CURRICULUM VITAE

Identification

Name: Ilan Irony
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Licensure Information

Maryland Medical License Number D42786

Board Certification

1. Endocrinology, Diabetes and Metabolism – 1997 Recertified until 2027
2. Internal Medicine – 1995 Recertified until 2025

Current Position

9/2021 – Present Senior Director – Global Regulatory Lead
Janssen Research and Development
Johnson and Johnson Family of Companies

In this position, located in the Cardiovascular, Metabolism and Retina (CVMR) therapeutic area, I am primarily responsible for the global regulatory work for products in my portfolio, including a gene therapy and small molecule drugs intended for treatment of retinal disorders. However, my role is substantially expanded to include:

- Regulatory and clinical review of assets undergoing due diligence, from discovery to late development
- Guidance to other product leads in CVMR, as well as in other therapeutic areas
- Consultation with other regulatory and clinical leadership for advanced development programs in preparation for Development Committee review
- Lead training and provide consultation expertise in cellular and gene therapies and rare diseases for all Janssen programs
- Representing Janssen before outside organizations such as World Health Organization on regulatory convergence, BIO, Alliance for Regenerative Medicine on issuing public comments on FDA guidances
- Guiding and training new regulatory scientists and managers on protocol review, study design and overall clinical development issues

Professional Experience

4/2017 – 9/2021 Deputy Division Director
Division of Clinical Evaluation and Pharmacology / Toxicology
Office of Tissues and Advanced Therapies
CBER
Food and Drug Administration

In this position, I led a group of almost 100 physicians, biologists, biomedical engineers and clinical pharmacologists in the review of regulatory submissions (investigational new drug applications, investigational device exemptions, biologics license applications, premarket applications and their supplements) for cellular therapies, gene therapies and plasma-derived and recombinant proteins for use in the treatment of conditions in all therapeutic areas, alongside the Division Director.

In addition to the regulatory review work, I led or participated in a number of intercenter and interagency activities to support the work of FDA and promote and protect the public health.

I have led and contributed to draft and final FDA guidances to industry, focused on clinical aspects of medical products development, meet and communicate regularly with sponsors of these products and with industry and scientific groups, patients and patient advocacy groups, and regulators from other agencies, such as European Medicines Agencies, Health Canada and Pharmaceutical and Medicinal Devices Agency in Japan.

I also gave formal and informal presentations to various groups regarding our regulatory activities. In conjunction with the Division Director, we had several outreach activities a year.

In view of the rapid growth in interest in advanced therapies, our division has nearly doubled in size in the last 4 years. The division leadership advises the Office and Center on the upcoming work in the immediate horizon and mid-term, in order to plan and allocate appropriate resources and training.

During this role, I had temporary positions as:

- Director, Office of Orphan Products Development 5/2018 – 07/2018
- Deputy Director, newly formed Office of Cardiology, Hematology, Endocrinology and Nephrology in the Office of New Drugs / CDER,
  05/2020 – 09-2020

12/2011 – 4/2017	Branch Chief General Medicine Branch 1 Division of Clinical Evaluation and Pharmacology / Toxicology Office of Tissues and Advanced Therapies CBER Food and Drug Administration
	From 12/2011 through 10/2016, I was chief of the General Medicine Branch in the former Office of Cellular, Tissues and Gene Therapies, which was reorganized in October 2016 to become the Office of Tissues and Advanced Therapies. The scope of therapeutic areas I oversaw during this role excluded only Oncology (solid tumors) and Malignant Hematology.
4/2009 – 12/2011	Lead Medical Officer Division of Metabolism and Endocrinology Products Office of Drug Evaluation II OND, CDER Food and Drug Administration
	While working at FDA, I was also an attending physician in Internal Medicine at the Mid-Atlantic Permanente Medical Group After Hours Care in Kensington MD, from 4/2001 to 4/2011.
9/2005 – 4/2009	Medical Officer Division of Metabolism and Endocrinology Products Office of Drug Evaluation II OND, CDER Food and Drug Administration
	From 2/209 to 4/2009 I was acting as Lead Medical Officer Division of Gastroenterology Products, Office of Drug Evaluation III, OND, CDER.
9/2003 – 9/2005	Medical Officer Division of Therapeutic Biologic Internal Medicine Products Office of Drug Evaluation VI OND, CDER Food and Drug Administration
9/2000 – 9/2003	Medical Officer General Medicine Branch Division of Clinical Trials Design and Analysis OTRR, CBER Food and Drug Administration

FDA Activities

1. Lecturer for the CBER New Reviewer Training Course: BLA Clinical Review and Issues (twice a year from 2013 to 2019)
2. Member of the CBER Rare Diseases Coordinating Committee and the FDA Rare Disease Council (these are PDUFA-directed activities – representing the Office and the Center)
3. Member of the FDA-NIH Biomarkers Working Group – creating BEST (Biomarkers, EndpointS, and other Tools) resource
4. FDA Biomarkers Working Group
5. Contributed to or led multiple CBER, CDER and intercenter guidances
6. Office or Division Representative before
    a. Patient organizations and advocacy groups (a few examples follow below)
        i. Parent Project Muscular Dystrophy
        ii. JDRF
        iii. HIV Cure Research
        iv. Choroideremia Research Foundation
        v. Cooley's Anemia Foundation
    b. Extramural groups representing or advancing treatments for rare diseases (a few examples follow below):
        i. National Organization for Rare Disorders
        ii. NIH National Center for Advancing Translational Sciences
        iii. International Rare Disease Research Consortium iv. Stanford – UCSF Center for Excellence in Regulatory Science and Innovation
    c. Professional organizations and think-tanks (a few examples follow below):
        i. The Endocrine Society
        ii. American Diabetes Association
        iii. North American Spine Society
        iv. International Cartilage Research Society
    d. Foreign regulatory agencies (EMA, Australia TGA) and sister agencies in the US Department of Health and Human Services (NIH, CDC, HRSA)
7. Representing FDA for diabetes-specific topics before other HHS agencies: CDC (National Diabetes Data Sheet 2011) and AHRQ (Comparative Effectiveness Research)
8. Representative of the Division of Metabolism and Endocrinology Products before the PRO Consortium Group in November 2008.
9. Member of the electronic Submission Interest Group. March 2008 to the 2010.

10. Author: Draft Guidance for Industry: Diabetes Mellitus: Developing Drugs and Therapeutic Biologics for Treatment and Prevention. March 2008
11. Member of the FDA Rare Disease Working Group. September 2007 to the present.
12. Member of the DTC Prescription Drug TV advertisements User Fee Program Working Group. June to October 2007
13. Member of FDA Cardiovascular Research Interest Group from May 2007 to November 2008.
14. Member of Interagency Artificial Pancreas Working Group from January 2007 to 2012
15. Co-founder of the Endocrine Journal Club – Division of Metabolism and Endocrine Products from 2006 to 2011
16. Initial co-planner of Predictors, Pathogenesis, and Prevention of Insulin Resistance and Type 2 Diabetes, October 2006.
17. Featured in FDA Consumer magazine: teaching diabetes at Suburban Hospital. July 2006
18. Consultant to CDER Review Divisions, CBER (OCTGT and OVRR), and CDRH. June 2006 to the 2011.
19. Member of the SMART Template User's Group for Clinical Review Template CDER, from March 2006 to May 2007.
20. Organizer of Diabetes Mellitus Update for Clinical Reviewers CDER. November 17, 2005
21. Member of CDER Committee for Advanced Scientific Education (CASE). 2004 – 2007
22. Co-planner of FDA / NIH Joint Symposium on Diabetes. May 2004
23. Consultant for FDA Orphan Products Grant Reviews. April 2002 to 2011.
24. Member of the Working Group writing the Guidance on Collection of Race and Ethnicity Data in Clinical Trials. March 2002 to August 2005.
25. Member of the Xenotransplantation IND Reviewer Focus Group – CBER. May 2001 to February 2004.

9/1998 – 9/2000	Internal Medicine / Endocrinology Attending Physician Private Practice in Bethesda and Chevy Chase
7/1994 – 9/1998	Internal Medicine / Endocrinology Attending Physician in Private Practice in Northern Virginia
7/1993 – 6/1994	Internal Medicine Resident (as foreign medical graduate, this was required training for eligibility to admission to the examination by the American Board of Internal Medicine and its subspecialties) Georgetown University Hospital and affiliated hospitals, Washington DC

7/1990 – 6/1993	Visiting Associate National Institutes of Health National Institute of Child Health and Human Development Developmental Endocrinology Branch
1/1986 – 6/1990	Post-doctoral Research Fellow General Clinical Research Center of the University of California, San Francisco Endocrine Service of San Francisco General Hospital, San Francisco CA

During the post-doctoral research fellowship, I was the UCSF Endocrinology Clinical Fellow at the San Francisco General Hospital Diabetes Clinic, in San Francisco, CA, from 8/1986 to 6/1990.

Other Professional Activities

- Officer of the Clinical Research Subcommittee of The Endocrine Society. Tenure from June 2009 through June 2012.
- Member of the Beta Cell Working Group – Metabolic Disorders Steering Committee of the FNIH Biomarker Consortium. Tenure from July 2009 through June 2018.
- Participant in the Leadership for a Democratic Society training sponsored by the Federal Executive Institute. Class 405, from October 5th through 31st, 2014.
- Excellence in Government Fellows Program from August 2009 to August 2010, with the presentation of the Project "The State of Federal Succession Planning – Selected Agency Reviews" on July 28th 2010 before the Partnership for Public Service and representative agencies of the Federal Human Capital Collaborative.

Education and Training

7/1990 – 6/1993	Visiting Associate National Institutes of Health National Institute of Child Health and Human Development Developmental Endocrinology Branch
1/1986 – 6/1990	Post-doctoral Research Fellow General Clinical Research Center of the University of California, San Francisco Endocrine Service of San Francisco General Hospital, San Francisco CA
7/1993 – 6/1994	Internal Medicine Resident Georgetown University Hospital and affiliated hospitals, Washington DC

Investigator in Clinical Trials

1. Carbenoxolone use in 21-hydroxylase deficiency, at the National Institutes of Health, Bethesda MD, supplied by Biorex Laboratories, United Kingdom, 1992-1994.

2. Cozaar, at the Hypertension Research Center, Falls Church VA, sponsored by Merck and Co., 1995.
3. Avapro, at the Hypertension Research Center, Falls Church VA, sponsored by Bristol-Myers Squibb, 1997.

Presentations given at Scientific Events

1. Irony I. "FDA Introductory Remarks" June 2021, delivered to open the virtual Workshop Design of Clinical Trials in New-Onset Type 1 Diabetes: Regulatory considerations for drug development.
2. Irony I. "Gene Therapy for Rare Diseases" June 2021, virtual talk presented during the Conference "Regenerative Medicine: Regulatory, Legal, and Compliance Challenges for Cell and Gene Therapies" sponsored by the Food and Drug Law Institute.
3. Irony I. "Medical treatments for rare diseases: my FDA perspective" May 2021, virtual talk presented at the Workshop Decision Making in Health and Medical Care Modeling and Optimization sponsored by the Institute for Mathematical and Statistical Innovation.
4. Irony I. "Regulatory Topics on Allogeneic Pancreatic Islet Transplantation" June 2020, webinar at the 80th Scientific Session of the American Diabetes Association.
5. Irony I, Gudmundsson K. "Are FDA and EMA guidance aligned regarding clinical development of drugs for rare/orphan diseases?" at the 16th Global Cardiovascular Clinical Trialists Forum (CVCT), December 2019 in Washington DC.
6. Irony I. "CBER Updates on Rare Disease Topics" at the DIA Global Annual Meeting, June 2019 in San Diego CA.
7. Irony I. "FDA Gene Therapy Draft Guidances – disease specific guidances and long term follow up" at the World Orphan Drug Congress on April 11, 2019, in Oxon Hill MD.
8. Irony I. "Regulatory Challenges in CBER" at the 2019 PPMD Duchenne Healthcare Professional's Summit, on January 25, 2019 in Fort Myers FL, with Dr. Janet Woodcock presenting "Regulatory Challenges in CDER" (presented remotely from the FDA campus).
9. Irony I. "Perspectives on Rare Diseases and Gene Therapies" at the DIA Global Annual Meeting, June 2018 in Boston MA.
10. Irony I. "Considerations on Regulation of Gene Therapy for Hemophilia" at the World Federation of Hemophilia 2018 Congress, on May 23, 2018 in Glasgow Scotland.
11. Irony I. "FDA Perspectives on Rare Diseases and Gene Therapies" at the National Organization for Rare Disorders in October 2017, in Washington DC.
12. Irony I. "Careers at FDA" presented at the Annual Meeting of the Endocrine Society, on March 31, 2017 in Orlando FL.
13. Irony I. "Discussion of a CBER Breakthrough Designation Request" at Brookings Center for Health Policy Workshop on Breakthrough Therapy Designation, on April 25, 2015 in Washington D.C.

14. Irony I. “FDA Spine Forum” presented at the North America Spine Society Forum, on March 13, 2013 in Washington DC.

15. Irony I. “Biomarkers and Surrogate Endpoints in Therapy Development” at the Clinical Development in Frontotemporal Degeneration Conference, on June 4, 2012 in Washington DC.

16. Irony I. “Cellular and Gene Therapies for Treatment of HIV” at the Federal AIDS Policy Partnership, on December 5, 2012, in Washington DC.

17. Irony I. “Diabetes Guidelines and Clinical Trial Challenges” presented at 2010 Critical Markers of Disease Symposium: Science, Economics and Globalization of Healthcare sponsored by the National Heart, Lung and Blood Institute and the International partnership for Critical markers of Disease, on September 27, 2010 in Bethesda MD.

18. Irony I. “Cardiovascular Risk Assessment studies in Type 2 Diabetes Mellitus – Design, Patient Populations and Endpoints” presented at the workshop entitled “Cardiovascular Safety and Development of Type 2 Diabetes Mellitus Medications: Current State of the Art and Opportunities to Advance the Science” sponsored by the Drug Information Association on September 23 and 24, 2009 in Washington DC.

19. Irony I and Sahlroot JT. “Adaptive Designs / Non-inferiority case presentation”. November 7, 2008 at FDA White Oak, Silver Spring MD.

20. Organizer of the event “FDA/NIH Joint Symposium on Diabetes: Targeting Safe and Effective Prevention and Treatment” in Bethesda MD, May 13 and 14, 2004.

21. Moderation of the session “Beta cell preservation” in the meeting above.

22. Irony I. “Clinical Trial Design” presented at the CBER 101 Conference, co-sponsored by CBER, the Regulatory Affairs Professionals Society, and the Drug Information Association, on March 25, 2003.

23. Irony I. “Laronidase for the treatment of Mucopolysaccharidosis Type I” presented before the Endocrinologic and Metabolic Drugs Advisory Committee, on January 15, 2003.

24. Irony I. “Guidance for Industry: Collection of Race and Ethnicity Data in Clinical Trials for FDA Regulated Products” presented to the Division of Clinical Trials Design and Analysis on November 4, 2002.

25. Irony I. “Guidance for Industry: Collection of Race and Ethnicity Data in Clinical Trials for FDA Regulated Products” presented to the CBER Medical Policy Coordinating Committee on May 20, 2002.

26. Irony I. “Effects of Carbenoxolone on ACTH levels in Nelson Syndrome” presented at the International Meeting on Neuro-Psycho-Endocrinology in Rome Italy, on April 19-20, 2002.

27. Irony I. “Mineralocorticoid Hypertension” presented at a Meet the Professor session at the 80th Annual Meeting of the Endocrine Society in New Orleans LA, June 23-27, 1998.

28. Irony I “Carbenoxolone effects in Nelson syndrome” presented at the Department of Medicine Research Day at Georgetown University, Washington DC on September 18, 1993.

29. Arai K, Karl M, Irony I, Suzuki Y, Chrousos GP. "The mineralocorticoid receptor cDNA in type I pseudohypoaldosteronism". 75th Annual Meeting of the Endocrine Society in Las Vegas NV, June 9-12, 1993.

30. Irony I, Haughey M (SPON: John R. Gill, Jr.). "The effect of carbenoxolone on plasma ACTH in Nelson syndrome" 75th Annual Meeting of the Endocrine Society in Las Vegas NV, June 912, 1993.

31. Irony I, Haughey M, Cutler Jr GB. "The effect of carbenoxolone on plasma ACTH and 17hydroxyprogesterone levels in congenital adrenal hyperplasia" American Federation for Clinical Research Annual Meeting in Washington D.C., April 30 to May 3, 1993.

32. Tsigos K, Irony I, Arai K, Mercado-Assis L, Chrousos GP. "Congenital resistance to aldosterone (pseudohypoaldosteronism): clinical picture and response to the 11 □ hydroxysteroid dehydrogenase carbenoxolone" 20th Annual Meeting of the Greek Endocrine Society in Athens, Greece, April 1-3, 1993.

33. Irony I. "Evaluation of Cushing Syndrome: The NIH experience" talk presented before the Brazilian Society of Endocrinology and Metabolism in São Paulo, SP, Brazil, August 14, 1992.

34. Irony I. "The syndrome of hypermineralocorticoidism" talk presented before the HypertensionEndocrine Branch, National Heart, Lung and Blood Institute in Bethesda MD, June 4, 1992.

35. Irony I. "The syndromes of hyperdeoxycorticosteronism" talk presented during the Brazilian Society of Endocrinology and Metabolism-sponsored symposium: "Adrenal and hypertension" in São Paulo, SP, Brazil, October 5, 1991.

36. Kater CE, Irony I, Biglieri EG, Lewi DS. "Impaired increases of 17-deoxy steroids to ovine corticotropin releasing hormone in AIDS: evidence for a deficient secondary regulator" talk presented during the 73rd Annual Meeting of the Endocrine Society in Washington D.C., June 19-22, 1991.

37. Irony I, Biglieri EG, Faiçal S, Kater CE. "Normal microsomal with reduced mitochondrial zona fasciculata enzyme activities during continuous ACTH stimulation in hypopituitarism" talk presented during the Annual Meeting of the Western Section of the American Federation for Clinical Research, February 6-9, 1990.

38. Irony I, Biglieri EG. "Impaired DOC regulation in acquired immunodeficiency syndrome (AIDS)" talk presented during the Annual Meeting of Western Society for Clinical Investigation in Carmel, California, February 7-10, 1989.

39. Biglieri EG, Kater CE, Brust N, Chang B, Hirai J, Irony I. "The regulation and diseases of deoxycorticosterone (DOC)" talk presented during the International Congress of Endocrinology in Tokyo, Japan, July 25-26, 1988.

40. Biglieri EG, Kater CE, Irony I. "The distinct types of mineralocorticoid hypertension" talk presented during the XIII Meeting of the International Study Group for Steroid Hormones, in Rome, Italy, November 30-December 2, 1987.

41. Biglieri EG, Irony I, Kater CE. "The implications of deoxycorticosterone levels in adrenocortical disorders" talk presented during the 18th Brazilian Congress of Endocrinology and Metabolism in Rio de Janeiro, RJ, Brazil, June 12-17, 1988.

42. Irony I, Biglieri EG. "Eixo hipófise-adrenal na síndrome da imunodeficiência adquirida" 18th Brazilian Congress of Endocrinology and Metabolism in Rio de Janeiro, RJ, Brazil, June 12-17, 1988.

43. Irony I, Kater CE, Biglieri EG. "Dual phases of Zona Fasciculata deoxycorticosterone regulation" Annual Meeting of The Endocrine Society, in New Orleans, Louisiana June 8-11, 1988.

44. Irony I, Kater CE, Arteaga E, Biglieri EG. "Characteristics of correctible types of primary hyperaldosteronism" Third Annual Meeting of the American Society of Hypertension in New York, New York, May 22-26, 1988.

45. Biglieri EG, Irony I: "Deviation of pituitary control of adrenal production in acquired immunodeficiency syndrome". Annual Meeting of the Universitywide Task Force on AIDS, San Diego, California, March 15-16, 1988.

46. Irony I, Biglieri EG. "New types of primary aldosteronism". Western Section Meeting of the American Federation for Clinical Research, Carmel, California, February 16-19, 1988.

47. Irony I, Biglieri EG, Opocher G. "Dissociation of 17-deoxy- and 17-hydroxysteroids of the zona fasciculata: Arguments for a non-ACTH regulator". Annual Meeting of The Endocrine Society, Indianapolis, Indiana, June 10-12, 1987.

48. Biglieri EG, Kater CE, Irony I. "The mineralocorticoid hormones in human hypertension". Second Annual Meeting of the American Society of Hypertension, New York, New York, May 17-21, 1987.

49. Biglieri EG, Irony I, Membreno L, Cobb E. "A putative pituitary regulatory deficiency in the acquired immunodeficiency syndrome (AIDS)". Annual Meeting of the Universitywide Task Force on AIDS, San Diego, California, March 19-20, 1987.

50. Irony I, Biglieri EG, Perloff D. "Regulation and effects of steroids in the 17-deoxypathway revealed by their clinical disorders". Western Meeting of the American Federation for Clinical Research, Carmel, California, February 3-6, 1987.

Published Articles

1. Day S, Jonker AH, Lau LPL, Hilgers R-D, Irony I, Larsson K, Roes KC, Stallard N. "Recommendations for the design of Small Population Clinical Trials". Orphanet Journal of Rare Diseases 2018 13:195.

2. Xu L, Irony I, Bryan WW, Dunn B. "Development of Gene Therapies – lessons from nusinersen". Gene Therapy 2017, September; 24: 527-528.

3. Pinkos, A, Arreaza-Rubin G, Heetderks WJ, Irony I, Joffe HV, Schneider B, Zimliki CL. "FDA's proactive role in the development of an artificial pancreas for the treatment of diabetes mellitus". Drug Discovery Today: Technologies 2007, December; 4(1): 25-28.

4. Irony I, Parks MH, Meyer RJ. Letter to the Editor. New England Journal of Medicine 2007, May 24; 356 (21): 2221.

5. Weber D, McFarland R, Irony I. "FDA regulation of allogeneic islets of Langerhans as somatic cell therapy". Transplantation 2002 Dec 27; 74(12): 1816-20

6. Irony I, Cutler GB. "Effect of carbenoxolone on the plasma renin activity and hypothalamic pituitary-adrenal axis in congenital adrenal hyperplasia due to 21 - hydroxylase deficiency". Clinical Endocrinology 51:285-291, 1999; also discussion by Walker BR in Clin Endocrinol 52(2): 246-247, 2000 and reply by Irony I, Cutler GB Clin Endocrinol, 52(2): 247-248, 2000

7. Arai K, Tsigos C, Suzuki Y, Irony I, Karl M, Listwak S, Chrousos GP. "Physiological and molecular aspects of mineralocorticoid receptor action in Pseudohypoaldosteronism: a responsiveness test and therapy". Journal of Clinical Endocrinology and Metabolism 79(4): 1019-1023, 1994

8. Kater CE, Biglieri EG, Irony I. "Low sodium intake enhances sensitivity of 11-deoxycortisol and deoxycorticosterone to ACTH in ACTH-suppressed normal subjects". Journal of Steroid Biochemistry and Molecular Biology 42(6): 617-623, 1992

9. Chen CC, Irony I, Jaffe GS, Norton JA. "Technetium-99m uptake in a parathyroid adenoma: potential pitfall in technetium-99m/thalium-201 subtraction scanning". Clinical Nuclear Medicine 17: 539-541, 1992

10. Fontes RG, Kater CE, Biglieri EG, Irony I. "Reassessment of the predictive value of the postural stimulation test in primary aldosteronism". American Journal of Hypertension 4: 786791, 1991

11. Farese RV, Biglieri EG, Shackleton CHL, Irony I, Gomes-Fontes, R. "Licorice-induced hypermineralocorticoidism". New England Journal of Medicine 325(17): 1223-1227, 1991

12. Kater CE, Irony I, Biglieri EG, Faiçal S. "Continuous ACTH administration in hypopituitarism produced asynchronous increases of deoxycorticosterone and 11-deoxycortisol relative to the other zona fasciculata steroids" Journal of Clinical Endocrinology and Metabolism 71(2): 305310, 1990

13. Irony I, Kater CE, Biglieri EG, Shackleton CHL. "Correctable subsets of primary aldosteronism: primary adrenal hyperplasia and renin responsive adenoma" American Journal of Hypertension 3(7): 576-582, 1990

14. Kater CE, Biglieri EG, Brust N, Chang B, Hirai J, Irony I. "Stimulation and suppression of the mineralocorticoid hormones in normal subjects and adrenocortical disorders". Endocrine Reviews 10(2): 149-164, 1989

15. Biglieri EG, Irony I, Kater CE. "The implications of deoxycorticosterone levels in adrenocortical disorders" published in the Proceedings of 18th Brazilian Congress of Endocrinology and Metabolism by Elsevier Science Publishers, Netherlands (Excerpta Medica): 163-168, 1988

16. Biglieri EG, Irony I, Kater CE. "The regulation of 17-deoxysteroids in man". Endocrine Research 15(1&2): 183-201, 1989

17. Biglieri EG, Irony I, Kater CE. "Identification and implications of new types of mineralocorticoid hypertension" Journal of Steroid Biochemistry 32(1B): 199-204, 1988

18. Irony I, Biglieri EG, Perloff D, Rubinoff H. "Pathophysiology of deoxycorticosterone-secreting adrenal tumors" Journal of Clinical Endocrinology and Metabolism. 65 (5): 836-840, 1987

19. Membreno L, Irony I, Dere W, Klein R, Biglieri EG, Cobb E. "Adrenocortical function in acquired immunodeficiency syndrome" Journal of Clinical Endocrinology and Metabolism. 65 (3): 482-487, 1987

20. Kater CE, Czepielewski MA, Biglieri EG, Irony I "Hypertension with deoxycorticosterone excess in androgen producing adrenocortical carcinoma" Journal of Hypertension. 4 (suppl 6): S604-606, 1986

Published Books and Chapters

1. Irony I. Chapter 26 Passive Immunization. American Academy of Pediatric Red Book 2021 Edition.

2. Huang Y, Havert M, Irony I. "Regulation of Adenoviral Vector-Based Therapies: An FDA Perspective" chapter in the book Adenoviral Vectors for Gene Therapy, edited by David T. Curiel, 2nd Edition, Elsevier, 2016.

3. Irony I, Biglieri EG, Kater CE. "The Adrenocortical Hormones in Hypertensive Disorders" chapter in Vol.2 (Endocrine Mechanisms in Hypertension) in the series Perspectives in Hypertension, pages 1-18, edited by John H. Laragh, Barry M. Brenner and Norman M. Kaplan, publisher Raven Press, New York, in 1989.

4. Irony I, Biglieri EG. "Adrenocortical insufficiency" published in the Conn's Current Therapy, pages 553-556, edited by Robert E. Rakel; W.B. Saunders Company, 40th edition (1989).

4. Biglieri EG, Kater CE, Irony, I. "Adrenocortical forms of human hypertension" published as a chapter in the book Hypertension: Pathophysiology, Diagnosis and Management, pages

16091623, edited by John H. Laragh and Barry M. Brenner, publisher Raven Press, New York, 1990.

5. Biglieri EG, Kater CE, Brust N, Chang B, Hirai J, Irony I. "The regulation and diseases of Deoxycorticosterone (DOC)" published as chapter of the book The Adrenal and Hypertension: from cloning to clinic (Serono Symposia), vol. 57, pages 355-366 edited by E.G. Biglieri, F. Mantero, J.W. Funder, R. Takeda publisher Raven Press, New York, 1989.

6. Biglieri EG, Irony I. "The syndrome and subsets of primary aldosteronism" chapter in the book Endocrine Hypertension, pages 71-85 edited by Edward G. Biglieri and James C. Melby, publisher Raven Press, New York, 1990.

7. Irony I, Biglieri EG. "The syndrome of hyperdeoxycorticosteronism" chapter in the book Endocrine Hypertension, pages 175-181 edited by Edward G. Biglieri and James C. Melby, publisher Raven Press, New York, 1990.

Selected Published Abstracts

1. Irony I, Biglieri EG, Opocher G. "Dissociation of 17-deoxy and 17-hydroxysteroids of the zona fasciculata: arguments for a non-ACTH 17-deoxysteroid regulator" Endocrinology (Program and Abstracts). 120 (suppl): 523, 1987.

2. Irony I, Biglieri EG, Perloff D. "Regulation and effects of steroids in the 17-deoxypathway revealed by their clinical disorders" Clinical Research. 35 (1): 120A, 1987.

3. Irony I, Biglieri EG. "New types of primary aldosteronism" Clinical Research. 36 (1), 1988.

4. Biglieri EG, Kater CE, Irony I. "The distinct types of mineralocorticoid hypertension". Journal of Steroid Biochemistry (supplement) 28:14, 1987.

5. Irony I, Kater CE, Arteaga E, Biglieri EG. "Characteristics of correctible types of primary aldosteronism". American Journal of Hypertension 1(3-Part 2): 50A, 1988.

6. Irony I, Kater CE, Biglieri EG. "Dual phases of Zona Fasciculata deoxycorticosterone regulation". Endocrinology (Program and Abstracts): 101, Abstract 324, 1988.

7. Biglieri EG, Irony I, Cobb E. "Putative pituitary deficiency in acquired immunodeficiency syndrome". University-wide Task Force on AIDS, 1987.

8. Biglieri EG, Kater CE, Irony I. "The mineralocorticoid hormones in human hypertension". American Journal of Hypertension, (Abstracts), 1987.

9. Biglieri EG, Irony I. “Deviation of pituitary control of adrenal production in acquired immunodeficiency syndrome” University-wide Task Force on AIDS, 1988.

10. Irony I, Biglieri EG, Kater CE. “Impaired DOC regulation in acquired immunodeficiency syndrome (AIDS)”. Clinical Research 37(1): 151A, 1989.

11. Irony I, Biglieri EG. “Only deoxycorticosterone (DOC), 11-deoxycortisol (S) and aldosterone respond normally to continued administration of superphysiologic doses of ACTH in ACTHdeficient states”. Endocrinology (Programs and Abstracts) # 660, page 187, 1989.

12. Irony I, Biglieri EG, Faiçal S, Kater CE. “Normal microsomal with reduced mitochondrial zona fasciculata enzyme activities during continuous ACTH stimulation in Hypopituitarism”. Clinical Research 38(1), page 97A, 1990.

13. Kater CE, Irony I, Biglieri EG, Lewi DS. “Impaired increases of 17-deoxy steroids to ovine corticotropin releasing hormone in AIDS: evidence for a deficient secondary regulator”. Endocrinology (Programs and Abstracts) # 1382, page 376, 1991

Research Projects

1. Study of the physiology of the renin-angiotensin system in normal and diabetic rats, in collaboration with Judith Kalinyak M.D., at Stanford University, Palo Alto CA, 1989.

2. Study of genetics of hypertension in rats, under the supervision of Dr. Theodore Kurtz, at the University of California, San Francisco, San Francisco CA, 1989.

Talks given to the general public prior to FDA employment

- Lectures on Diabetes Mellitus. Suburban Hospital Division of Endocrinology, in partnership with Johns Hopkins Medicine at Suburban Hospital, Bethesda MD, from 1998 to 2007.

- Discussion on Pain Management. The Promenade Bethesda MD April 11, 2000.

- Talk on Thyroid Disorders. Lord & Taylor (Chevy Chase Store) March 24, 1999.

- Talk on Diabetes Therapy. Reston Hospital, Reston VA. November 14, 1994.

Manuscript Reviewer for Medical Publications

- Journal of Clinical Endocrinology and Metabolism: manuscript 003989, 2001
- The Medical Letter. Article on laronidase. August 2003

Knowledge of other languages:

- Portuguese
- Hebrew
- Spanish

Awards and Scholarship

- Award given by the Brazilian government (CNPq) to pursue a research fellowship program at UCSF, in 1987, for US $ 25,000.
- CBER Award "for high quality work achieved with new approaches and methods that resolved regulatory issues." August 2001.
- Commissioner's Award of Excellence "for the development of a guidance recommending standards for the collection of race and ethnicity data in clinical trials conducted domestically and internationally." May 2003.
- CDER Special Recognition Award "For exceptional performance in the review of the laronidase application, the first product approved for the treatment of mucopolysaccharidosis Type I." May 2004.
- CDER Certificate of Appreciation: "For outstanding Service and dedication to the Committee for Advanced Scientific Education 2004 – 2007." June 2007.
- FDA Award "in recognition of ten years of service in the Government of the United States of America." September 2007.
- CDER Center Director Special Citation CDER Committee for Advanced Scientific Education: "For exemplary performance in providing innovative and emerging science to CDER's scientific personnel despite tremendous challenges." November 2007.
- FDA Group Recognition Award (as a member of the DTC User Fee Working Group): "For superior achievement of FDA's mission through the design and implementation of the DTC User Fee Program for the review of prescription drug television advertisements." May 2008. • FDA Office of Women's Health Certificate of Appreciation: "In acknowledgement of your outstanding contribution to the success of the FDA Office of Women's Health program initiatives." July 2008.
- CDER Center Director Special Recognition Award (as a member of the Rare Disease Working Group): "For scientific and regulatory excellence in the development of Orphan Drug Products, and for a thoughtful approach to the challenges of oversight of these products." November 2008.
- CDER Spring Honors Awards Team Excellence Award to the Diabetes CV Risk Assessment Working Group. June 2009.
- CDRH Group Recognition Award: Artificial Pancreas Review Team "For sustained superior performance in the review of proposed clinical studies for Artificial Pancreas device systems

resulting in the accelerated approval of studies for the treatment of Diabetes Mellitus." August 2009.

- FDA Outstanding Service Award: Artificial Pancreas Working Group "for superior performance in the planning / execution of the Artificial Pancreas Initiative to increase user awareness of Artificial Pancreas Systems, the development of guidelines for product approval, and improved outreach with other Government Agencies while continuing to work with medical device manufacturers / academia using the interactive review process to approve first-in-man clinical studies." June 2012.

- CBER Award "in recognition of fifteen years of service in the Government of the United States of America." September 2012.

- FDA Group Recognition Award: HPC, Cord Blood BLA Review Teams (Ducord Review Team) "For outstanding dedication and service during the review and approval of two new BLA applications for HPC, Cord Blood." July 2013.

- FDA Plain Language Award: OCTGT Learn Clinical Webinar Group "For significant contributions in planning, executing and making publicly available, the OCTGT Learn web-based educational series." July 2013.

- FDA Group Recognition: FAERS Project Team. December 2013.

- FDA Honors Award: Rare Diseases Public Workshop Planning Committee "For exceptional teamwork and collaboration to fulfill a FDASIA mandate requiring a public workshop for discussion of complex issues in drug development for rare diseases." June 2014.

- CDER Certificate of Recognition: CDER Committee for Advanced Scientific Education (CASE): "For recognition of your outstanding service through your involvement in CASE in developing advanced scientific training activities for over 25 years for CDER staff". May 2015.

- FDA CBER Group Award: Mitochondrial Technologies Advisory Committee Planning Group "For furthering FDA's mission by holding an Advisory Committee meeting on oocyte modification for the prevention of transmission of mitochondrial disease or treatment of infertility". May 2015.

- FDA Group Award: Breakthrough Therapy Program Evaluation and Public Workshop Group "For exceptional contribution providing significant benefit to the pharmaceutical and patient communities through increased understanding of the FDA breakthrough therapy designation criteria and 2-year analyses". September 2016.

- CDER Team Excellence Award: Neurocognitive Outcome and Neurocognitive development Group "For exceptional teamwork resulting in a successful two-day workshop on the assessment of neurocognitive outcomes in patients with inborn errors of metabolism". September 2016.

Membership in Professional Societies

Endocrine Society – active since 1995

Educational and Professional Activities in Brazil

Licensure Information

São Paulo State Medical License Number 43.337 (inactive)

Professional Experience

4/1985 – 1/1986	Internist Municipality of São Paulo Department of Public Health, Brazil
2/1985 – 7/1985	Internist São Paulo State Department of Public Health, Brazil
1/1985 – 12/1985	Internist / Homeopathy Consultant Hospital do Servidor Público Municipal, São Paulo, Brazil
1/1984 – 12/1984	Post-doctoral Fellow Clinical Genetics Division at Associação Maternidade de São Paulo, Brazil
2/1983 – 1/1985	Internist Emergency Department of Hospital Cruzeiro do Sul, Osasco Brazil
9/1983 – 10/1984	Internist Intensive Care Unit of Hospital São Camilo, São Paulo Brazil
2/1981 – 12/1981	Genetic Counseling Fellow Biosciences Institute of Universidade de São Paulo, São Paulo Brazil

Education and Training

3/1984 – 2/1986	Endocrinology and Metabolism Resident Hospital Brigadeiro (INAMPS), São Paulo Brazil
2/1982 – 1/1984	Internal Medicine Resident Santa Casa de São Paulo, São Paulo Brazil
2/1980 – 9/1981	Medical Intern Faculdade de Ciências Médicas da Santa Casa de São Paulo, São Paulo Brazil • Department of Gynecology and Obstetrics • Department of Orthopedics and Trauma • Department of Medicine • Department of Surgery • Department of Pediatrics

3/1976 – 12/1981 Medical Doctor Degree
Faculdade de Ciências Médicas da Santa Casa de São Paulo Brazil

3/1976 – 12/1980 B.S. in Biological Sciences
Instituto de Biocências da Universidade de São Paulo Brazil

Published Articles in Foreign Languages

1. Irony I. "Síndrome de Cushing: Experiência do National Institutes of Health". Arquivos Brasileiros de Endocrinologia e Metabolismo, 37 (2): 47-53, 1993.

2. Fontes LR, Gollop TR, Lucchesi EA, Nery CAS, Irony I. "Nanismo proporcionado simulando Síndrome de Seckel" Pediatria Moderna. 20 (3): 154-158, 1985.

3. Irony I, Haman ACS, Totri MDO, Pires A, Santo GC. "Mediastinite de longa evolução causada por espinha de peixe: estudo de um caso" Revista Paulista de Medicina. 102 (6): 283-284, 1984.

4. Irony I, Gorzoni ML, Sens YAS. "Procedimentos diagnósticos em hipertensão arterial: a propósito de um caso de hipertensão reno-vascular" Arquivos Médicos dos Hospitais e da Faculdade de Ciências Médicas da Santa Casa de São Paulo. 16 (4): 32-36, 1984.

Research Projects

"H-Y Antigen and its application to Human Genetics"
Study performed in the Biology Department of Biosciences Institute of Universidade de São Paulo - São Paulo SP Brazil, with Prof. Carlos Alberto Moreira Filho, 1979.

Presentations given at Scientific Events

1. Kater CE, Czepcelewski M, Biglieri EG, Irony I. "Hypertension with deoxycorticosterone excess in androgenic producing adrenocortical carcinoma". XI Scientific Meeting of the International Society of Hypertension, Heidelberg, Federal Republic of Germany, August 31st to September 7, 1985.
2. Irony I, Santomauro AT, Liberman B, Wajchemberg BL. "Avaliação do Sistema Nervoso Autônomo Cardio-Circulatório no Diabetes Mellitus". 5th Brazilian Congress of Diabetes, Foz do Iguaçu, Paraná, Brazil, September 7-11, 1985.

Membership in Professional Societies (Inactive Status)

1. American Society of Hypertension – inactive
2. Associação Médica Brasileira - inactive
3. Conselho Regional de Medicina - inactive