Efraim Eric Katz

Healthtech leaders & investors turn to Efraim to navigate government & market roadblocks to the US market.

Efraim provides clients with insights that help breakthrough technologies obtain key product approvals, insurance coverage and fair reimbursement. His secret sauce is combining pre-approval goalposts like FDA's with post-approval needs at Medicare and elsewhere. This means, perhaps, collecting pharmacoeconomic data during clinical trials, or building support with key opinion leaders before requesting Medicare coverage.

Another unique contribution is Efraim's ability to build a comprehensive mosaic view of both high-level policy and detailed regulatory requirements. This involves the constant revisions in both high-level national policy reforms (like value-based care) and low-level updates (like CPT application timetables) that can change the coverage and reimbursement landscape in an instant.

Efraim often provides services through national "expert networks," including over 300 client projects and 20 international investor calls. Topics run the full gamut of healthcare law, policy and regulation.

Increasingly, clients include financial firms and venture funds that focus on emerging healthcare technology. The work can include due diligence services, threats and opportunities analysis and bridging the expertise between investors and company leadership.

Efraim brings to the table 10 years in FDA policy, plus 10 years managing coverage and reimbursement policy at Medicare headquarters (CMS). He has run a Washington-based consultancy since 2007.

Pharma and Health, since 2007, looks at Washington policy trends affecting FDA-regulated products and Medicare-based reimbursement. PharmaAndHealth.com

Healthtech GPS, since 2020, focuses on leaders and investors in early-stage companies. The focus is effective and successful US market access, at launch time and beyond. HealthTechGPS.com

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Efraim Eric Katz, JD

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I provide health technologies a clear route through complex US regulations, offering effective strategies for market success, based on high-level positions in law and government policy

Professional Experience

Health Tech GPS — *HealthTechGPS.com*

Market Access for Healthcare Technologies

Founder and President — 2020-Current

We help innovative healthcare technologies reach the market successfully. We work with C-Suite executives, investors and other stakeholders to plan successful market developments in the face of an ever-changing US healthcare delivery system. We also offer due diligence services across the healthtech space.

•• For a startup looking to support home-based family caregivers, we explored market niches in home health and dialysis care. ** Over 200 helpful projects assisting investors, through several US Expert Networks. For a firm building telehealth services in cardiac health, we looked at potential revenue streams from new models of US managed care. ** For a gene-based testing firm, we looked at 510(k) options at FDA.

Pharma and Health — *PharmaAndHealth.com*

Washington. Healthcare. Translated.

President — 2007-Current

We equip clients with tools to master the intertwined regulatory systems facing innovative healthcare technology:

•• **Translate complex regulatory roadblocks** into clear and successful roadmaps for healthtech products – navigating the detailed administrative & scientific requirements for coverage, payment and compliance

•• **Analyze regulatory challenges** that arise at every stage of a product's lifecycle – testing & approval, coverage & reimbursement, compliance & reporting, regulatory & system change (Congress, White House)

•• **Build compelling big-picture narratives** – combining historical precedent, political realities, health policy, industry trends, clinical quality, legal factors, financial markets and scientific research into a clear mosaic view

•• **Assess detailed needs for a successful launch** — looking past FDA approval to fine points of coverage codes, billing, pricing, technology add-on payments, formularies, clinical practice adoption and data on value & quality

Recent engagements:

- ***On-the-spot analysis*** of how a Medicare decision might impact a high-cost, high-impact cancer drug – one of over 250 one-on-one consultations and national teleconferences through expert network referrals
- ***Regulatory policy strategy*** for CEO facing imminent launch of a surgical device – a last-minute CMS advocacy project, targeting technology add-on payments, new billing codes and data on costs & quality
- ***Technical assistance*** to association of Israeli healthtech startups – revamping corporate structure, building access to overseas markets, capital infusions and strategic partners for clinical trials & data

Centers for Medicare and Medicaid Services (CMS)

Group Director, Coverage & Reimbursement R&D 1997-2007

Led a team of data, technology and policy experts, managing and disseminating research studies for regulatory reforms improving Medicare and Medicaid. Produced compelling research results through:

- ***Anticipating the policy challenges*** that might face HHS, White House and other policymakers in 3-5 years – then designing and conducting studies to provide meaningful, data-driven findings to fuel reforms
- ***Sponsoring complex research*** serving both expert and lay audiences – using CMS datasets (claims, drug pricing (ASP)) and other sources) – then disseminating results to key constituencies
- ***Providing data-driven policy input*** toward CMS internal operations and national health reform – serving National Coverage Decisions (NCD), advisory councils (MedCAC) and technology assessments

US Agency for Healthcare Research and Quality (AHRQ)

Counselor to the Administrator 1995-1997

Provided confidential policy, legal and political counsel to the Agency Head during a period of major healthcare reforms, in support of a mission of healthcare quality improvement and cost-effectiveness research:

- ***Built coalitions*** of medical societies, drugmakers, patient advocates and government agencies to develop over 100 Clinical Practice Guidelines – a landmark campaign to promote universal quality in healthcare
- ***Funded and managed*** the development of novel quality and patient satisfaction measures (HEDIS, CAHPS), now used in Medicare and private plans for risk-based payments & quality incentives

US Advisory Committee on the Food & Drug Administration (FDA)

Executive Director 1987-1995

Coordinated the major FDA reforms of the decade, restructuring the review, approval and monitoring of FDA submissions. The landmark report and technical studies met favorable reactions from Congress, industry and national press, leading to reforms in drug approvals, user fees and patient access:

- ***Commissioned a top-to-bottom reform*** of new drug reviews, leading to the first purely-electronic NDAs, drug user fees and updated review procedures for generic drugs (ANDA)
- ***Expanded and redefined*** FDA efforts in compassionate use access, fast-track reviews for life-saving therapies, regulation of complex medical devices and commitments to public accountability
- ***Established and coordinated a Blue Ribbon Committee*** (Edwards Commission) that brought guidance from former and incoming FDA Commissioners, industry leaders, key opinion leaders

Kaye, Scholer (Health Law Section, Washington Office)

Associate Attorney (now Arnold & Porter Kaye Scholer) 1983-1987

Healthcare and Pharmaceutical Attorney in major international law firm, serving drugmakers, university researchers, healthtech innovators. Projects: generic drug legislation (Hatch-Waxman), pricing of NIH-funded new drugs (march-in rights). Staff counsel to Special Master of Agent Orange mass tort cases (Ken Feinberg)

Education

Law School:	University of Texas at Austin (Law Review Editor, Fifth Circuit Clerk)
Business School:	Wharton School of Finance
Public Health:	*Fulbright Fellow*, Technische Universität, Berlin Germany
University:	University of Pennsylvania
Languages:	English (mother tongue), German (academic), Hebrew (basic)