MICHAEL A. SWIT

Representative Matters

Medical Devices and In Vitro Diagnostics

- Represented Kindstar Diagnostics Co. Ltd., in connection with its agreement with BG Medicine, Inc. for Kindstar to offer galectin-3 testing services for heart failure management in China (October 2012).
- Coordinated response of Canadian device manufacturer to FDA detention of devices allegedly misbranded by including claims outside allowed intended uses. Conducted detailed review of labeling claims, including website, Facebook and Twitter postings, to allow client to revise claims to enable it to reintroduce device into U.S. market.
- Coordinated major remediation effort for device maker facing systemic QSR deficiencies following FDA inspection and Warning Letter; effort led to FDA follow-up inspection with just a single observation.
- Counseled on reclassification petitions for devices including under the FDA's de novo process for down-classifying devices involving new technology that are automatically classified in most restrictive device class (III), but can be regulated under controls applicable to Class II devices.
- Construed applicability of Investigational Use Only (IUO) and Research Use Only (RUO) regulations to marketing of line of diagnostic products.
- Developed FDA regulatory strategy for device that monitors key body functions and activities (e.g., heart rate, sleeping, steps, calorie burn) and links to mobile app.
- Counsel on FDA regulatory and advertising issues for mobile medical application designed to help consumers manage a major disease condition.

Innovative Drug Issues

- Developed overall strategy leading to filing and approval of New Drug Application (NDA) for innovative drug/device combination narcotic product for breakthrough cancer pain.
- Secured FDA reversal of agency's initial denial of 3-year exclusivity under Waxman-Hatch Act for OTC switch of drug previously available only via prescription. Involved detailed written submission to FDA on how law applied to particular factual scenario regarding client's NDA for the Rx-OTC switch.
- On behalf of a pharmaceutical firm pursuing approval of a product that combined both a drug and medical device, conducted detailed review of applicability of FDA's "Combination Product" policies. Effort clarified for client when it would need to apply the drug and/or device regulations to its operations relative to a unique combination product that was awaiting imminent FDA approval.
- Coordinated all aspects of recall of pharmaceutical, including securing health assessment, drafting recall letters and press releases, and coordinating with FDA.
- Secured issuance of FDA regulatory letter against brand name drug firm making improper comparative claims.
- Served on detail for over six months as in-house regulatory vice president for client involved with combination biologic/device product, allowing client to resume clinical studies that had been stalled.

- Penned waiver requests under Pediatric Research Equity Act (PREA) as applicable to NDAs being filed by clients with innovative analgesic products being reviewed under FDA's 505(b)(2) NDA process.
- FDA counsel to major compounding pharmacy; led strategy to establish separate subsidiary to obtain formal FDA approval of specialty compounding formulations while maintaining compounding status.
- Cleared import detention for importer of combination drug/device from China by conducting detailed label reviews and corrections to labeling.

Generic Drug Issues

- Led strategy to fight FDA's proposed withdrawal of client's abbreviated new drug application for unique topical drug product. Representation involved detailed written submission, including coordination with expert witnesses. securing drug's continued marketing.
- Coordinated generic drug company's cooperation with federal criminal and congressional investigations leading to plea bargain agreement that allowed company to stay in business.
- Developed and oversaw operations of first corporate ethics program for generic drug firm as part of firm's rehabilitation program following plea bargain for illegal activities of prior senior management.
- Negotiated agreement with Defense Logistics Agency successfully ending generic drug company's three-year suspension from federal government contracting.
- Led consortium of eight generic clients fighting FDA's withdrawal of new drug applications for generic versions of Persantine® (dipyridamole) allowing clients to remain on market.

Over-the-Counter Drug Issues

- Defended OTC drug client's advertising from competitor's challenge before National Advertising Division (NAD) of Better Business Bureau.
- Detailed review and analysis of impact of FDA's then new T.E.A. (Time and Extent Application) regulations for OTC drugs.
- Prepared detailed comments on proposed change to FDA OTC Monograph on hydrocortisone products.

Dietary Supplement Issues

- Outside FDA counsel to family of firms bringing innovative dietary supplement and cosmetic products to market based on one of world's oldest cultivated plants. Counseling includes not only FDA issues, but FTC compliance analyses for advertising and promotion activities.
- Provided legal analysis on new dietary ingredient status of ingredient client wishes to market as a dietary supplement.
- FDA counsel to major diet program which includes both conventional foods and dietary supplements as part of its diet regimen.
- Co-counsel in litigation on behalf of dietary supplement maker seeking to recover costs of a very expensive recall from supplier that sold client an ingredient that was adulterated, but in a manner that the client could not possibly detect before using the ingredient to make supplements that the client sold in commerce.

Cosmetics

- Represented Maryland-based JADS International in addressing Disney/Marvel legal and technical concerns concerning JADS' innovative sunscreen wrist bands - which turn color to remind you to reapply sunscreen - by demonstrating that the product was outside FDA purview and worked as claimed.
- Intensive review of client's cosmetic product's labeling and advertising claims to ensure not "drug" in nature, as well as assessment of comparative and other claims under FTC standards.
- Secured imposition of import alert on gray market Dial® soap (on behalf of "real" Dial®) by showing FDA that foreign-made Dial® contained color additives illegal in United States.

Clinical Research Issues

- Prepared reply to warning letter issued to IRB resulting in IRB being able to continue operations without further FDA enforcement action.
- Drafted informed consent documents for clinical study of food product.
- Developed procedures needed for biotech firm to be able to show compliance with Good Clinical Practice to be able to initiate clinical study.

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