

## Appendix 1. *Obstetrics & Gynecology* Disclosure: Richard S. Legro, M.D., 10/20/2020

**Title:** Chair and University Professor, Department of Obstetrics and Gynecology  
Professor of Obstetrics and Gynecology and Public Health Sciences

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Please indicate whether you have financial relationships (regardless of amount of compensation) with entities. You should report relationships that were present during the 36 months prior to submission including board membership, consultancy, employment, expert testimony, grants/grants pending, payment for lectures including service on speakers bureaus, payment for manuscript preparation, patents (planned, pending or issued), royalties, payment for development of educational presentations, stock/stock options, travel/accommodations/meeting expenses unrelated to activities listed (for example, if you report a consultancy above there is no need to report travel related to that consultancy), etc

### Board Membership

PCOS Challenge (patient support group) Member, Medical/Scientific Advisory Board 2017-Present

Endocrine Society: Member Executive Committee, 2015-18, Secretary-Treasurer, Secretary-Treasurer 2016-2018, Member Investment Subcommittee 2018-Present

*Member*, International Advisory Board and Guideline Committee, National Health and Medical Research Council (NHMRC) funded Centre for Research Excellence (CRE) in Polycystic Ovary Syndrome (PCOS), Melbourne Australia, June 2016-May 2018

### Editorial Boards:

Co-Editor in Chief, Seminars in Reproductive Medicine, 2015-2019  
Associate Editor, Human Reproduction Update, 2017-20  
Associate Editor, Fertility and Sterility, 2009-2020  
Editorial Editor, Fertility and Sterility, 2020-Present  
Associate Editor, Global Reproductive Health, 2017-Present  
Editorial Board, Endocrinology 2016-2019,

### Consultant Grant Reviewer:

**NIH:** ZHD1 DSR-K (LR) 1 Loan Repayment Program (Annually, 2008-Present), U54 Contraceptive Center Grant, Special Emphasis Panel ZHD1 DSR – L50 (2017), Special Emphasis Panel/Scientific Review Group 05 CHHD-W 1 Population Sciences Subcommittee (2018), Special Emphasis Panel/Scientific Review Group 10 ZHD1 DSR-M (55): National Centers for Translational Research in Reproduction and Infertility (2020).

Downs DS, Pauley AM, Leonard KS, Satti M, Cumbo N, Teti I, et al. Obstetric physicians' beliefs and knowledge on guidelines and screening tools to reduce opioid use after childbirth. *Obstet Gynecol* 2021;137.

The author provided this information as a supplement to their article.

**Misc:** Kuwait Foundation for the Advancement of Science (KFAS) (2017)  
Appalachian Translational Research Network (ATRN) (2018), Karolinska Institute,  
Stockholm Sweden (2020)

**Consultant Pharmaceutical:** (Ongoing, last date of consulting): Insudd (2020), Bayer (2019), Fractyl (2019),  
Abbvie (2019), Ferring (2018)

### **Data Safety Monitoring Board Service**

Chair, Data Monitoring Committee, The Fertility, IVF and Intrauterine Insemination trial in couples with  
uneXplained infertility (the FIIX study), Sponsor: University of Auckland, Trial Registration:  
ACTRN12619001003167, Principle Investigator: Professor Cynthia Farquhar, Initiated January 2019

### **GRANTS/ GRANTS PENDING**

#### **ACTIVE**

5 R01 HD091350-04	Dokras/Legro (PI)	08/01/17-04/30/22	0.6 Calendar
NIH/University of Pennsylvania		\$1,489,384	

The COMET-PCOS Trial: Comparing the effects of Oral Contraceptive Pills versus Metformin in the medical  
management of overweight/obese women with Polycystic Ovary Syndrome

Our working hypothesis states that OCPs, through lowering the androgenic profile, and metformin, through  
improvement in insulin sensitivity, affect the development of MetSyn in overweight/obese women with PCOS and,  
thus, contribute in altering the risk profile for the development of diabetes and CVD.

*Overlap:* There is no overlap for the grant for which the non-competing renewal is being submitted.

5 R01AT009484-02	Legro (PI)	09/01/18-08/31/22	1.8 Calendar
NIH/NCCIH		\$2,120,403	

Inositol Supplementation to Treat Polycystic Ovary Syndrome: A Double Blind Dose Ranging RCT (INSUPP-P

This is a four group dose ranging study in which we are studying a widely used dietary supplement that may  
have a broad indication across all phases of the lifespan of a woman with PCOS. We are performing this under  
an IND and contraception is required.

COS)

*Overlap:* None

Guerbet USA	Legro (PI)	06/26/18-06/25/21	0.18 Calendar
Investigator Initiated/Industry		\$84,858	

Therapeutic Effect of Sonographic Hysterosalpingography: Oil vs. Water Based Media: The SHOW Pilot Trial

This is a pilot randomized study to assess the willingness of subjects undergoing sono HSG to be randomized  
into a saline based Sono HSG compared to an oil based test.

*Overlap:* None

5 U10HD055925-10REV	Legro (PI)	12/01/2019 – 11/30/2020	0.6 Calendar
Data Coordinator Center for the RMN		\$324,728	

This revised award extends the budget and project end dates for the PSU Repository to store and maintain  
samples shipped from the biorepository, the RMN clinical sites and the UVA Core laboratory.

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screening tools to reduce opioid use after childbirth. *Obstet Gynecol* 2021;137.

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Hass Avocado Board Kris-Etherton (PI) 12/01/17-12/31/20 0.6 Calendar  
 Pennsylvania State University Park \$1,532,000  
 A Multi-Site Randomized Clinical Trial to Compare Healthy Eating Recommendations for Six Months on Changes in Visceral Adiposity in Overweight/Obese Americans (Penn State Avocado Study)  
 This study will evaluate the effect of consumption of one avocado per day on established parameters of health including: visceral adiposity, hepatic lipid content, markers of metabolic syndrome and hsCRP compared to only nutrition education.  
*Overlap:* None

5 UL1 TR002014-04 Sinoway (PI) 09/15/16-05/31/20 1.56 Calendar  
 Penn State Clinical and Translational Science Institute \$15,614,466 (0.6 contributed)  
 This new application for a CTSA at Penn State builds on our efforts to reshape the University's clinical and translational science (CTS) enterprise toward continually improving the Institute's research support and resource use and seeking novel directions for growth, we have worked closely with both Internal and External Advisory Committees. Role: HUB Capacity Leader  
*Overlap:* None

5 R01 HD083323-04 McAllister/Strauss (PI) 09/15/16-05/31/21 0.24 Calendar  
 NIH/NICHD \$2,667,472  
 Functional Analysis of PCOS Candidate Genes  
 These studies will clarify the molecular pathology of the PCOS and identify new approaches to diagnosis and therapy.  
*Overlap:* None

**PROJECTS FUNDED SINCE LAST REPORT:**

1 R01HD100630-01 McAllister(PI) 06/01/2019-02/28/2021 0.36 Calendar  
 NIH \$1489,711  
 AMH Signaling Pathway Variation in PCOS  
 This proposal is to identify the function of PCOS causal variants in the broader AMH signaling pathway which will explain the molecular basis and phenotypic heterogeneity of PCOS and the successful implementation of Precision Medicine.

**PENDING PROPOSALS**

UL1 TR002014 Sinoway(PI) 07/01/2021 – 06/30/2026 1.56 Calendar  
 National Center for Advancing Translational Sciences \$22,113,244  
 This project builds on the Institute's cross-university foundation and generates innovation, enables efficient research, educates the existing and next generation of scientists and focuses on the health needs of rural communities.

**COMPLETED PROJECTS SINCE LAST REPORT:**

5 U10 HD038992-15(Ext) Legro (PI) 07/01/07-06/30/19 2.4 Calendar  
 NIH \$269,274  
 Cooperative Multicenter Reproductive Medicine Network (RMN)

A RCT of preconception weight loss vs. OCP in overweight infertile PCOS women  
 In this competing renewal of our RMN site, we will continue our excellent track record of performance in infertility trials. We propose as a concept protocol, a two arm clinical trial of a preconception intervention of weight loss vs continuous OCP in overweight/obese women with PCOS designed to improve live birth rates. This study addresses an important public health issue on how to best treat infertility in overweight/obese women.

*Overlap:* None

5 U10 HD038992-10 (Ext) Legro (PI) 12/01/2017-11/30/2019 Effort Stated on Parent Grant  
 NIH/NICHD \$245,842

Yale University Data Coordination Center for the Reproductive Medicine Network.

Patient Care Costs

*Overlap:* None

5 R01 HL119245-05 Downs (PI) 08/15/13-04/30/19 0.36 Calendar  
 NIH/NHLBI \$255,157

Control Systems Engineering for Optimizing a Prenatal Weight Gain Intervention

This research project uses dynamical modeling and control systems engineering to develop an individually-tailored (adaptive) behavioral intervention for managing gestational weight gain among overweight and obese pregnant women.

*Overlap:* None

Wright State University (Ext) Lindheim (PI) 01/01/17-10/31/19 0.12 Calendar  
 Patty Brisben Foundation for Women's Sexual Health \$12,753

Evaluation of Vitamin D With and Without Hormonal Contraception on Sexual Function in Women with Polycystic Ovary Syndrome

This study will assess the impact of PCOS on Quality of Life and Sexual Function and evaluate possible benefits of Vitamin D in combination with oral contraceptives.

*Overlap:* None

**FOREIGN INFLUENCE (includes compensated travel and honoraria):**

2010-2017 Longjiang Scholar, Chair Professorship, Heilongjiang University, Harbin, China  
 Thousand Talents Program Fellowship (Grant) (2015-Feb 2017). This grant was designed to teach courses on reproduction, obstetrics and gynecology to train research personnel in performing clinical trials. I also assisted in designing trials aiming at the integration of Western and Chinese medicine. My participation at the university and in the Thousand Talents Program ended after publication of our PCOS-Act acupuncture trial in 2017.

2012-Present Honorary Professor, National Research Center for Assisted Reproductive Technology and Reproductive Genetics, Shandong University, Jinan, China. This participation involved formation of a multicenter clinical trial network to perform randomized trials in in vitro fertilization. We have multiple completed studies and ongoing clinical trials. I am a member of the steering committee and participate in the development of protocols, ongoing review of protocols and author of articles. We meet 2 times a year in China for steering committee meetings.

2015-2018. Member, International Advisory Panel, International evidence-based guideline for the Assessment and management of Polycystic Ovary Syndrome (PCOS), funded by The Australian National Health and Medical Research Council (NHMRC) through the Centre for Research Excellence in Polycystic Ovary Syndrome (CREPCOS), Monash University, Melbourne Australia.

Downs DS, Pauley AM, Leonard KS, Satti M, Cumbo N, Teti I, et al. Obstetric physicians' beliefs and knowledge on guidelines and screening tools to reduce opioid use after childbirth. *Obstet Gynecol* 2021;137.

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We had multiple international meetings in Europe and Australia assembling these guidelines which were published in 2018.

- 2016-Present Member, Steering Committee. Eastern Siberia PCOS Epidemiology & Phenotype study, Scientific Center of Family Health and Human Reproduction, Irkutsk, Russian Federation. This is a population based research study. I participated in the development of the protocol, its implementation and will assist in publications. This has involved a trip to Siberia and meetings at national and international conferences.
- 2017-Present Member, International Advisory Panel, Developing, disseminating and implementing a core outcome set for infertility. Funded by the Royal Society of New Zealand Catalyst Fund and the University of Auckland, New Zealand. This involved meetings in New Zealand and Europe and eventual publication of the core outcome set.
- 2019-2021 Advisor, A metabolomic approach to redefine diagnostic criteria and classification of polycystic ovary syndrome (PI: Professor Chi Chui Wang, Chinese University of Hong Kong). This involves analyzing 1600 samples of patients through various -omic technologies. Funded by the Research Fund, Food and Health Bureau, The Government of the Hong Kong Special Administrative Region. There are no in-person meetings.

#### **Payment for Lectures (NOTE: I am not on any speaker's bureaus)**

#### **Invited Presentations for National and International Meetings With Travel Compensation and/or Honoraria**

1. Invited Speaker and Faculty Member, "Ovulation Induction in PCOS", "Treatment of Hirsutism in PCOS", "Treatment of the Metabolic Syndrome in PCOS" Master Class in PCOS, Hanoi, Vietnam, January 19-21, 2017
2. Invited Speaker, "Use of Oral Ovulation Induction Agents in PCOS" Annual Meeting of the Reproductive Endocrine Society of China, Guangzhou, China, February 25, 2017
3. Invited Speaker, "Why Does an Euploid Embryo Not Implant: Lessons from Clinical Trials" Reproductive Medicine and Beyond: What more can we do to understand the process and to improve our results?, 7th International IVI Congress, and "Clinical IVI Investigator Award Lecture", Spain, May 11-13, 2017
4. Invited Speaker and Visiting Professor, University of Auckland, Auckland, New Zealand, Lecture 1: Insulin Resistance vs Hyperandrogenism in PCOS: Etiology and Treatment Consideration. Lecture 2: What has the Human Genome Project taught us about PCOS?. Lecture 3: The Construction of Multi-Faceted Clinical Trials: Beyond Primary and Secondary Hypotheses (Seminar) Public lecture: Obesity and Fertility in Women: Can we and should we treat obesity prior to conception? July 31-August 13, 2017
5. Invited Speaker, "Evidence Based Long Term Care in Women with PCOS" Symposium: Update on Polycystic Ovarian Syndrome, The University of Auckland, Auckland NZ August 10, 2017-08-22
6. Invited Speaker "Fertility Plus critique: Analysis and Recommendations for 2016 ART Results" and "Perspectives on whether NZ should lower the BMI threshold for Fertility treatment" National Women's Annual Clinical Report, Auckland DHB National Women's Hospital, Auckland NZ, August 11, 2017
7. Invited Speaker, "Ovulation Induction in PCOS: Best Practices" and "Treatment of Obesity in Infertile Patients: Is there any Benefit?" 11th Croatian Congress on Gynaecological Endocrinology, Human

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Reproduction and Menopause. Brijuni, Croatia September 7-10<sup>th</sup>, 2017

8. Invited Speaker “Genomics in the Diagnosis and Management of PCOS” Paediatric & Adolescent Gynecology Working Group Symposium, 10th International Meeting of Pediatric Endocrinology, Washington DC, September 14, 2017
9. Invited Speaker, “OCP and Progestins in PCOS: Benefits and Harms”. 15<sup>th</sup> Annual Meeting of the AE-PCOS Society, San Antonio, TX, October 27<sup>th</sup> 2017
10. Invited Speaker and Symposium Chair, “Fresh versus Frozen Embryo Transfer in Women with Polycystic Ovary Syndrome: What is the Evidence and What Are the Mechanisms?” and Roundtable Leader, “When to Use Clomiphene and When to Use Letrozole” ASRM 2017 Scientific Congress, San Antonio, Texas, October 28 – November 1, 2017
11. Invited Speaker, Preconception Interventions in Women with Polycystic Ovary Syndrome “The Patrick Steptoe Memorial Lecture” FERTILITY 2018 CONFERENCE. Annual Meeting of the The British Fertility Society (BFS), the Association of Clinical Embryologists (ACE) and the Society of Reproduction and Fertility (SRF). Liverpool, UK, 4-6 January 2018
12. Invited Speaker and Faculty Member, “Long Term Medical Complications in Women with PCOS” “Non-Contraceptive Use of the OCP: Risks and Benefits”, “New Medical Treatments for Leiomyomas and Endometriosis” University of Colorado 44<sup>th</sup> Annual Vail Obstetrics and Gynecology Conference, Feb 18-23, 2018
13. Invited Symposium Chair. An International Initiative to Improve Outcomes in PCOS: Evidence-based Guidelines and Endocrine Society's 100th Annual Meeting & Expo (ENDO 2018) Chicago, Illinois Mar 20 2018
14. Invited Speaker and Faculty Member, “Obesity and Fertility in Women: Can We and Should We Treat Obesity Prior to Conception?” and “Evidence Based Long Term Care in Women with Polycystic Ovary Syndrome.” 9<sup>th</sup> Endocrine Summit, Mumbai, India, April 27-28, 2017.
15. Invited Speaker, 1/07/18 "Fertility Treatment in PCOS part 1: what to do step by step? Clomiphene, Aromatase inhibitors, Metformin, Weight reduction, FSH low dose step up" Precongress Course: PCC07: The PCO syndrome: From diagnosis to health risk management. At the 34th Annual Meeting of the European Society of Human Reproduction and Embryology (ESHRE), Barcelona, Spain July 1, 2018
16. Invited Speaker, “PCOS, Obesity and Pregnancy: Effects and Treatment” at the Interactive Session: Polycystic Ovary Syndrome: Obesity and Lipids” at the 2018 ASRM Scientific Congress in Denver, Co, October 10, 2018.
17. Invited Speaker, “Effect of Periconceptional Lifestyle Interventions on Fertility Outcomes” and “Achieving Optimal Ovulation and Pregnancy Outcomes in Women with Polycystic Ovary Syndrome”. 28<sup>th</sup> Brazilian Congress of Human Reproduction, Belo Horizonte, Brazil, Nov 14-16, 2018.
18. Invited Speaker and Panel Member, Lecture: “Challenges of Managing the Infertile Patient with PCOS”, Panel Member “Systemic Disease Associated with Infertility”, “Case Studies in Polycystic Ovary Syndrome”. 2019 IFFS World Congress, Shanghai China, April 11-14, 2019

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19. Invited Speaker, "Top Treatments of Infertility in Women with PCOS" in Session; Edtalks: PCOS presented at the Annual Meeting of ACOG, Nashville, TN, May 4<sup>th</sup>, 2019
20. Invited Speaker, "Management of PCOS in Adults", Best Infertility Treatments in Women with PCOS" At the: 30 Años Aniversario IDIMI (Instituto de Investigaciones Materno – Infantil, Universidad de Chile) Eje Gonadal, Genética y Ambiente. Desde la Infancia a la Adulthood, Santiago Chile May 23-24, 2019
21. Invited Speaker, "Research priorities in fertility treatments: Female and Unexplained Infertility Topics", At the 35th Annual Meeting of the European Society of Human Reproduction and Embryology (ESHRE), Vienna, June 25<sup>th</sup>, 2019
22. Invited Speaker, "Protective Mechanisms against Pregnancy Loss in Women with PCOS", PEACOCKS Biennial Meeting, Mas de Torrent, Costa Brava, Spain, September 28, 2019
23. Invited Speaker, "The Evolving Long Term Treatment of Polycystic Ovary Syndrome" 2019 Canadian Society of Endocrinology and Metabolism/Diabetes Canada Professional and Annual Meeting, Winnipeg, Manitoba, October, 4, 2019
24. Invited Speaker, "What have we learned about the treatment of PCOS from clinical trials" University of California at San Diego Ob/Gyn Grand Rounds. San Diego, CA, October. , 2019
25. Invited Speaker, "The Obesity Society President's Symposium: Are the Cards Stacked Against Us? The Intergenerational Transmission of Obesity: Lecture title: Obesity and Its Implications on Fertility. Obesity Week, Las Vegas, November 4, 2019
26. Visiting Professor and Invited Speaker, Seminars in Obstetrics, Gynecology and Reproductive Biology, The Genetics of Polycystic Ovary Syndrome: The Long and Winding Road, Grand Rounds Obstetrics and Gynecology: Polycystic Ovary Syndrome: Lessons from Clinical Trials, University of Kansas Medical Center, Kansas City, Kansas, November 13-15, 2019
27. Invited Webinar Speaker, "How to select a research topic from clinical practice & How to design a high quality trial." Human Reproduction Update Chinese Edition Young Editor Meeting. April 23, 2020.
28. Invited Webinar Speaker, "Is Periconception Weight Management in Women with Obesity Harmful or Just Futile?" Obesity and Women's Health Webinar: NIH Obesity Research Task Force (ORTF) Seminar Series, September 10, 2020.

#### **Invited Presentations for Lectureships With Travel Compensation and/or Honoraria**

1. Invited Speaker, "Overview of PCOS: Best Treatment Practices" Department of Ob/Gyn Grand Rounds, SUNY Stony Brook, October 11, 2017
2. Invited Speaker, "Obesity Treatment in Women and Fertility Outcomes: The Tangled Web" The Milton McCall Memorial Lecture, Annual Alumni Day of Magee Womens Hospital/University of Pittsburgh, Pittsburgh, PA, October 20, 2017
3. Invited Lecturer, Walter Futterweit Annual Endowed Lecture, Achieving Optimal Ovulation and Pregnancy Outcomes in Women with Polycystic Ovary Syndrome, Division of Medical Endocrinology, Department of Medicine, Mount Sinai School of Medicine, December 14, 2017, New York, NY

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4. Invited Speaker, "Role of Lifestyle Modification (and other treatments) in the treatment of PCOS" Grand Rounds, Department of Ob/Gyn, Yale University School of Medicine, New Haven, CT May 10, 2018
5. Invited Speaker, "Obesity and Fertility in Women: Can We and Should We Treat Obesity Prior to Conception?" Grand Rounds, Division of Medical Endocrinology, Yale University School of Medicine, New Haven, CT May 11, 2018
6. Invited Speaker and Resident Research Day Judge, Effect of Periconceptional Lifestyle Interventions on Fertility Outcomes, Dept of Ob/Gyn West Penn Hospital, June 15, 2018
7. Invited Speaker and Resident Research Day Judge, Preconception Interventions in Women with Polycystic Ovary Syndrome: Do they work? The Roland S. Kron Annual Lecture, Dept of Ob/Gyn, Medical College of Wisconsin, Milwaukee, WI, June 20, 2018.
8. Invited Speaker, "Improving Pregnancy Outcomes in Patients with Obesity". Penn State College of Medicine Emeritus Faculty Organization Spring Meeting, Penn State College of Medicine, Hershey, PA, April 18, 2019.
9. Inaugural Chair Lecture. Clinical Trials in Women and their Tribulations, Penn State College of Medicine, Hershey, PA, June 11, 2019.
10. Webinar Speaker, The PCOS Society of India, "Optimizing Ovulation Induction in Women with Polycystic Ovary Syndrome, August 30, 2019.
11. Grand Rounds Speaker, "Perturbing the Hypothalamic Pituitary Ovarian-Periphery Axis to treat Gynecologic Disorders", Department of Obstetrics and Gynecology, Penn State College of Medicine, Nov 20, 2019
12. Physician Assistant Student Lecture, "Polycystic Ovary Syndrome". Penn State College of Medicine, February 12<sup>th</sup>, 2020.
13. Endocrine Grand Rounds, "Fitness or Fitless? What is best for pregnancy in women with obesity?" Penn State College of Medicine, February 19<sup>th</sup>, 2020.
14. Grand Rounds Speaker, "Lessons for the Clinic from the FIT-PLEASE Trial". Department of Obstetrics and Gynecology, Penn State College of Medicine, September 23, 2020.

**PAYMENT FOR MANUSCRIPT PREPARATION: NONE**

**PATENTS (PLANNED, PENDING OR ISSUED): NONE**

**ROYALTIES: NONE**

**PAYMENT FOR DEVELOPMENT OF EDUCATIONAL PRESENTATIONS: NONE**

**STOCK/STOCK OPTIONS:** I own 500 shares of Biodesix (BDSX)

**TRAVEL/ACCOMMODATIONS/MEETING EXPENSES UNRELATED TO ACTIVITIES LISTED: NONE**

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