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Chief Medical Officer, Siemens Healthcare
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MD – Internal Medicine
(NY State Licensure)
PhD – Pharmacology
BA – Chemistry
(Phi Beta Kappa, Honors in Biology, minor in Math)

SUMMARY

I bring 30 years' global success in design of, regulatory labeling of, public and private payment for, and clinical adoption of therapeutic and diagnostic drugs and devices, with commensurate skillsets, domain knowledge, and network.

My proven skillset includes design and conduct of clinical trials programs from phase I to post-market registries, preparation and presentation of summary reports of safety and efficacy, and leadership of product teams in development and implementation of strategy and tactics vis-à-vis regulators, payers, professional societies, and patient advocates. I am particularly adept at persuasive deployment of clinical and economic evidence to key influencers and decision-makers (including Ministers of Health and government agencies around the world), credibly asserting the safety, efficacy, reasonableness, necessity, and economic benefits of the product or service. The result has been growth in appropriate and efficient use of novel therapeutic and diagnostic products, alone or in combination. I represent industry on the National Biomarker Development Alliance (http://www.nbdabiomarkers.org/), with a view to validation/labeling of companion diagnostics whether imaging or in vitro biomarkers cum diagnostics.

In 2014, as Chair of the Coverage and Research Committee of the Medical Imaging Technology Alliance, I shaped and drove the industry agenda- in careful consideration of patients as represented by advocacy groups - for private insurers' and Medicare reimbursement of low-dose CT in Screening for Lung and Colon Cancers. Such efforts included written input to USPSTF and CMS dockets, expert testimony to MEDCAC, CMS and FDA, and publication strategy including an actuarial analysis of Lung Cancer Screening. I also sit on various committees, eg AdvaMed.

Persuasive advocacy has led to reform of national barriers to labeling, coverage, and adoption in clinical practice including pilot projects, public-private partnerships, and import-export matters (eg serialization and quality assurance). The result is growth in the capacity of healthcare delivery systems to deliver quality care, broader access by patients in need, and growth of whole markets in the US, Brazil, Chile, India, Canada, China, Central America, and Eastern Europe. Changes in the healthcare market are rendering the US less unlike the rest of the world and hence this creative and pragmatic experience is increasingly relevant to the largest and most carefully regulated market, the US.

The credibility and network accruing to 3 decades' pursuit of objectives shared among stakeholders in industry, academia, NGOs, and government agencies has facilitated my opinion leadership in clinical evidentiary standards and related matters of government policy. These skillsets, domain knowledge, and networks qualify me to address product-, market-, or delivery system-specific inefficiencies and issues which burden payers and delay or skew patients' access to the benefits of innovation.

CAREER HISTORY

Chief Medical Officer, Clinical Strategy and Policy, Siemens Healthcare Jun'13 – present
Provide medical and policy input to design, approval, coverage, and adoption of innovative drugs and devices based on clinical evidence; promote policies enabling sustainable access appropriate to patient management. This involves direct engagement of patient advocacy groups and professional societies, legislators and officials in government agencies, as well as strategic partners among innovators in drugs and devices.

Principal, Frank Healthcare Advisors LLC, Jan'13-present
My clients include NGOs, industry groups, and innovators, on whose behalf I address product-, market-, or delivery system-specific inefficiencies and issues which burden payers and delay or skew patients' access to the health benefits of innovation in drugs and devices both therapeutic and diagnostic.

VP, Global Clinical Strategy and Policy, GE Healthcare Aug'05 – Dec '12
Established influential working relationships with government agencies in various countries, shaping policy (eg cGMP, CED), building public-private partnerships and pilots, and channeling clinical evidence for labeling, payment, and use, (eg coverage, payment, and practice guidelines for FDG PET in Brazil and Chile). Developed industry communications strategies (eg dose exposure for Molecular Imaging) and conceived and implemented clinical evidentiary standards for labeling, coverage, and adoption. In my prior role as Director, Clinical Strategy and Medical Affairs ('05-'08), I organized industry advocacy groups and collaborations with Pharma, academia, and government, tapped into databases for retrospective clinical assessments, and gained FDA approval for digital mammography and diverse clinical programs in pharmacogenomics, anaesthesia, colonography, etc.

Chief Clinical Scientist, GE Global Research Aug'03 – Jul'05
Provided clinical, toxicologic, pharmacologic, and strategic input for diagnostics development and co-development with therapeutics. Integrated acquisition of Amersham and chaired the Transformational Development Team for long-term strategic direction post acquisition.

VP, Experimental Medicine, Global Clinical Research, Pharmacia '01 – '03
Built Translational Medicine Group (23 clinicians, techs, statisticians and geneticists) across therapeutic areas and technology platforms. Developed, validated, and applied imaging and IVD biomarkers to drug development in Oncology, Cardiology, and Neurology. Provided phase I/IIa input to portfolio management, serving as voting member of the Exploratory Development Group spanning late pre-clinical development, toxicology, pharmacology, and early clinical trials.

Senior Director Exploratory Medicine, Sanofi-Synthelabo '95 – '01
Developed and implemented biomarker strategies for Phase I-IIa portfolio management.

Senior Director Clinical Pharmacology, Sterling Winthrop '93 – '95
Conceived, designed, and implemented Clinical Pharmacology strategies across therapeutic areas. Managed outsourcing of tasks from trial management to data analysis and reporting.

Group Director, Internal Medicine, RPR Central Research (change in control) '92 – '93
Managed GI, Oncology portfolios; gained approval for DDAVP & Mononine by FDA & CPMP.

Asst/Assoc Dir; Medical Adviser, Clinical Team Leader/Phase I Unit, Zeneca PLC '85 – '92
Four promotions and a 2-year secondment to Headquarters in the UK resulted from successful delivery of a) 7 INDs and 35 Phase I-IIa clinical trials, b) Clinical Pharmacology sections of 5 NDAs, c) 3 CTX's and 12 in-house Phase I trials, d) a global phase III program (Zoladex in benign gynecology), and e) approved dossiers/labeling for Zoladex by the FDA and the CPMP. Assessment of licensing candidates, design of databases and reporting systems, clinical input to ICH, and novel clinical trial design (Bayesian, with IRB oversight).

PERSONAL INTERESTS

Humanitarian medical clinics, having served in Kyrgyzstan, Colombia, Belize, and Myanmar.

KEY PUBLICATIONS

Seidel, D, Schmidt, S, and Frank, RA; The Evidence Value Matrix for Diagnostic Imaging (submitted) J Am Coll Radiol.
First in a series introducing the concept of clinical efficiency of early and accurate diagnosis from appropriate use of imaging within episodes of care and population health, and the metrics and framework for same.

Hillman, B, Frank, RA, and Abraham, B; The Medical Imaging and Technology Alliance (MITA) Conference on Research Endpoints Appropriate for Medicare Coverage of New PET Radiopharmaceuticals (2013) J Am Coll Radiol 10:689-694.
Second in a series of workshops; resulted in CMS reconsideration of the NCD for PET

Hillman, B, Frank, RA, and Rodriguez, G; New Pathways to Medicare Coverage for Innovative PET Radiopharmaceuticals: Report of a Medical Imaging and Technology Alliance (MITA) Workshop (2012) J Am Coll Radiol 9:108-114.
First in a series of workshops; resulted in CMS reconsideration of the NCD for PET

Frank, R, Rucker, D, Ferguson, M, Sweeney, T; Evidence Requirements for Innovative Imaging Devices; from Concept to Adoption (2011) J Am Coll Radiol 8:124-131.
Industry review of and recommendations for evidentiary standards for innovative devices

Hampel, H, Frank,R, Broich, K, et al Biomarkers for Alzheimers' Disease; Academic, Industry, and Regulatory Perspectives. (2010) Nat Rev Drug Dev 9:560-574.
Biomarkers with potential to serve as diagnostics for stratification of patient populations, treatment planning, and monitoring of effect as a basis for individualization of therapy

Frank R, Hargreaves R. Clinical Biomarkers in Drug Discovery and Development. (2003) Nature Rev in Drug Disc 2(7):566-80.
Watershed article on biomarkers catalyzed translational medicine in portfolio management

Frank R, Galasko D, Hampel H, et al. Biological Measures of Alzheimers Disease; Proceedings of a Working Group of the NIA Initiative on Neuroimaging in Alzheimer's Disease. (2003) Neurobiol Aging 24:521-536.
Contributed to design of Alzheimers Disease Neuroimaging Initiative

Eckel F, Frank RA. Monitoring of Tumor Glucose Metabolism by Positron Emission Tomography in a Phase I Study Evaluating Hormonal Therapy in Advanced Pancreatic Cancer. (2002) Scand J Gastroenterol 8:972-977.
Early assessment of quantitation for drug development decisions

Katz R, Fauntleroy M, Kuwert T, Wagner H, and Frank RA. The Use of Imaging as Biomarkers in Drug Development; Regulatory Issues Worldwide. (2001) J Clin Pharmacol; July Supplement.
Harvard Business Review approach to innovation in drug development and clinical practice

Innis R, Ferguson S, Brady L, Esmond R, Frank RA. PET Tracers as Intellectual Property (2001) J Clin Pharmacol Pharmacol; July Supplement.
Harvard Business Review approach to innovation in drug development and clinical practice

Huestis MA, DA Gorelick, SJ Heishman, KL Preston, R Nelson, ET Moolchan, RA Frank. "Blockade of Effects of Smoked Marijuana in Humans by the Oral CB1 Selective Cannabinoid Receptor Antagonist SR141716" (2001) Archives of General Psychiatry 58:322-328.
Classical clinical pharmacology for an innovative drug target in a novel population

Miller RM, RA Frank, "Zoladex (Goserelin) in the Treatment of Benign Gynaecological Disorders: An Overview of Safety and Efficacy" (1992) Br J of Obsteterics and Gynaecology vol 99 supp 7 pp 37-41.
Review of a global, multi-center clinical trials program for a hormone in depot formulation