



Julia Baldi

Special Counsel

Melbourne
+61.3.9640.4212

julia.baldi@klgates.com

OVERVIEW

Julia Baldi is a corporate and regulatory special counsel with a focus on the healthcare and life sciences services industries. She advises clients on a range of issues including commercial contracting, compliance with Australian regulatory requirements, privacy, risk management and transaction structuring.

Julia's clients include public and private health service providers, pharmaceutical, medical device and biotechnology companies, private health insurers and aged care and retirement living operators.

EDUCATION

- Bachelor of International Relations, La Trobe University, 2012
- LL.B., La Trobe University, 2012

ADMISSIONS

- Supreme Court of Victoria

THOUGHT LEADERSHIP *POWERED BY HUB*

- 26 March 2020, COVID-19: (Australia) Illegal Therapeutic Goods Advertising and COVID-19
- 17 September 2018, Royal Commission into Aged Care Quality and Safety
- 3 November 2016, What happens when electronic signatures are affixed without authority?
- 20 May 2015, Cyber Resilience for Financial Services Entities

AREAS OF FOCUS

- Mergers and Acquisitions
- Food, Drugs, Medical Devices, and Cosmetics (FDA)

- Health Care and FDA

REPRESENTATIVE EXPERIENCE

- Advised an operator of residential aged care facilities on compliance with federal and state legislation and regulatory considerations, including implementation of the Living Longer Living Better reforms.
- Advising clients on compliance with regulations relating to the advertisement of health services with a particular focus on compliance with the uniform Health Practitioner Regulation National Laws, the Privacy Act and the Australian Health Practitioner Regulation Agency codes of conduct.
- Mergers and acquisitions of pharmaceutical companies, medical practices and corporate health service providers, aged care facilities (including structuring and due diligence) and advising on regulatory issues.
- Advising pharmaceutical, medical device and biotechnology clients on compliance with obligations resulting from inclusion, listing, or registration on the Australian Register of Therapeutic Goods including with respect to sale, distribution, import and export of therapeutic goods.
- Advising on establishing Australian subsidiaries for foreign based entities including structure of incorporation, ongoing compliance matters and liaising with the Australian Securities and Investments Commission.
- Advising Catalent Pharma Solutions, Inc., a global listed pharmaceutical company headquartered in the U.S., in relation to the sale of 100% of its tablet and soft-gel capsule manufacturing facility in Victoria, Australia for AUD43.2 million to Blackmores Limited.
- Advising research institutions and life sciences clients on the conduct of research and collaboration agreements with respect to health and life science developments, including commercial arrangements with researchers, funding agreements, global collaborations and regulatory and ethics compliance.
- Corporate and commercial contracting with respect to healthcare and life sciences industries including specialised contacts in relation to: the provision of health services and engagement of health care providers, and supply and wholesale and retail distribution of therapeutic goods.
- Advising pharmaceutical, medical device and biotechnology clients on compliance with regulations relating to the advertisement of therapeutic goods, including labeling regulations and compliance with the Medicines Australia Code of Conduct, Generic and Biosimilar Medicines Association Code of Practice, Medical Technology Industry Code of Practice and requirements of the Australian Self-Medication Industry and the Complementary Healthcare Council.
- Advising pharmaceutical, medical device and biotechnology clients on the conduct and management of Australian and global multi-center clinical trials (from phase I to phase III), including commercial arrangements with institutions, contract research organisations and service providers, compliance with Medicines Australia standards, and regulatory and ethics approvals and compliance.
- Advising on structuring and establishing corporate health models including contractor arrangements for a range of healthcare providers such as general practitioners, dentists, ophthalmologists, physiotherapists and in-hospital service clinics.

- Advising pharmaceutical, medical device and biotechnology clients on applications for inclusion, listing or registration of medicines and medical devices on the Australian Register of Therapeutic Goods and listing on the Australian Pharmaceutical Benefits Scheme.
- Advising major private health insurance providers on structuring of product offerings and compliance with the Private Health Insurance Act, privacy and ongoing regulatory obligations.
- Advising clients on compliance with the Health Insurance Act including in relation to the payment of Medicare benefits and compliance with permitted benefits under Part IIBA of that Act.