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IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA

RACHEL CONDRY, JANCE HOY, CHRISTINE ENDICOTT, LAURA BISHOP, FELICITY BARBER, and RACHEL CARROLL on behalf of themselves and all others similarly situated,

Plaintiffs,

v.

UnitedHealth Group Inc.; UnitedHealthcare, Inc.; UnitedHealthcare Insurance Company; UnitedHealthcare Services, Inc.; and UMR, Inc.,

Defendants.

Case No.: 3:17-cv-00183-VC

PLAINTIFFS' MEMORANDUM OF POINTS AND AUTHORITIES IN OPPOSITION TO DEFENDANTS' *DAUBERT* MOTION CONCERNING THE EXPERT TESTIMONY AND OPINIONS OF DR. LAUREN E. HANLEY IN CONNECTION WITH PLAINTIFFS' MOTION FOR CLASS CERTIFICATION

Date: April 25, 2019
Time: 10:00 AM
Place: Courtroom 4

Honorable Vince G. Chhabria

TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES

Page(s)

STATUTES

OTHER AUTHORITIES

Plaintiffs, Rachel Condry, Jance Hoy, Christine Endicott, Laura Hipple (nee Bishop), Felicity Barber, and Rachel Carroll (collectively, the "Plaintiffs"), on behalf of themselves and the members of the proposed Classes, hereby oppose Defendants'[1] *Daubert* Motion, and accompanying Memorandum, Concerning the Expert Testimony and Opinions of Plaintiffs' Expert Dr. Lauren E. Hanley ("Dr. Hanley") in Connection with Plaintiffs' Motion for Class Certification ("UHC Memo") (Dkt. 180). Filed concurrently herewith is the Declaration of Kimberly Donaldson-Smith with respect to Plaintiffs' Opposition to Defendants' *Daubert* Motion and exhibits thereto ("KMDS Decl.").

I. INTRODUCTION

Defendants' Motion directed to Dr. Hanley is purposefully and solely grounded on a wrong proposition: that Dr. Hanley is offering opinions on medical coding. (UHC Memo, at 1:18-21; 1:22-2:8.) From that, Defendants then proffer arguments about her "methodology" and reliability, none of which warrant limiting this Court's consideration of Dr. Hanley's expert opinions. Dr. Hanley offers opinions with respect to the diagnostic codes that, based on her experience, a trained lactation provider may use to reflect services rendered for breastfeeding support and counseling. Defendants' rhetoric concerning Dr. Hanley's lack of formal training in medical coding misses the mark entirely: Plaintiffs are not offering Dr. Hanley to opine on *how* medical codes are created; Plaintiffs offer Dr. Hanley's opinions to demonstrate *what* the diagnostic codes cover as they relate to lactation and breastfeeding services. Dr. Hanley also offers direct rebuttal, grounded in her experience, to three of Defendants' experts who Defendants rely on and cite to in their Opposition to Plaintiffs' Class Certification Motion.

As set forth in more detail below, Dr. Hanley's credentials and experience are relevant and significant. Dr. Hanley is an obstetrician and gynecologist at the Massachusetts General Hospital Department of Obstetrics & Gynecology and is an International Board-Certified Lactation Consultant ("IBCLC"). Dr. Hanley has significant experience specific to the rendering and teaching of

[1] Defendants are comprised of UnitedHealth Group Inc., UnitedHealthcare, Inc., UnitedHealthcare Insurance Company, UnitedHealthcare Services, Inc. and UMR, Inc. (collectively, "UHC" or "Defendants").

comprehensive breastfeeding support and counseling services. The methodology she used in reaching her conclusions is sound, and she is qualified to offer the opinions she renders. Defendants' attempts to dissuade the Court from placing due weight on Dr. Hanley's testimony are without merit, and Dr. Hanley's opinions are pertinent to Plaintiffs' Motion for Class Certification.

II. BACKGROUND

Plaintiffs filed this action on January 13, 2017 to challenge Defendants' failure to meet the ACA's preventative coverage mandate for comprehensive lactation support and counseling ("CLS").

Pursuant to the Court's October 2, 2018 Scheduling Order (Dkt. 158), the parties exchanged Affirmative Expert Disclosures in December 2018 and Rebuttal Expert Disclosures in January 2019. In addition, beginning in January 2019, the parties deposed each of opposing side's proffered experts. Consistent with the Court's Scheduling Order, Plaintiffs provided the expert report of Dr. Hanley on December 11, 2018 and provided an Amended Report on February 15, 2019. Therein, Dr. Hanley proffered opinions concerning the clinical indications and diagnosis codes that may reasonably indicate the provision of comprehensive breastfeeding support and counseling services to patients, pre-natal through post-partum. (*See* Hanley Amended Report, at 1, Exhibit 34 (Dkt. 161-2 at page 339-362) to KMDS Decl. in Support of Plaintiffs' Motion of Points and Authorities in Support of Plaintiffs' Motion for Class Certification filed in this matter at Dkt. 161-1 and the exhibits associated therewith at Dkt. 161-2. ("Pls.' Ex.").) Dr. Hanley opines that there is not only one International Classification of Disease ("ICD") code (or "diagnoses code") used by providers to indicate a lactation visit or a visit during which comprehensive breastfeeding support and counseling was provided to a patient. (*Id.* at 3.) Dr. Hanley then elucidates this point by clearly laying out five tables of ICD codes that can be used to identify an encounter with a breastfeeding dyad or triad. *Id.* at 4-8. Such ICD codes can be used for billing purposes. (*Id.* at 4.)

On December 11, 2019, Defendants served the Expert Reports of:

(a) Palma D'Apuzzo dated 12/11/2018 ("D'Apuzzo Initial Report"). Plaintiffs deposed Ms. D'Apuzzo on January 15, 2019, and on January 16, 2019, Ms. D'Apuzzo submitted an Amended Expert Report ("D'Apuzzo Amended Report", Pls. Ex. 18) to, as Ms. D'Apuzzo states, "clarify my opinion about how breastfeeding services should be billed

focuses on the provision of services to women." (*id.*); and,

(b) Henry Miller, Ph.D dated 12/11/2018 ("Miller Report").

On January 18, 2019, Dr. Hanley provided a Rebuttal Expert Report addressing the D'Apuzzo Amended Report and the Miller Report. Dr. Hanley's January 18, 2019 Rebuttal Expert Report is attached as Exhibit A to the KMDS Decl. ("Dr. Hanley's 1/18/19 Rebuttal Report.") Among other things, in Dr. Hanley's 1/18/2019 Rebuttal Report, she identifies her disagreements with Ms. D'Apuzzo's statements regarding:

(a) the one billing code UHC and its expert, Ms. D'Apuzzo, deem sufficient for capturing breastfeeding support and counseling services rendered by a non-physician provider, which code for "lactation classes" does not, in Dr. Hanley's opinion, accurately portray the comprehensive breastfeeding services provided by a lactation provider (*id.* at ¶5A); and

(b) a policy by UHC, as articulated by Ms. D'Apuzzo, to not allow physicians to bill separately for lactation services for certain periods around birth, which policy fundamentally relegates breastfeeding support and counseling to a part of post-partum routine check-ups, and not as separately rendered and reportable services (*id.* at ¶5B).

With respect to Dr. Miller's Report, Dr. Hanley disagrees with Dr. Miller's contentions about the reasonableness of patients contacting their providers about denial and remark codes received from their insurance companies and cost-share billing conventions. (*Id.* at ¶6 A-E.) As Dr. Hanley opines, it is not reasonable to expect or assume that patients will contact providers under those circumstances, that providers can and will provide a response, and that providers are trained on remark codes generally or specifically as to any insurance company's remark codes. (*Id.* at ¶6A, B, D.) Moreover, as Dr. Hanley opines, Dr. Miller's opinions are based on unfounded presumptions that: (i) providers will change their codes as it is a provider's professional responsibility to bill a code that accurately describes the service (*id.* at ¶6C) and (ii) providers routinely waive or fail to collect co-payments or co-insurance from their patients. (*Id.* at ¶6E.)

Defendants made Dr. Lee available for deposition on January 21, 2019, and thereafter, Plaintiffs served Dr. Hanley's Rebuttal Report directed to Dr. Lee. (Exhibit B to the KMDS Decl.

("Dr. Hanley's 1/25/19 Rebuttal Report").) In Dr. Hanley's 1/25/19 Rebuttal Report to Dr. Lee, Dr. Hanley details her disagreement with Dr. Lee's assessment and conclusion about the purported sufficiency of breastfeeding support and counseling services received after birth and discharge from the hospital by general practitioners. (*Id.*)

On February 20, 2019, Plaintiffs moved for certification of three nationwide Classes—the Claims Review Class, the Lactation Services Class, and the ACA Class—of individuals who had been harmed by Defendants' failure to provide coverage and/or imposed cost-sharing for lactation services coverage as mandated under the Affordable Care Act. *See* Plaintiffs' Class Certification Motion (Dkt. 161). In support of their Motion for Class Certification, Plaintiffs rely upon Dr. Hanley's opinions in challenging Defendants' restrictive definition of diagnoses codes that may reasonably be used by providers to indicate that their encounter with a patient was for CLS. (*See id.*, at 15.)

In addition, Defendants' Opposition to Plaintiffs' Class Certification Motion references and relies on all three of their experts -- Ms. D'Apuzzo, and Drs. Miller and Lee--and their respective Reports: (Dkt. 163, at 5-8, 17, 23). Defendants also cite to Ms. D'Apuzzo in their motion to limit consideration of Dr. Hanley's opinions. (UHC Memo, at 2, 3, 10.)

III. APPLICABLE LEGAL STANDARDS

Federal Rule of Evidence 702 permits an expert to testify where he or she "is qualified as an expert by knowledge, skill, experience, training, or education and his or her testimony will help the trier of fact to understand the evidence or to determine a fact in issue, is based on sufficient facts or data, is the product of reliable principles or methods; and the expert has reliably applied the principles and methods to the facts of the case." *In re MyFord Touch Consumer Litig.*, 2016 U.S. Dist. LEXIS 179487, at *12 (N.D. Cal. Sept. 14, 2016) (citing FED. R. EVID. 702) (internal quotations omitted). "[N]ot only must the trial court be given broad discretion to decide *whether* to admit expert testimony, it must have the same kind of latitude in deciding *how* to test an expert's reliability." *United States v. Hankey*, 203 F.3d 1160, 1168 (9th Cir. 2000). The requirement that the expert testimony "assist the trier of fact goes primarily to relevance." *Primiano v. Cook*, 598 F.3d 558, 564 (9th Cir. 2010).

At the class certification stage, "a district court should evaluate admissibility under the standard set forth in *Daubert.*" *Sali v. Corona Reg'l Med. Ctr.*, 909 F.3d 996, 1006 (9th Cir. 2018). Such admissibility, however, "must not be dispositive," but rather "an inquiry into the evidence's ultimate admissibility should go to the weight that evidence is given at the class certification stage" which accords with the Ninth Circuit's guidance that "a district court should analyze the 'persuasiveness of the evidence presented' at the Rule 23 stage." (*Id.*) (citing *Ellis v. Costco Wholesale Corp.*, 657 F.3d 970, 982 (9th Cir. 2011)). "A trial court has broad latitude not only in determining whether an expert's testimony is reliable, but also in deciding how to determine the testimony's reliability." *Ellis*, 657 F.3d at 982. Indeed, at the class certification stage, district courts are "license[d] greater evidentiary freedom," as "relying on formalistic evidentiary objections" may "unnecessarily exclude[ ] proof that tends to support class certification." *Sali*, 909 F.3d at 1006.

IV. ARGUMENT

A. Dr. Hanley is Qualified to Serve as an Expert and her Opinions are Reliable

Pursuant to Rule 702, an expert may be qualified by "knowledge, skill, experience, training, or education." FED. R. EVID. 702. As recognized by the Ninth Circuit, "the advisory committee notes emphasize that Rule 702 is broadly phrased and intended to embrace more than a narrow definition of qualified expert." *Thomas v. Newton Int'l Enterprises*, 42 F.3d 1266, 1269 (9th Cir. 1994) (finding expert's qualifications of "29 years of [ ] experience" and work history in the field sufficient to lay "the minimal foundation of knowledge, skill, and experience required in order to give 'expert' testimony"). "The threshold for qualification is low for purposes of admissibility; minimal foundation of knowledge, skill, and experience suffices." *PixArt Imaging, Inc. v. Avago Tech. Gen. IP (Singapore) Pte. Ltd.*, 2011 U.S. Dist. LEXIS 133502, 2011 WL 5417090, *4 (N.D. Cal. Oct. 27, 2011). "In certain fields, experience is the predominant, if not sole, basis for a great deal of reliable expert testimony." *See* Advisory Committee Notes, FED. R. EVID. 702.

Dr. Hanley's education and experiences demonstrate that she is qualified to serve as an expert witness in this case. Dr. Hanley is an obstetrician and gynecologist at the Massachusetts General Hospital Department of Obstetrics & Gynecology and an IBCLC. Dr. Hanley is the founder of and runs the Massachusetts General Hospital Lactation Clinic for women and children with lactation

issues. (Dkt. 161, at Ex. 34 ("Amended Hanley Report"), at 1.) Dr. Hanley has also been involved in organized medicine through the American College of Obstetricians and Gynecologists ("ACOG"), and, through her work at the Massachusetts Breastfeeding Coalition, has lectured family practice, pediatric, internal medicine and Ob/Gyn residents and physicians through the multidisciplinary seminar, "Breastfeeding for Physicians by Physicians" from 2008 through 2012 locally. (*Id.*) Her community involvement also includes participation on the Executive Board of the MBC, the mission of which is to improve public health by making breastfeeding the norm through education, advocacy, and collaboration. (*Id*). Dr. Hanley is a founding member and the Chair of the ACOG National Expert Working Group on Breastfeeding since its creation in 2013. (*Id.*) She further serves as the ACOG National Delegate to the US Breastfeeding Committee which works to advocate at a national level for breastfeeding support and reduction of disparities in breastfeeding outcomes. *Id.*

Her experience and knowledge are directly foundational, pertinent and supportive of the opinions given by Dr. Hanley with respect to: the use of International Classification of Diseases ("ICD") codes and their use by providers in their patients' records to indicate the diagnosis of the conditions being evaluated and/or discussed with the patient during the visit; and the clinical breastfeeding and lactation-related diagnoses she identifies in Tables 1-5 in her Amended Report. (*Id.* at 3-8.) Dr. Hanley concluded that providers may use maternal and/or pediatric codes to indicate that a patient encounter was for lactation and breastfeeding support, and, in her opinion, both maternal and pediatric ICD Codes can indicate a lactation visit for breastfeeding support. (*Id.* at 9.) Likewise, her experience and knowledge render her rebuttal opinions to Drs. Miller and Lee and Ms. D'Apuzzo (discussed *supra*) sound and supported.

B. <u>Dr. Hanley is Not Proffered as a "Medical Coding Expert"</u>

Whatever a "medical coding expert" may be, Plaintiffs did not offer Dr. Hanley as one. Defendants attempt to detract from Dr. Hanley's expertise by emphasizing what they contend Dr. Hanley is not - an expert in medical coding. Defendants use this argument to expound upon industry standards for lactation services and the use of diagnostic codes in health care claims.

But Defendants' contentions about industry coding conventions for breastfeeding support and counseling services, and thus Dr. Hanley's purported lack of relevancy, are unsupported. (UHC

Memo at 2:11-3:17.) Defendants cite to their proffered expert, Ms. D'Apuzzo, in support of such position. Ms. D'Apuzzo, notably, did not survey the "industry" with respect to "lactation" codes and does not have direct experience as a provider of breastfeeding support and counseling, like Dr. Hanley, providing breastfeeding support and counseling services to state that "[t]here are numerous codes available that allow providers to expressly bill for lactation services." (*Id.* at 3:3-4.) There is nothing remarkable or disagreeable with that; there are, as Dr. Hanley notes, codes with the words "lactation." But, what Defendants then state, *without support*, in an attempt to discredit Dr. Hanley, is that "the industry expectation is that the lactation services provided will be billed with lactation-specific codes." (*Id.* at 3:6-7.) That position is not even the *ipse dixit* of Defendants' expert, it is Defendants' *ipse dixit*.

Defendants repeatedly belabor the inaccurate assumption that Plaintiffs are offering Dr. Hanley as an expert in medical coding. As made plain by Dr. Hanley's report and testimony at deposition, Dr. Hanley is not offering, and has never purported to offer, opinions on medical coding. (*Cf.* UHC Memo at 1; 4:9-5:7; 6:17-7:1). Thus, Defendants' attacks on Dr. Hanley's lack of education or training in medical coding are inapposite. Dr. Hanley's clinical credentials are directly relevant, however, to her opinions concerning diagnostic codes that a trained lactation provider may use to reflect series rendered for breastfeeding support and counseling. Dr. Hanley's opinions about diagnoses codes are based on her experience in the clinical context, as well as a review of various medical publications, reports, and guidelines concerning breastfeeding support. Further, as Dr. Hanley explains, the diagnoses codes she selects are used to provide necessary information for the patients' medical records and are used for billing and/or documentation purposes. (Amended Hanley Report, at 3-4.) This testimony supports Plaintiffs' allegations that there is not a singular "code" for comprehensive breastfeeding support and counseling ("CLS"), and the scope of diagnoses codes that may be reasonably used by providers to indicate that their encounter with a patient was for CLS goes far beyond the restricted definition of diagnoses codes used by Defendants. (*See* Dkt. 161, at 15.)

Defendants also criticize Dr. Hanley for not conducting a survey of how physicians or providers "lactation code". (UHC Memo, at 7:5-8:1.) However, a survey of physicians by Dr. Hanley was not necessary because Dr. Hanley did not need to question physicians about a subject that

she already is intimately familiar with; her clinical experience in the medical field informed her opinions. On this point, Defendants also mischaracterize Dr. Hanley's deposition testimony. To be sure, Dr. Hanley did not have "limited first-hand experience with codes in her report" and did not just include codes in her report received from Plaintiffs' counsel. (UHC Memo, 8 at fn. 5.) Rather, Dr. Hanley testified that for each code in her Report, she used her electronic medical record program, Epic, to pull the diagnoses codes that she frequently uses as an obstetrician/lactation consultant relating to lactation and breastfeeding, including terms that Dr. Hanley would commonly associate with breastfeeding and lactation issues. (*See, e.g.* Hanley Dep. Tr., at 31:10-36:23.) Contrary to UHC's assertions, the "task at hand" is precisely what Dr. Hanley's testimony accomplishes. (*Cf.* UHC Memo, at 8:17-9:4.)

Relatedly, Dr. Hanley never "admitted that an individualized assessment of medical records would be required to determine whether lactation-related services were needed by or rendered to a patient" in the context that Defendants wish to now argue. (*Id.*, UHC Memo, at 1; 5:5-7, citing Hanley Dep. at 155:16-157:11.) Defendants' attempt to use Dr. Hanley's statements about medical records as legal conclusions and assessments about the Class members' typicality are unpersuasive. Fundamentally, UHC's business includes the reprocessing of denied or improperly processed claims. Even if UHC may have to seek and receive information from a member directly (particularly when due to its failure to establish systems to adjudicate claims for CLS in accordance with the ACA), that would simply be a normal part of its business. Also, Plaintiffs' rebuttal expert, Mr. Labovitz, readily refutes the "individualized" contentions (*see* Labovitz Rebuttal Report, Ex. 36, ¶¶ 47-56). Mr. Labovitz explains that UHC's auto-adjudication system (the means by which 90% of UHC's claims are processed) is a rules-based computer program that determines the claim treatment; and to which sampling and statistical methods can applied to identify from the data "factors and filters values that drive a claim result, including but not limited to the relationship among claim elements such as provider type, provider network status, procedure codes and diagnosis codes that resulted in cost-share being applied and/or a claim being denied." UHC's arguments are unpersuasive and contradict the fundamental constructs of its insurance business.

C. Dr. Hanley's Methodology is Sound

Dr. Hanley's methodology does not suffer from the "serious methodological flaws" that Defendants allege. (UHC Memo at 5:16-17 (citing *Senne v. Kansas City Royals Baseball Corp.*, 315 F.R.D. 523, 586 (N.D. Cal. 2016), on reconsideration in part, No. 14-cv-00608-JCS, 2017 WL 897338 (N.D. Cal. Mar. 7, 2017) (rejecting the defendants' *Daubert* challenge where defendants did not demonstrate that the methodology was flawed in such a way that a more comprehensive survey at a later stage of the case would suffer from the same flaws).) Indeed, there is nothing improper about Dr. Hanley's methodology— relying upon her experience—in reaching her opinions. (*Cf.* UHC Memo, at 10:3-5.) *See United States v. Sandoval-Mendoza*, 472 F.3d 645, 655 (9th Cir. 2006) ("When evaluating specialized or technical expert opinion testimony, the relevant reliability concerns may focus upon personal knowledge or experience.") (internal quotations omitted). Similarly, there is nothing unreliable about Dr. Hanley's opinions, as they are consistent with industry standards and informed by her extensive experience in the field. (*Id.* at 10:13-12:19.)

Accordingly, Dr. Hanley's opinions are grounded in sufficient facts and data and informed by her own experience, and not, as Defendants contend, based on her own unfounded *ipse dixit*. (UHC Memo, at 12:20-22) (citing *Gen. Elec. Co.*, 522 U.S. 136, 146 (1997) (upholding the district court's exclusion of an expert where the studies relied upon by respondents' experts "were so dissimilar to the facts presented in this litigation" that they were not a sufficient basis for the experts' opinions).) Critically, Defendants do not challenge the accuracy of the codes included in Dr. Hanley's tables, and provide no colorable argument why this Court should ignore Dr. Hanley's compilation of diagnoses codes as they relate to lactation services.

In a final misstatement, Defendants mischaracterize Dr. Hanley's amended Report. At her deposition, Dr. Hanley affirmatively (*not*, as Defendants misleading portray it as "later," essentially, after their questioning) stated that she wanted to clarify that her opinions were from the clinical perspective. (*See* Hanley Dep. Tr., at 135:5-136:24 and 248:1-249:17.) Dr. Hanley affirmatively stated "[a]nd incidentally, I do need to make a clarification in my report" with respect to combining codes in Table 1 with codes in Tables 2, 3, 4, and 5 and "I do need to make a clarification on that, because clinically" Dr. Hanley sees the clinical conditions together all the time her clinical work.

From a billing perspective, Dr. Hanley stated "I need to clarify" that a baby code would not be used on a maternal chart. (*See, id.*, at 135:5-136:24). Dr. Hanley affirmed that the codes on Exhibit 3 "are clinical diagnoses for scenarios or encounters that I would see in a breastfeeding dyad (*id*., 248:6-14) and would be used by providers to indicate that a patient encounter was for lactation and breastfeeding support (*see, id*., at 248:22-249:17), but "the clarification I needed to make was with respect to coding so not with respect to clinical occurrence" (*id*., at 249:13-16). Dr. Hanley then promptly served her Amended Report to reflect her proffered clarification. There is nothing improper in her doing so.

Dr. Hanley's opinions should be afforded due consideration in evaluating Plaintiffs' Motion for Class Certification.

V. CONCLUSION

For all the foregoing reasons, Defendants' Motion must be denied.

Dated: April 4, 2019

CHIMICLES SCHWARTZ KRINER & DONALDSON-SMITH& LLP

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Counsel for Plaintiffs and the Proposed Classes

CERTIFICATE OF SERVICE

I hereby certify that on April 4, 2019, I served the foregoing **PLAINTIFFS' MEMORANDUM OF POINTS AND AUTHORITIES IN OPPOSITION TO DEFENDANTS' *DAUBERT* MOTION CONCERNING THE EXPERT TESTIMONY AND OPINIONS OF DR. LAUREN E. HANLEY IN CONNECTION WITH PLAINTIFFS' MOTION FOR CLASS CERTIFICATION** on the following counsel of record via email:

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Attorney for Plaintiffs, and Additional Counsel for Plaintiffs identified in Signature Block.

IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

RACHEL CONDRY, JANCE HOY, CHRISTINE ENDICOTT, LAURA BISHOP, FELICITY BARBER, and RACHEL CARROLL on behalf of themselves and all others similarly situated,

Plaintiffs,

v.

UnitedHealth Group Inc.; UnitedHealthcare, Inc.; UnitedHealthcare Insurance Company; UnitedHealthcare Services, Inc.; and UMR, Inc.,

Defendants.

Case No.: 3:17-cv-00183-VC

DECLARATION OF KIMBERLY DONALDSON-SMITH IN SUPPORT OF PLAINTIFFS' MEMORANDUM OF POINTS & AUTHORITIES IN OPPOSITION TO DEFENDANTS' *DAUBERT* MOTION CONCERNING THE EXPERT TESTIMONY AND OPINIONS OF PLAINTIFFS' EXPERT DR. LAUREN E. HANLEY IN CONNECTION WITH PLAINTIFFS' MOTION FOR CLASS CERTIFICATION

Date: April 25, 2019
Time: 10:00 am
Place: Courtroom 4

Honorable Vince Chhabria

I, Kimberly Donaldson-Smith, declare that the following is true and correct:

1. I am a Partner of the firm of Chimicles Schwartz Kriner & Donaldson-Smith, LLP, and am one of the attorneys representing Plaintiffs, Rachel Condry, Jance Hoy, Christine Endicott, Laura Bishop, Felicity Barber, and Rachel Carroll, in the above-captioned matter. I make this declaration in support of Plaintiffs' Opposition to Defendants' *Daubert* Motion Concerning the Expert Testimony and Opinions of Plaintiffs' Expert Dr. Lauren E. Hanley in Connection With Plaintiffs' Motion For Class Certification.

2. I have personal knowledge of the facts set forth herein and, if called as a witness, could testify competently as to the matters stated in this Declaration.

3. Attached hereto as Exhibit "A" is a true and correct copy of the Rebuttal Expert Report of Lauren Elyse Hanley, MD, IBCLC, FACOG, FABM, dated January 18, 2019.

4. Attached hereto as Exhibit "B" is a true and correct copy of the Rebuttal Expert Report of Lauren Elyse Hanley, MD, IBCLC, FACOG, FABM, dated January 25, 2019.

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

Executed on April 4, 2019, in Haverford, Pennsylvania.

/s/ *Kimberly Donaldson-Smith*
Kimberly Donaldson-Smith

Exhibit A

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA

Case No.: 3:17-cv-00183-VC

RACHEL CONDRY, JANCE HOY, CHRISTINE ENDICOTT, LAURA BISHOP, FELICITY BARBER, AND RACHEL CARROLL,

Plaintiffs,

v.

UNITEDHEALTH GROUP, INC.; UNITEDHEALTHCARE, INC.; UNITEDHEALTHCARE INSURANCE COMPANY; UNITEDHEALTHCARE SERVICES, INC.; AND UMR, INC.,

Defendants.

REBUTTAL EXPERT REPORT OF LAUREN ELYSE HANLEY, MD, IBCLC, FACOG, FABM

Dated: January 18, 2019

1. I was retained by the Plaintiffs to provide my December 11, 2019 Expert Report and retained by the Plaintiffs to respond to certain statements made in the Expert Report of Palma D'Apuzzo executed on December 11, 2018 ("D'Apuzzo Report") and the December 11, 2018 Expert Report of Henry Miller, Ph.D ("Miller Report").

2. I understand from counsel that Ms. D'Apuzzo provided an Amended Expert Report on January 16, 2019 at 6:00 pm. Because of the time when it was provided, I did not review the Amended Expert Report for this Report but Counsel advised me that the changes from the D'Apuzzo Report were:

   A. This statement was added: "Summary of amendments: I have amended my report to clarify that my opinion about how breastfeeding services should be billed focuses on the provision of services to women. In sum, my amendments reflect that not all breastfeeding services should be billed under lactation-specific codes, but rather that all breastfeeding services provided to women should be billed in that manner. The changes I have made in these amendments do not change my opinions, but rather are provided to clarify my opinions."

B. The words "for women" were added in Paragraph 12 to the sentence, "The ACA requires most commercial insurance carriers to cover breastfeeding counseling for women."

C. The words "Provided to Women" was added in the Section D heading, "Opinion 2: Breastfeeding Services Provided to Women Should be Billed Under Lactation-Specific Diagnosis and Procedure Codes"

3. In my December 11, 2019 Expert Report and included as Exhibit A to my December 11, 2019 Expert Report, I provided the summary of my qualifications and my Curriculum Vitae, which details my qualifications and experience including publications authored in the previous ten years. I also stated that during the previous 4 years I have not testified as an expert at trial or by deposition. My compensation for this report and testimony in this matter is $500.00 per hour. The information in my December 11, 2019 Expert Report is made part of my Rebuttal Expert Report.

4. In addition to the documents that I stated I considered in my December 11, 2019 Expert Report, I considered the D'Apuzzo Report, the Miller Report and the documents I reference in this Report.

5. Based on my experience, I offer these opinions in response to certain statements that were made in the D'Apuzzo Report:

A. In paragraphs 25-26 of the D'Apuzzo Report, it states that the "The billing codes UHG instructs providers to use are sufficient for providers to accurately bill for lactation related services" which instructions include "UHG's reimbursement policy regarding non-physicians" that "does not allow a provider such as a lactation consultant to bill the E/M codes" and "the CDG does offer an HCPCS code, S9443 (Lactation classes, non-physician provider, per session), for them to utilize in billing services." Based on my experience, I disagree with the statement that UHG's instructions are sufficient for providers to accurately bill for breastfeeding support and counseling services. I also disagree that by offering only the HCPCS code, S9443 (Lactation classes, non-physician provider, per session), non-physician lactation specialists are able to fulfill their professional responsibility to accurately bill. Based on my experience the HCPCS code S9443

does not accurately reflect the breastfeeding support and counseling services that are provided by non-physician lactation specialists.

B. In paragraph 27 of the D'Apuzzo Report, it states that "UHG's policy and practice of not allowing providers to bill for lactation services separately for [] certain periods of time around birth…is consistent with industry practices." Based on my experience, I disagree with the statement that UHG's policy and practice is consistent with industry practices and ACOG's clinical maternity guidance as it relates to breastfeeding support and counseling services. The ACOG Committee Opinions[1] and Post-Partum Coding Guidance[2] refer to discussions with respect to intended methods of feeding and referral to resources other than those provided by the obstetrician-gynecologist as a component of routine care. This guidance is clear that non-routine care is a separately reportable service. In the weeks after birth, if a patient is in need of breastfeeding support and counseling services because she is encountering problems with being able to successfully breastfeed, then that involves a separate service from the obstetrical services package. Ms. D'Apuzzo appears to only view a routine factual inquiry as to whether a patient is breastfeeding, which may be part of a post-birth obstetrics visit, as the full spectrum of the breastfeeding support and counseling services that patients may require. That is incorrect. It is consistent with my experience that in the weeks after birth separately reportable visits related to breastfeeding support and counseling services are an integral and necessary component of the post-partum care plan and often result in referral to a lactation specialist.

C. In paragraph 36 of the D'Apuzzo Report, it states that "If lactation services were billed to an infant record, it would raise concern that either the provider does not understand the coding rules or that the provider made a mistake and billed the

[1] https://www.acog.org/Clinical-Guidance-and-Publications/Committee-Opinions/Committee-on-Obstetric-Practice/Optimizing-Postpartum-Care; https://www.acog.org/Clinical-Guidance-and-Publications/Committee-Opinions/Committee-on-Obstetric-Practice/Optimizing-Support-for-Breastfeeding-as-Part-of-Obstetric-Practice

[2] https://www.acog.org/About-ACOG/ACOG-Departments/Coding/Coding-for-Postpartum-Services-The-4th-Trimester

wrong code." Based on my experience, I disagree with these statements. They reflect a failure to understand the scope of service for breastfeeding support and management. I provided in my December 11, 2018 Report codes and combination of codes that indicate breastfeeding support services occurred during a patient encounter including codes that a provider could appropriately bill to an infant record.

6. Based on my experience, I offer these opinions in response to certain statements in the Miller Report:

A. The Miller Report makes several statements about patients contacting their providers about denial and remark codes. On page 9 of the Miller Report, it states that "For example the first denial statements identified in the Order reads, "This is not a reimbursable service. There may be a more appropriate CPT or HCPCS code that describes this service and/or the use of the modifier or modifier combination is inappropriate. Although the reference to the codes may seem somewhat technical, it is reasonable to expect that members will contact their providers in response to this denial reason." On page 10, the Miller Report states that "it is reasonable to expect the member who receives a denial regarding a CPT and HCPCS would contact the provider to address the issue…" On page 10, the Miller Report also states that, "Again, it is reasonable to expect that members will reach out to their provider or UHG if they have questions about this remark code. . ." Finally, on page 10, the Miller Report states: "Alternatively, the member may contact his or her provider."

B. Based on my experience, I disagree with statements that it is reasonable to expect that patients will contact their providers about denials regarding a CPT or HCPCS, and the assumption that providers can and will provide a response.

C. Based on my experience, if the service is not a reimbursable service, that is between the patient and the insurance company. It would be inappropriate for a provider to change the CPT or HCPCS code for a service based on a remark code. It is a provider's professional responsibility to bill a CPT or HCPCS code that accurately describes the service.

D. Based on my experience, providers are not trained on remark codes generally or specifically as to any insurance company's remark codes. It is not an industry standard or reasonable to state that a provider is to interpret and explain an insurance company's remark codes to patients. It is not an appropriate function, and it is not part of any provider contract of which I am aware, for a provider to interpret an insurance company's remark codes for patients.

E. On page 11 of the Miller Report, it states that "determining whether a member paid out of pocket for a health care service would require an individualized analysis of multiple factors, including whether the provider billed the patient for the cost-share or other amount, and whether the member actually paid that amount." In my experience, an insurance company states whether I am to charge a co-pay and co-insurance for the services provided for a patient, and I am not permitted to waive those charges.

7. The opinions expressed in this report are based on my review of information and documents received by me to date. I am also aware that Defendants in the above referenced Action may retain experts that may respond to my December 11 Expert Report or this report. I reserve my right to modify or supplement my opinions based on additional information that may be provided in the future, and also the right to reply to any response to either of my reports by any expert retained by Defendants.

Executed this 18th day of January, 2019

LAUREN ELYSE HANLEY, MD

Exhibit B

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA

Case No.: 3:17-cv-00183-VC

RACHEL CONDRY, JANCE HOY, CHRISTINE ENDICOTT, LAURA BISHOP, FELICITY BARBER, AND RACHEL CARROLL,

Plaintiffs,

v.

UNITEDHEALTH GROUP, INC.; UNITEDHEALTHCARE, INC.; UNITEDHEALTHCARE INSURANCE COMPANY; UNITEDHEALTHCARE SERVICES, INC.; AND UMR, INC.,

Defendants.

REBUTTAL EXPERT REPORT OF LAUREN ELYSE HANLEY, MD, IBCLC, FACOG, FABM

Dated: January 25, 2019

1. I was retained by the Plaintiffs to provide my December 11, 2019 Expert Report, to respond to certain statements made in the Expert Report of Palma D'Apuzzo executed on December 11, 2018 ("D'Apuzzo Report") and the December 11, 2018 Expert Report of Henry Miller, Ph.D ("Miller Report"), and to respond to certain statements made in the Expert Report of Henry Lee, MD executed on December 11, 2018 ("Lee Report"). My response to the D'Apuzzo and Miller Reports is contained in my Rebuttal Expert Report dated January 18, 2019. My response to the Lee Report is the subject of this Rebuttal Expert Report.

2. In my December 11, 2019 Expert Report and included as Exhibit A, I provided the summary of my qualifications and my Curriculum Vitae, which details my qualifications and experience including publications authored in the previous ten years. I also stated that during the previous 4 years I have not testified as an expert at trial or by deposition. My compensation for this report and testimony in this matter is $500.00 per hour. The information in my December 11, 2019 Expert Report is made part of my Rebuttal Expert Report.

3. In addition to the documents that I stated I considered in my December 11, 2019 Expert Report, I considered the Lee Report and the documents I reference in this Report.

4. Based on my experience, I offer opinions in response to certain statements that were made in the Lee Report:

A. "As discussed more fully below, lactation counseling typically encompasses the care women receive from multiple healthcare providers in the antepartum and post-partum periods, as well as during the in-patient stay associated with the delivery." (Lee Report page 1).

B. "Thus, the pediatrician is the main point of contact for the mother and infant in providing breastfeeding services as well as the broad goal of optimal nutrition and growth starting at the hospital, in the transition to home, and then in the days, weeks and months to follow." (Lee Report page 3).

C. "In summary, breastfeeding and lactation counseling will often encompass the care provided by multiple healthcare providers, starting prior to childbirth, during the childbirth hospitalization, and afterwards. These services are provided by obstetricians, nurses, pediatricians, and sometimes lactation consultants. Women are exposed to and made aware of these providers throughout the various stages of pregnancy and expected postpartum visits, both for themselves and their children." (Lee Report pages 3 and 8 Conclusion).

D. "Although not all women give birth in the hospital, with some women giving birth with the assistance of midwives outside the hospital, midwives may provide the same support and information about breastfeeding as obstetricians and thus render lactation counseling and education to women prior to and immediately following childbirth." (Lee Report page 3 footnote 1).

5. Dr. Lee emphasizes the care provided by multiple healthcare providers "starting prior to childbirth", "during the childbirth hospitalization" and afterwards[1] but fails to understand: (1) the significant and material deficiency of access to trained lactation specialists and experts in the clinical management of breastfeeding, (2) the material gaps in physicians' education, training and experience regarding breastfeeding support and counseling, and (3) an absence of coordinated care among providers during the post-partum period. Dr. Lee implies that the hand-off of care from a hospital team or mid-wife to a pediatrician provides adequate and complete patient access to breastfeeding and lactation counseling; I disagree.

[1] Lee Report p 8 Conclusion; similar opinion expressed on pages 1 and 3.

A. Dr. Lee opines that the pediatrician is the "main point of contact for the mother and infant in providing breastfeeding services."[2] While a pediatrician may be the primary health care provider for the infant, it cannot be extrapolated from that relationship that the pediatrician provides breastfeeding support services; nor can it be extrapolated that a pediatrician or a pediatrician's practice as a whole provides comprehensive lactation services ("CLS").

B. The Physician Engagement and Training focused on Breastfeeding project is a project, funded through a grant by the Centers for Disease Control and Prevention ("CDC"), currently in its implementation phase. This project originated with a grant to the American Academy of Pediatrics ("AAP") by the CDC. The AAP along with representatives of 11 other organizations, including the American College of Obstetricians and Gynecologists ("ACOG"), formed a Project Advisory Committee to conduct research, develop a comprehensive staged action plan and develop resource dissemination.[3]

C. The resulting Physician Education and Training on Breastfeeding Action Plan was issued by the AAP in 2018 ("Physician 2018 Breastfeeding Action Plan") specifically designed to, among other goals: (1) engage physicians and stakeholders to address the continuing material and significant gaps in breastfeeding training and education of physicians and (2) "develop a scope of practice for physicians in breastfeeding and describe other members of the health care team and lay personnel who provide breastfeeding support and how physicians might refer and or consult with them."[4]

D. The Physician 2018 Breastfeeding Action Plan is consistent with the recommendations of the ACOG Committee Opinion number 756 ("ACOG 756")

[2] Lee Report p 2.
[3] *Id.*
[4] Physician Education and Training on Breastfeeding Action Plan. This action plan is supported by the American Academy of Pediatrics Physician Engagement and Training Focused on Breastfeeding Project, a grant from the Centers for Disease Control and Prevention, Division of Nutrition, Physical Activity, and Obesity, Department of Health and Human Services; Cooperative Agreement 6 NU38OT000167-04-01. 2018. https://www.aap.org/en-us/advocacy-and-policy/aap-health-initiatives/Breastfeeding/Pages/Physician-Education-and-Training-on-Breastfeeding-Action-Plan.aspx Last visited January 21, 2019.

dated October 2018[5] in its aspirational goals for physician development and maintenance of "skills in anticipatory guidance, support for normal breastfeeding physiology, and management of common complications of lactation"[6] and recognition that "education surrounding lactation is often lacking in graduate and postgraduate medical education."[7]

1. As a co-author of ACOG 756, my intent was to convey that uniform breastfeeding knowledge and application in practice is an aspirational goal. The objective of an enhanced breastfeeding support role, expanded specified training and continuing education opportunities are among the goals of the Physician 2018 Breastfeeding Action Plan.
2. Further, when ACOG 756 refers to management of common complications of lactation, this is not intended to include all aspects of the clinical management of breastfeeding. Even if the aspirational goals were achieved, lactation specialists (physicians skilled in breastfeeding medicine, International Board Certified Lactation Consultants ("IBCLCs") and Certified Lactation Counselors ("CLCs") will continue to be needed as vital members of a CLS team.

E. The specialties of pediatrics and obstetrics/ gynecology each focus care on one half of the breastfeeding relationship; to date, neither specialty absent additional specific lactation training, has a scope of care that encompasses the full scope of conditions necessary to provide the clinical management of breastfeeding. As a two-person activity, the breastfeeding dyad may be influenced by conditions affecting the mother, the infant or both. Early cessation of breastfeeding primarily occurs due to the failure to: (1) properly identify and address emerging concerns and/or (2) provide adequate timely support when challenges emerge, often soon following hospital discharge.[8] This imbalance of knowledge among physicians,

[5] https://www.acog.org/-/media/Committee-Opinions/Committee-on-Obstetric-Practice/co756.pdf?dmc=1&ts=20181007T0234383136 last visited January 21, 2019
[6] *Id.*. p e190.
[7] *Id*. p e188.
[8] Based on my professional experience and the lactation related research, including but not limited to: Odom, Scanlon, Perrine, Grummer-Strawn, Reasons for Earlier than Desired Cessation of Breastfeeding, *Pediatrics*. 2013 March; 131(3); e726-e732. https://www.ncbi.nlm.nih.gov/pubmed/23420922, last visited January 22, 2019.

the frequent failure of coordination of care between a pediatrician and an obstetrician/gynecologist, and the significant consequences that derived from it, are among the present conditions the Physician 2018 Breastfeeding Action Plan seeks to address.

F. As recommended in ACOG 756, timely triage of breastfeeding concerns and identification of clues to breastfeeding challenges are vital and referral to a certified lactation professional such as an IBCLC is a critical component of the clinical management of breastfeeding.[9] It is not possible to provide a full complement of CLS in the absence of the availability of trained lactation specialist providers such as physicians trained in breastfeeding medicine, IBCLCs and other lactation consultants such as a CLC[10].

6. In my professional opinion, there remains a significant unmet need for post-partum breastfeeding support and counseling by trained lactation specialist providers. In my practice, approximately 90% of mothers initiate breastfeeding, and most require support following discharge from the hospital with the first 1 to 2 weeks being the most vulnerable. Access to skilled lactation care during these first two weeks is often critical to successful sustained breastfeeding. The time proximate to the mother returning to work or school is another vulnerable time, as well as any period of maternal or infant illness. Many women experience financial difficulty seeking lactation services that are not covered by their medical insurance or where they are required to pay upfront out of pocket; this hurdle directly impacts the scope of care they receive and contributes to their breastfeeding goals not being met. In my experience, many women struggle to identify a provider who can address their breastfeeding concerns and challenges.

7. Physicians with advanced training in breastfeeding medicine and IBCLCs are provided specified training directed to the care of both the mother and the infant in the context of breastfeeding[11]. IBCLCs are required to submit documentation to other members of the patients'

[9] ACOG #756, p e192.
[10] In my experience, when referring to a lactation consultant, I prefer referral to an IBCLC because an IBCLC training is the most comprehensive, including specific clinical training. In some instances, with more routine concerns a CLC, especially when a CLC who also is an RN, may have a sufficient scope of care to address the condition.
[11] https://iblce.org/wp-content/uploads/2017/05/ibclc-detailed-content-outline-for-2016-for-publication.pdf, last visited January 22, 2019.

health care team, which provides vital information to all care providers to the breastfeeding dyad.[12]

8. I recommend that all pregnant mothers have the opportunity to receive counseling from a lactation specialist before birth and be offered a minimum of one visit during the first two weeks following discharge from the hospital.[13] Additionally, the need for sustained trained lactation specialist provider support in addition to the pediatrician and obstetrician/gynecologist care is critical for many conditions, including, but not limited to multiple gestation, preeclampsia, hypertension and/or diabetes. Pre-term infants and early term infants (birth at or near 36 weeks) require specific sustained lactation specialist support in addition to the pediatrician and obstetrician/gynecologist care. Continuation of coordinated care, including lactation specialists, is required for infants who received care in the neonatal intensive care unit ("NICU") or Level II nursery in the hospital. The integrated health care team of the NICU or Level II nursery typically includes lactation specialists as a core member. Upon discharge, these babies are particularly vulnerable and at risk of early cessation of breastfeeding, thus it is vitally important for these mothers and infants to have access to a lactation specialist in an outpatient setting.

9. While some midwives have additional training as lactation specialists, not all midwives are trained in lactation and breastfeeding support. Like physicians, such midwives require a lactation specialist as part of the health care team.

10. The opinions expressed in this report are based on my review of information and documents received by me to date. I reserve my right to modify or supplement my opinions based on additional information that may be provided in the future, and the right to reply to any response to any of my reports by any expert retained by Defendants.

[12] https://iblce.org/wp-content/uploads/2017/05/code-of-professional-conduct.pdf, last visited January 22, 2019.
[13] This recommendation is based on my professional experience and the lactation related research, including but not limited to: Wagner, Chantry, Dewey, Nommsen-Rivers; Breastfeeding Concerns at 3 and 7 days postpartum and feeding status at 2 months, *Pediatrics* 2013 Oct, 132(4): e865-75. https://www.ncbi nlm nih.gov/pubmed/24062375

Executed this 25th day of January 2019

LAUREN ELYSE HANLEY, MD