Representative Legal Matters

Chia-Feng Lu

Licensing & Transaction

- Advised a US biotechnology company on its co-development and licensing deal for its novel immunotherapy product in China, Japan, the US and Latin America.
- Advised a Japanese conglomerate on its acquisition of a US diagnostic company to build up its precision medicine capacity in the US.
- Represented a US biotechnology company to frame a global supply framework with a major pharmaceutical company regarding its newly approved orphan drug.
- Advised a US bioventure on its structured monetization of a portion of its royalty interests of an ophthalmology peptide product.
- Assisted a Japanese pharmaceutical company in its post-merger integration with a European pharmaceutical company across seventy six jurisdictions.

Regulatory

- Represented a Japanese pharmaceutical company in its interactions with the regulatory agencies regarding numerous guidance documents impacting the product development of its cell/gene therapy products.
- Advised a leading in vitro diagnostics company on its PMA process of a next-generation sequencing product.
- Represented a US device company to respond Form 483s and warning letters.
- Advised a global technology conglomerate on the least burdensome approach to launch its digital health product in more than twenty jurisdictions.
- Advised a specialty pharmaceutical company in its negotiations with regulatory agencies in multiple jurisdictions concerning product approval and risk mitigation plans for its novel cancer immunotherapy, and subsequently its cancer immunotherapy became the first approved product in several indications in a number of countries.

Compliance

- Led the initiative to prepare and implement global policies and procedures, such as anti-bribery, sponsorship, donation, fair market value, transparency, interactions with the stakeholders, on behalf of a leading pharmaceutical companies
- Led the investigation on behalf of a global biotechnology company regarding any potential FCPA violations of its overseas distributor.
- Helped defend a global medical device company against the investigation concerning its unfair competition practices.
- Conducted an assessment of a pharmaceutical company's promotional review committee, and developed a pharmaceutical company's compliance manual in advertisement and promotion.
- Routinely advise pharmaceutical and biotechnology companies regarding communication to healthcare professionals, patients, and payers.

Intellectual Property & Data Privacy

- Developed a trade secrets protection program to leading pharmaceutical company's emerging technology business division.
- Advised a US healthcare conglomerate in its establishment of an innovation incubation center affiliated with a healthcare institution in Abu Dhabi regarding technology transfer and intellectual property protection.
- Assisted a major pharmaceutical companies in the establishment of its cross-border data transfer framework.
- Led the investigation of a patient data leakage incident on behalf of a leading biotechnology company.
- Advised on a leading biotechnology company's authorized generic strategy of its blockbuster cancer product.