

*Health Sciences Practice Group*

**KIRTON &  
McCONKIE**  
ATTORNEYS AT LAW

Local Roots, Global Reach



# Health Sciences Practice Group

Law and Intellectual Property Specialists in

Pharmaceuticals  
Biotechnologies  
Nutritionals  
Medical Devices  
and  
Personal Care Products

Salt Lake City,  
Utah

Princeton,  
New Jersey

Nanjing, China

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## Section I

## Our Practice

**Kirton & McConkie** is a full service law firm with both a United States domestic and an international law practice. Our lawyers have provided legal services in all 50 states of the United States and in over 100 countries. We speak 18 languages. We have lawyers resident in Utah, New Jersey, and China. In our Salt Lake City office, we have lawyers from Japan, China, and Mexico. Through its membership in TAGlaw, KMC is a part of a worldwide network of associated law firms.

### Product Experience

Our **Health Sciences Practice Group** is comprised of attorneys and other professionals who have experience as counsel for clients in (1) pharmaceutical and biotechnology companies (including large and small producers of both ethical and over-the-counter products), (2) nutritional and dietary supplement companies, (3) medical device, diagnostic, and therapeutic companies, and (4) personal care companies, selling a range of products from cosmetics to toothpaste.

### Professional Experience

Our core legal staff includes MDs, MBAs, and CPAs. We are a team of experienced professionals who understand the operation of health and personal care companies. We have experience in the internal interaction of divisions and departments within the corporation (scientists, businessmen, and staff departments — corporate development, corporate finance, manufacturing, tax, treasury, sales and marketing, information technology, and corporate compliance). We have years of participation in complex negotiations both within and between corporations and government.

Our professionals, who have practiced “in-house”, in law firms, and in government can assist you anywhere in the gamut from single transactions or disputes, at one extreme, and, at the other extreme, conceptualizing, planning, managing, and completing the entire legal/business interface of a complex longer term project — interacting closely with company counsel, other law firm counsel, governments, management, and corporate staff department —with close attention to the designated legal budget.

### International Experience

We are especially strong in transnational, trade, and non-United States matters of the global economy — matters in and between the United States, Europe, Japan, Latin America, Eastern Europe, the Pacific Rim, China, Africa, the Middle East, and the Sub-continent. We have dealt with **Pharmaceutical, Biotechnology, Nutritional, Medical Device, and Personal Care** matters in the United States and in over 50 countries outside the United States. We have represented United States companies and non-United States companies, as well as divisions of each.

Our **Health Sciences Practice Group** professionals profiled in Section II are prepared to assist clients in the full range of their legal needs in the **Pharmaceutical, Biotechnology, Nutritional, Medical Device, and Personal Care** industries.

## Section II

## Our Professionals



**Conan P. Grames** [B.A., Economics, University of Utah; J.D., Harvard Law School] was Senior Counsel and Vice President of Bristol-Myers Squibb Company in charge of its International Law Department, comprising 30 lawyers who handled the full range of legal problems of integrated businesses in the Worldwide Medicines Group (ethical and over-the-counter pharmaceuticals), nutritionals, medical devices, and Worldwide Personal Care Products. His lawyers handled all of the company's legal work outside the United States, which included over 100 markets in Western and Eastern Europe, Japan, the Middle East, Africa, Latin America, China, Asia/Australia, and the Sub-continent. He was responsible for providing counsel for the legal needs of operations totaling US\$ 7 billion and managed an outside counsel budget in the millions of dollars. Prior to Bristol-Myers Squibb, he was a Partner at Baker & McKenzie where he served in the Tokyo office. He is fluent in Japanese and has lived in Japan cumulatively for 15 years. He has taught Japanese at Middlebury College, The Japan Society of New York, and the University of Utah.



**John S. Boyden, Jr.** [B.S., Medical Biology, J.D., M.D., University of Utah — selected as the outstanding medical student in pharmacology; Internship in Surgery, The New York Hospital—Cornell Medical Center in New York] is an independent, medical/legal consultant who works closely with the firm to meet the domestic and foreign regulatory needs of our clients. He assists in the preparation of various applications to regulatory agencies to enhance the likelihood of approval and serves as a troubleshooter to prevent or resolve disputes with regulatory agencies so that litigation can be avoided where possible. For example, he works with the FDA's Center for Drug Evaluation and Research, Center for Devices and Radiological Health, and Center for Biological Evaluation and Research. He collaborates with teams of scientific and marketing professionals in formulating product development strategy and designing test protocols, then assists in collecting, organizing, analyzing, and presenting the results. He has a strong background in information technology which is useful in resolving issues related to data collection, presentation, and electronic filing. He is resident in Utah, licensed to practice medicine in Utah, and a member of the Utah Bar.



**Donald F. Crane** [B.A., Communications, J.D., University of Georgia] was General Counsel of Cytogen Corporation, a New Jersey biotechnology firm, and Senior Counsel of U.S. Surgical Corporation, a developer, manufacturer, and marketer of medical devices headquartered in Connecticut. Beyond his extensive knowledge of the pharmaceutical and medical device industries, he has special depth in corporate finance, securities regulation, raising funds, and corporate governance — both within the United States and outside. He has years of experience dealing with

highly regulated industries. He is resident in New Jersey, and is a member of the Georgia Bar. He has basic fluency in Bulgarian and French.

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**Kevin F. Cunningham** [B.A., Political Science and Spanish, Duke University; M.B.A., Finance and Business Economics, Columbia University; J.D., Yale Law School] was Senior Counsel and Vice President of Bristol-Myers Squibb Company dealing with law concerns of its ethical and over-the-counter pharmaceutical products, Mead Johnson Nutritional products, ConVatec [a medical device company], and Worldwide Beauty Care. He assisted these clients, which had a combined budget of over US\$ 2 billion dollars, in the United States, Europe, North and South America, the Caribbean, Iberia, the Middle East, and the Pacific Rim. He supervised seven lawyers in the United States and outside and controlled an outside counsel budget of over US\$ 1 million for more than 25 countries. Prior to practicing with Bristol-Myers Squibb, he was Counsel to Gulf Oil/Chevron in Houston, an Associate at Morgan Lewis & Bockius in Washington, D.C., and Clerk to a United States Federal District Judge. He is resident in New Jersey and is a member of the Bars of the District of Columbia and Texas. He has lived in Latin America and is fluent in Spanish and familiar with Swedish, Portuguese, and Italian. He has taught at Princeton University, Georgetown, Columbia, and Rice.



**Kenneth E. Horton** [B.S., Chemical Engineering, University of Utah; M.B.A., George Washington University; J.D., The Catholic University of America] was a United States Patent Examiner in the Office of Technology Policy in the Department of Commerce, and practiced with Finnegan, Henderson, Farabow, Garrett & Dunner, L.L.P. in Washington, D.C., where he carried out work for clients such as Eli Lilly, Hoechst Pharmaceuticals, Rhone-Poulenc Rorer, and SmithKline Beecham. He is expert in all aspects of United States and non-United States patents, trade-marks, copyrights, trade secrets, intellectual due diligence, and license agreements. He is resident in Utah, a member of the Bars of the District of Columbia, Virginia, and Utah, and is licensed to practice before the United States Patent and Trademark Office. He is fluent in Norwegian and familiar with Swedish and Danish.



**Jarod Marrott** [B.S., Biochemistry, University of Washington; J.D., University of California, Davis] was a Laboratory Technician Supervisor at Myriad Genetics in Salt Lake City, and a Research Associate in the Department of Molecular Biology at the University of Utah. He is resident in Utah, a member of the Utah Bar, and is licensed to practice before the United States Patent and Trademark Office.

**Network of Contacts:** Beyond these experienced lawyers on our staff, we have available to us a former Assistant General Counsel at Pfizer, a former Associate General Counsel (Patents) at Bristol-Myers Squibb, a former Associate General Counsel (Litigation) at Bristol-Myers Squibb, a customs law attorney with expertise in pharmaceutical products, a former Assistant General Counsel at Johnson & Johnson, a former head of regulatory affairs at Bristol-Myers Squibb, a Director of public relations at Bristol-Myers Squibb, Counsel for Nikkiso (Japan's leading dialysis company), an expert in drug registration in Japan and Europe, a firm of quality control specialists, developers of process systems software, etc. We also have a substantial network of pharmaceutical counsel throughout the United States and most countries outside the United States.

Finally, we also have a **Network of Contacts** throughout the **Pharmaceutical, Biotechnology, Nutritional, Medical Device, Personal Care Products** industries as well as in professional consulting groups for each industry.



## Section III Our Experience

As companies in the **Pharmaceutical, Biotechnology, Nutritional, Medical Device, and Personal Care** industries develop, they enter new phases, each with its own legal concerns. Our **KMC Health Sciences Practice Group** has experience dealing with each phase and the transactions that grow the business.

### Business Experience

Our **KMC** professionals have experience in the legal aspects of:

- Basic research
- Product discovery
- Product development
- Product registration
- Ramping up production
- Manufacturing
- Distribution and warehousing
- Marketing
- Sales

### Technical Experience

Areas of legal practice, which are specific to these steps in the **Pharmaceutical, Biotechnology, Nutritional, Medical Device, and Personal Care** businesses, include (whether in the United States or outside the United States):

- Intellectual property – patents, trade secrets, trade marks, management and focus of intellectual property portfolios, and lifecycle management.
- Government regulatory matters – the FDA, the EMEA, the MHW, other non-United States regulatory agencies, GMP, GLP, and labeling.
- Pricing – Medicare, United States and non-United States government pricing.
- Regulation of marketing – support of claims, anti-fraud, and anti-kickback laws.
- Government affairs – trade associations (PHARMA, etc.) and legislation.
- FDA law.

### Industry Experience

In addition, there is an array of other areas of law with specific application to the **Pharmaceutical, Biotechnology, Nutritional, Medical Device, and Personal Care** industry:

- Collaboration agreements/strategic alliances (in basic research, discovery, development).
- Agreements for discovery and development – sponsored research – universities, research institutes, the NIH, CROs, trials.
- Manufacturing – third party, own, joint, interim, United States and outside the United States, and recalls.
- Marketing arrangements – distribution arrangements, warehousing, termination of dealers, co-marketing, co-promotion.
- Promotion and advertising – Lanham Act.

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## Legal Experience

Beyond these disciplines are areas of law necessary for **Pharmaceutical, Biotechnology, Nutritional, Medical Device, and Personal Care** practice:

- Focused and complex negotiations.
- Business organization – corporations, joint ventures, partnerships, LLPs, by-laws, shareholder agreements, periodic meetings.
- Mergers/acquisitions/dispositions of intellectual property, lines of products, entire divisions, and physical assets – both within the United States and outside the United States.
- Direct selling (multi-level marketing) – legal and regulatory issues in the United States, China and Japan.
- Licensing in and out.
- Personnel/labor concerns – hiring, terms of employment, ERISA, compensation and benefit packages, pension plans, personal income taxes, downsizing and terminations.
- International movement of personnel – immigration.
- Privacy laws and protection of confidential data.
- Dispute settlement – mediation, arbitration, litigation, ADR, and administrative proceedings.
- Corporate finance – strategic investment, angels, venture capital, IPOs, etc.; dealing with financial regulatory bodies and securities exchanges, both in and out of the United States, and investor relations.
- Corporate compliance, codes of conduct, Sarbanes-Oxley securities exchanges.
- Acquisition and development/construction of sites and facilities – real estate, office buildings, factories, distribution centers – both in the United States and outside the United States.
- Taxation of transactions – United States, non-United States, transfer pricing.
- Trade law – foreign trade control, sanctions, boycotts, anti-dumping, customs, valuation.
- Internal investigations and criminal matters – Foreign Corrupt Practices Act, white collar crime, etc.
- Anti-trust – including scientific collaborations, M&A.
- Foreign investment – both into and from the United States.
- Full range of other contracts from packaging materials, to transport, to computer licenses, etc.
- Environmental law.

Our **KMC Health Science Practices Group**, and its associated practice groups, have depth and breadth of experience in each of the areas listed above.

Beyond the **Pharmaceutical, Biotechnology, Nutritional, Medical Device, and Personal Care** practice, **Kirton & McConkie** has a **Health Care & Risk Management Practice** which deals with medical staff issues, risk management and quality assurance, medical malpractice defense, Medicare/Medicaid representation, bioethical legal issues, consent polices and procedures, death and dying, and emergency medicine.

In addition, the following **Kirton & McConkie** legal practice groups support various aspects of the **Health Sciences Practice**: Construction and Land Development, Corporate and Taxation, Employment Law, Immigration, Intellectual Property, International Law, Real Estate and Land Use Planning, and Business Litigation.

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## Section IV

## Our Commitment

Our Health Sciences Practice Group is committed to assisting clients in the full range of their legal needs in the **Pharmaceutical, Biotechnology, Nutritional, Medical Device, and Personal Care** industries in the law specialties and matters listed in Section III, in the United States, outside the United States, or in international trade.

We are committed to providing services at the highest quality and at a cost that is competitive with the best available.

We are committed to being the standard in legal consulting in the health sciences industry.

### Contact Us

Please contact our **Kirton & McConkie Health Sciences Practice Group** at:

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