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Manfred E. Wolff, Ph.D., FAAPS

- Senior consultant with broad background in both academic and industrial environments; in the following areas: pharmacology, toxicology, medicinal chemistry, drug metabolism of steroids, retinoids, prostaglandins, performance enhancing drugs (PED) in athletics, drug-facilitated sexual assault (DFSA), driving under the influence of drugs or alcohol (DUI), drug allergy, Stevens-Johnson Syndrome and TEN; and pharmaceutical patent validity.

- I have been President and CEO of Intellepharm since 1996, where I am involved in biotechnology licensing, technical evaluation and intellectual property services for Japanese and US biopharmaceutical companies. I am a registered patent agent, and a registered pharmacist.

- U.S. citizen born in Berlin, Germany. I have a reading knowledge of the German language.

EDUCATION

- B.S., University of California, Berkeley; Ph.D., Pharmaceutical Chemistry, University of California, Berkeley.

- Postdoctoral Fellow, Department of Chemistry, University of Virginia, Charlottesville under the direction of the world famous authority in Medicinal Chemistry, the late Prof. Alfred Burger.

- Completed Tufts University 14th Annual Postgraduate Course in Clinical Pharmacology, Drug Development, and Regulation.

EXPERIENCE

- Former Senior Medicinal Chemist at Smith Kline & French Laboratories, Philadelphia, where I was inventor or co-inventor on 20 steroid patents.

- Professor and Chairman, Emeritus, Department of Pharmaceutical Chemistry, University of California San Francisco ("UCSF") As Department Chairman, I built a major academic center and graduate department of drug discovery and design.

- Sabbatical Fellowship, Department of Biochemistry, Imperial College, London, as the guest of the late Prof. Sir Ernst B. Chain, Nobel Laureate for the co-discovery of penicillin, and of the late Prof. D.H.R. Barton, Nobel Laureate for work in steroid chemistry.

- International authority in Medicinal Chemistry, with more than 100 steroid publications and patents in peer reviewed journals (most recent publication on tramadol toxicity is in press). My research at UCSF was supported by 20 years of grant support from the National Institutes of Health. I have lectured extensively as an invited lecturer worldwide in industrial and academic venues and at national and international scientific meetings.

- Elected Fellow, American Association for the Advancement of Science and Elected Fellow, Academy of Pharmaceutical Scientists.

- Member of the American Association of Pharmaceutical Scientists, the American Chemical Society, and the Division of Medicinal Chemistry of the American Chemical Society.

- I left USCF in 1982 to become Vice-President for Research at Allergan, Inc., a position I held from 1982-1988. In 1988, I left Allergan, Inc. to co-found ImmunoPharmaceutics, Inc. ("IPI") in San Diego, where I was Senior Vice-President for Research and Development. IPI was sold to Texas Biotechnology Corporation (1995) and subsequently to Pfizer, and I left to found Intellepharm, Inc.

- As a result of the work I carried out at Allergan, Inc. and ImmunoPharmaceutics, Inc., I was responsible for the discovery of the following marketed drugs: Tazorac® (for acne and psoriasis), Alphagan®, Combigan®, and Lumigan® (for glaucoma), and Thelin® (for pulmonary arterial hypertension).

- West Coast licensing executive for Hoechst Marion Roussel (now Sanofi) (1996-1999).

- Experience in licensing includes worldwide travel on behalf of Allergan, ImmunoPharmaceutics, and Hoechst Marion Roussel. Activities involved in-licensing, out-licensing, and research alliances. Responsible for successful in-licensing of UK-14,304 from Pfizer UK to Allergan (SKB), outlicensing of an endothelin antagonist from ImmunoPharmaceutics to Texas Biotechnology Corporation, and formation of research alliance for anti-VEGF biotechnology drugs between Eisai Ltd. and ImmunoPharmaceutics.

- Adjunct Professor of Medicinal Chemistry at the University of Southern California (1988-2008), and a member of the faculty of the Residential School of Medicinal Chemistry ("RESMED") at Drew University, Madison, NJ (1999-2009). The students at RESMED comprise 150 young Ph.D. chemists who are sent there annually by the worldwide pharmaceutical industry (including companies such as Pfizer, Inc., Merck & Co., GlaxoSmithKline and AstraZenica) for training in Medicinal Chemistry.

- Elected member of the United States Pharmacopoeia ("USP") Committee of Revision (1990-2010). The USP is the official compendium of drug standards in the United

States. The Committee of Revision is responsible for approving the standards of identity and purity for all new drugs approved in the U.S., and for changes in such standards.

- I have been the Editor or author of 9 volumes on Medicinal Chemistry and Drug Discovery (including the two editions of "Burger's Medicinal Chemistry and Drug Discovery," 4th ed. (Vol. 1-3), John Wiley & Sons, Inc. New York, NY (1979-1981) and 5th ed. (Vol. 1-5), John Wiley Sons, Inc., New York, NY (1995-1997)) and 5 book chapters in this area. I have written many Book Reviews of technical books in the field of Medicinal Chemistry and Drug Discovery for the Journal of Medicinal Chemistry.

PAST TESTIMONY

- Testified as an expert witness in a case regarding causation arising from inappropriate dosage schedules, drug effects, and drug toxicity of Imitrex® in a Sacramento (California) jury trial (2009).

- Testified as an expert witness to estimate lifelong prescription costs resulting from medical malpractice in a Kings County (California) jury trial (2005).

- Served as an expert witness regarding causation arising from inappropriate dosage schedules, drug effects, and drug toxicity in cases involving Alcohol, Butalbital, Propoxyphene, Diflucan, Diazepam, Diphenhydramine, Doxepin, Codeine, Acetaminophen, Silvadene, Tobradex, Terbinafine, Methadone, Morphine, and others, many of which were settled out of court. Services involved include review of medical records, literature work regarding evidence of toxicity, depositions, and court appearances (1989—)

- Provided Expert Written Opinion in Nevada case involving effect of long-term heavy marijuana use on automobile crash responsibility; case was settled favorably on basis of my opinion (2010).

- Provided Expert Written Opinion in California case involving drug facilitated sexual assault using GHB; case was settled favorably on basis of my opinion (2010).

- Served (CA, NJ, GA) in four separate cases) as an expert consultant in disputes regarding putative injurious adverse effects of illicit anabolic steroid use in athletics and law enforcement that were settled (2002-2010).

- Testified as an expert witness (2005) in an Arbitration wherein plaintiff alleged breach by contractor of a contract involving steroid synthesis and biological evaluation.

- Testified as an expert witness in § 271 (e)(2)(A) ANDA infringement lawsuits where invalidity (obviousness) under § 103 was an issue in bench trials in Federal Courts in San Diego (Judge Brewster) (2002) and Newark, NJ (Judge Lifland) (2006).

- Provided Affidavits (in two separate cases) and was deposed as an expert witness for Montreal Law firm for Canadian Federal Courts cases regarding patent validity for certain prostaglandin ophthalmic drugs (2009-2010).

- Provided Expert Written Opinion in California case involving lethal effect of methadone ingestion on two male teens (2010-2012 (settled).

- Provided Expert Written Opinion in Washington State case involving effect of long-term psychotropic prescription drug use on automobile crash responsibility (2012 – 2014) (settled).

- Provided Expert Written Opinion and deposition in Washington State case involving effect of off-label use of high dosage Benicar for fibromyalgia (2011-2014) (settled).

- Provided Expert Written Opinion and Court Testimony in Los Angeles Superior Court medical malpractice case involving effect of oxycodone, hydrocodone and tramadol medications in (2012 -- 2014).

- Provided Affidavits (in two separate cases) and was deposed as an expert witness for Toronto Law firm for Canadian Federal Courts cases regarding patent validity for certain prostaglandin ophthalmic drugs (2012-2014).

- Provided Expert Opinion and was deposed in Federal Court patent case involving proton pump inhibitor patents (settled) (2012-2014).

- Provided Expert Written Opinion in Southwest state case involving tissue damage effects of IV hypertonic drug solution infiltration and extravasation. (2014)

- Provided Expert Written Opinion in Arizona case involving effect of psychotropic drug use in auto--truck crash responsibility (2013 – 2014) (settled).

- Provided Expert Written Opinion in Utah case involving effect of psychotropic prescription drug use on automobile crash responsibility (settled) (2014).