the structure of TAF and how the fund would operate. In particular, Ms. Lynch asked me to confirm that TAF would not have waitlists, as waitlists would impair Teva's ability to get the maximum number of its patients covered by its donations. My response to Ms. Lynch and others at Teva was that TAF would provide all of the advantages that CDF did—including accepting “batch files” of patients from a manufacturer's “hub” or preferred specialty pharmacy, not utilizing waiting lists, and accepting donations at any time during the year. In other words, I made sure that Ms. Lynch understood that Teva effectively would be able to use TAF as it had CDF: essentially, as a “pass-through” donation vehicle to get Teva monies into the hands of Copaxone patients. (My recollection is that the questions that Teva asked me about TAF's structure and the information Teva hoped to receive about TAF's structure were consistent with questions asked by other pharmaceutical manufacturers that I spoke with regarding TAF.)
11. I told Ms. Lynch that TAF would be an improvement over CDF because TAF's administrative expenses would be lower (which meant an increased number of Copaxone patients would be covered by the manufacturer's donations) and because TAF would use any reserve funds to cover additional patients.
12. While at TAF, I knew, based on conversations with Mr. Blanc, who remained at ACS after I left, that Ms. Lynch continued to provide ACS with advance notice of Teva's forthcoming donations, such that ACS would have sufficient time to ready a batch file of Copaxone patients to send to TAF. TAF would accept these batch files no questions asked, despite

knowing that ACS had purposefully and strategically structured the batch file to benefit Copaxone patients rather than to fairly reflect ACS's population of financially needy MS patients.

#### **Teva's Donation Amounts to TAF**

13. I knew, based on conversations with Mr. Blanc, that Mr. Blanc continued to provide Ms. Lynch with information about how many of ACS's Copaxone patients were waiting to fill their prescription pending enrollment in a co-pay assistance foundation. I would regularly provide either Ms. Lynch or Mr. Blanc (or both) the "per-patient allocation" that TAF was using for its MS Fund at any given time. I sometimes did this proactively, but usually did this in response to a specific request by Ms. Lynch. Based on my course of dealing with Ms. Lynch, discussions I had with Ms. Lynch, and statements that Ms. Lynch made to me, I knew that the purpose of providing this information to Ms. Lynch was to enable her to determine how much money Teva needed to donate to TAF to cover all of ACS's waiting Copaxone patients.
14. I knew that Ms. Lynch was receiving information from both TAF and ACS that in combination would be sufficient to enable her to determine how much Teva should donate to TAF at the start of the year.
15. In the beginning of a new year, Teva would donate to TAF an amount less than what TAF requested in its "ask letter." TAF's "ask" amount was based on the number of patients in the MS Fund plus a projected increase in census over the course of the coming year. At sporadic times following that first donation, Teva would donate additional amounts, each of which brought Teva's donations for the year incrementally closer to TAF's "ask." This indicated to me that, as of Teva's first donation of the year, Ms. Lynch had an awareness

of (1) how many Copaxone patients were, at the start of the year, ready to be re-enrolled by TAF, and (2) how many new Copaxone patients ACS immediately had ready to refer to TAF. Based on the information that Ms. Lynch would then gather or receive from ACS, Ms. Lynch could determine the optimal timing and size of the smaller donations that Teva would tend to make after the initial, large donation that Teva typically would make during the first few days of January (*i.e.*, the timing and size that would be best cover the Copaxone patients that ACS had ready to refer to TAF at various points throughout the year, while minimizing the chances that non-Copaxone patients would receive any significant portion of these donations).

16. After TAF's processing of the batch file(s) that ACS had submitted, ACS would receive from TAF, in the ordinary course, information regarding each Copaxone patient that had been referred by ACS and successfully enrolled in the fund. Although not all Copaxone patients in the ACS Medicare Part D program used ACS as their specialty pharmacy, Teva knew, based on information it received from ACS, that approximately 90 percent of those patients did. This would enable ACS essentially to confirm for Teva how many Copaxone patients in fact were enrolled in TAF's MS Fund at any given time, which would enable Teva to determine the right size of its next start-of-year donations. Because the timing and information contained in the batch files sent by ACS to TAF were the same as the ones ACS had previously sent to CDF, and because ACS remained a contracted provider for Teva, I knew that Mr. Blanc would be providing such patient information to Ms. Lynch for that express purpose.

### **Consideration of Anti-Kickback Statute and OIG Guidance**

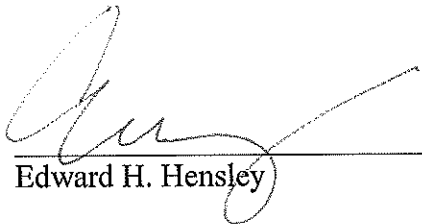
17. While at ACS and at TAF, I understood that as a general matter a pharmaceutical manufacturer could not provide co-pay assistance directly to patients. While at TAF, I also understood that TAF's and other co-pay assistance charities' OIG Advisory Opinions required that the co-pay assistance charity be "independent" of the pharmaceutical manufacturer that made the donation. I understood that Teva's conduct in alerting ACS of a forthcoming Teva donation to CDF or TAF was contrary to the spirit of the OIG guidance and, in substance, caused CDF and/or TAF not to be truly "independent" of Teva but rather to be mere "pass-through" vehicles. I understood that, by not objecting to Teva's conduct, TAF was allowing Teva to use the foundation in a way that was contrary to the purpose and spirit of the OIG guidance. I also knew that the foundations to which Teva was donating, and to which ACS was then directing Copaxone patients, were "independent" from Teva in name only.
18. I believe that Teva knew that its conduct circumvented the Anti-Kickback Statute and would be viewed as problematic by the OIG and DOJ. Specifically, in or around 2018, after her retirement from Teva, Ms. Lynch disclosed to me that she had warned Teva's senior leadership years before that Teva should "take a reserve" to cover False Claims Act liabilities associated with Teva's donations to CDF and TAF "in the event" that the donations came under government scrutiny. In addition, I was aware that Ms. Lynch avoided asking me, while I was at TAF, for information that the OIG Advisory Opinion expressly prohibited TAF from providing to Teva (namely, the number of Copaxone patients in the TAF MS Fund at any given time). I was aware, however, that Teva was



nevertheless obtaining the functional equivalent of that information from ACS and tailoring its donation amounts and the timing of its donation accordingly.

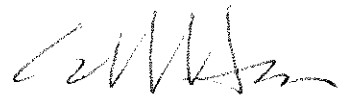
19. Although I believed that ACS, CDF, and TAF were benefitting patients with medically necessary MS prescriptions and legitimate financial need, I understood from at least 2010 forward that the donation “playbook” that Teva was utilizing, and that TAF was agreeing to follow, was contrary to the independence that the OIG Advisory Opinion was seeking to require from co-pay assistance charities.

I declare under penalty of perjury under the laws of the United States that the foregoing is true and correct.

  
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Edward H. Hensley

Sworn to before me this

11<sup>th</sup> day of MARCH, 2020

  
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Notary Public

