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Regulation of Medical Food and Nutritionals in the European Union, China, and the United States

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Regulation of Medical Food in the European Union

Sebastián Romero Melchor

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Definition of a Medical Food ("*Foods for special medical purposes*")

- Directive 1999/21/EC (Article 1(2)(b))
  - "(*…) category of foods for particular nutritional uses specially processed or formulated and intended for the dietary management of patients and to be used under medical supervision. (…)*
  - when the dietary management of persons to whom they are intended "*cannot be achieved only by modification of the normal diet, by other foods for particular nutritional uses, or by a combination of the two"*

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Definition of a Medical Food

Special characteristics of FSMP: **disease-oriented**

- **Specially** processed or **formulated** and intended for the **dietary management** of patients
- Used under **medical supervision**
- Formulation has to be based on **sound medical and nutritional principles**
- **Safe, beneficial** and **effective** in meeting the particular nutritional requirements of the persons for whom they are intended, as **demonstrated** by generally accepted scientific data

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Definition of a Medical Food

In addition, commercialization of FSMP can be subject to restrictions:

- Notification/Registration
- Subject to advertising restrictions
- Restrictions surrounding retail channels
- May be reimbursable by Member States' respective social security systems

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Claims

Voluntary claims vs. mandatory claims

- Difference between *voluntary claims* and *mandatory labelling information*
  - FMSP must include *"for the dietary management of…"*
  - The above is NOT considered a health claim
- FSMP
  - Subject to general regime - Regulation 1924/2006/EC
  - unless there are more specific rules in PARNUT Directive

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Examples of litigation

- **"*Glucosamin Naturell*" (BGH, judgment of 30.11.2011 – I ZR 8/11)**
  - 1,000 mg for the dietary management of insufficient cartilage formation in the joints
  - Several food supplements with similar quantities of glucosamine on the market
  - "…*cannot be achieved only by modification of the normal diet..*"
  - Demarcation of FSMP: recipe change or marketing as FS

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Examples of litigation

- **"Artrostar" (BGH, judgment of 15.3.2012 – I ZR 44/11)**
  - 905 mg glucosamine sulphate, 666 mg chondroitine sulphate, 40 mg hyaluroic acid for the dietary management of mild to medium arthritis in the joints
  - Lacked proof of effectiveness: meaning of "*demonstrated by generally accepted scientific data*"
  - Product-related randomised placebo- controlled double-blind study.
  - Only in case of pain relief products?

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The Future of Foods for Special Medical Purposes (in general)

- No major changes foreseen
- EU lists expected to have specific reference
- EP: include peer reviewed/medical opinion as part of substantiation
- Relevance of Interpretation clause
- Connection with infant formulae legislation as case study of what the future may bring

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The Future of Foods for Special Medical Purposes (Connection with infant formulae legislation)

- SCOFCAH meeting of June 22, 2012.

"*However, **the Committee took note of the evolution in the market** and considered that in the context of the revision of the framework legislation on foods for particular nutritional uses and acts thereof, **further consideration should be given to the inclusion of certain relevant specific provisions for FSMPs***"

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The Future of Foods for Special Medical Purposes (Connection with infant formulae legislation)

- Restrictions in Directive 2006/141
- **Compulsory statements** for infant formulae and follow-on formulae (e.g. superiority of breast feeding)
- **Ban on pictures** of infants, or idealisation of the use of the product
- Specific **list of nutrition and health claims** (only in the cases listed in Annex IV)
- **Applicable to advertisement and presentation** of the products (shape, appearance or packaging, the packaging materials used, the way in which they are arranged and the setting in which they are displayed)
- Restriction of advertising of infant formulae **to publications specialising in baby care** and scientific publications

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The Future of Foods for Special Medical Purposes (Connection with infant formulae legislation)

- Restrictions in Directive 2006/141
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- Restriction of advertising of infant formulae **to publications specialising in baby care** and scientific publications
- Ban on **point-of-sale advertising**, giving of **samples** or any other **promotional device to induce sales** of infant formula directly to the consumer at the retail level, such as **special displays, discount coupons, premiums, special sales, loss-leaders and tie-in sales**.
- Ban on **free or low-priced products**, samples or any **other promotional gifts**, either directly or indirectly via the health care system or health workers

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The Future of Foods for Special Medical Purposes (Connection with infant formulae legislation)

- Infant formulae as case study?
  - Background is the same: proliferation of FSMP in all categories
  - Increasingly food supplements being converted to FSMP
- **Limited to low birth weight and pre-term infants or extended to all FSMPs?**

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IV. The Future of Foods for Special Medical Purposes (Connection with infant formulae legislation)

(16a) According to the recommendations of the World Health Organization, low-birth weight infants should be fed their mother's own milk. Nonetheless, ***low birth-weight infants and pre-term infants*** *often have special nutritional requirements which cannot be met by the mother's own milk or standard infant formulae. Food for such infants* ***should comply with rules applicable to food for special medical purposes****, when this kind of food is chosen as the most appropriate formula, taking into account the specific medical situation of the infant. Formula intended for low birth weight or pre-term infants should* ***in any event comply with the requirements of Directive 2006/141/EC***

[European Parliament legislative resolution of 14 June 2012 on the proposal for a regulation of the European Parliament and of the Council on food intended for infants and young children and on food for special medical purposes (COM(2011)0353 – C7-0169/2011 – 2011/0156(COD))]

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Ideas to take home

- As of today, no major changes except for forthcoming rules on birth weight and pre-term infants
- Scientific substantiation requirements may become stricter
- Continue proliferation of FSMP as a route to market products previously conceived under other categories

Regulation of Medical Food in China

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Current State of the Chinese Clinical Nutrition Market

- Parenteral, intravenous nutrition predominates
- The Chinese enteral nutrition market is vastly underdeveloped – historical numbers:
  - Market size in RMB millions (2008): China- 286, HK- 355, Australia- 512, Japan- 3,703, US- 14,152
  - Sales per capita in RMB (2008): China- 0.2, HK- 51, Australia- 25, Japan- 29, US- 47
- Lacks a specialized 'medical food' category
  - All clinical nutrition products meant for oral or enteral administration are classified under one of two categories: food or pharmaceuticals

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Hindering Factors of Market Growth

- Regulation- Most (over 90%) medical food type products are classified as pharmaceuticals
  - Must pass years of clinical trials and increasing scrutiny due to recent safety concerns
  - Pharmaceuticals are only available at hospitals
- Lack of awareness- Chinese medical professionals are uneducated on the availability and benefits of medical food type products - China generally lacks skilled dieticians who typically advocate for utilization
- Market inertia- Deep entrenchment of parenteral nutrition in Chinese medical culture could mean substantial resistance from producers and consumers alike

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Reasons for Optimism

- Proven Asian examples- Hong Kong and Taiwan's enteral nutrition markets show robust potential for emerging markets
- Potential policy shift- Introduction of a 'foods for special medical purpose' category could eliminate or drastically reduce clinical trials – the draft 2012 MOH GB Standards.
- Education- Raising awareness in the medical community will loosen the grip of parenteral nutrition
- A matter of logic- Medical food type products have lower rates of complications and lower costs

Regulation of Medical Food in the United States

Suzan Onel

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Definition of a Medical Food

- Specially formulated for oral or enteral administration
- Under the active and ongoing supervision of a physician
- Intended for the specific dietary management of disease or condition with distinctive nutritional requirements
- Patient must have limited or impaired capacity to ingest, digest, absorb or metabolize ordinary food or certain nutrients
- Dietary management of disease cannot be achieved by modification of diet alone

21 C.F.R § 101.9(j)(8)

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Definition of a Drug

- Articles intended for use in the diagnosis cure, mitigation, treatment or prevention of disease
- Articles (other than food,) intended to affect the structure or any function of the body

→Requires FDA premarket approval unless subject to an OTC drug monograph

FDC Act § 201(g)

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Definition of a Dietary Supplement

- Intended to supplement the diet
- Contains one or more of the following dietary ingredients: a vitamin; a mineral; an herb or other botanical; an amino acid; a dietary substance to supplement the diet by increasing the total daily intake; or a concentrate, metabolite, constituent, extract, or combination of these ingredients
- Intended for ingestion
- Not represented for use as a conventional food or as the sole item of a meal or diet
- Prohibited from claiming to diagnose, mitigate, treat, cure or prevent a specific disease or class of diseases

FDC Act § 201(ff)

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Market Advantages of Medical Food Category

- No premarket submission or approval requirement
  →Distinguish from drugs
- Allowed to make disease claims
  →Distinguish from supplements

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Safety Standard for Medical Foods

- Medical foods, like “conventional” food products must contain only ingredients that are either GRAS for use in food or approved as food additives by FDA
- The ingredients must be generally recognized among qualified experts, as having been adequately shown to be safe under the conditions of intended use.
  - Prudent to have at least one safety study in the intended patient population, particularly when consider co-morbidities and medications being taken as part of treatment

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Effectiveness Standard for Medical Food

General principles:

- There should be scientifically validated distinctive nutritional requirements of the disease or condition
- There should be a scientific basis that the product is formulated for the dietary management of a particular disease
- There should be sound scientifically defensible evidence that the product does what it says it does in the designated population

ANPR, 61 Fed Reg 60668 (Nov. 29, 1996; withdrawn in 2004 to reduce regulatory backlog)

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Substantiation

- FDA Standard: "Truthful and not misleading"
- FTC Standard: "Competent and reliable scientific evidence"
  - FTC standard traditionally is flexible, based on nature of claim, totality of evidence and qualifications

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FDA Enforcement Activity Over Past 10 Years

- Metagenics, Inc. (2003 WL)
- Garden of Life (2004 WL)
- Ganeden Biotech, Inc. (2006 WL)
- Efficas, Inc. (2007 WL)
- Pan American Labs, LLC (2009 WL)
- Nestle Healthcare Nutrition (2009 WL)
- Bioenergy, Inc. (2010 WL)
- NeuroScience (2011 WL)

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FDA: No Distinctive Nutritional Requirements

NeuroScience 2011 – Alzheimer's Disease and Mild Cognitive Impairment

Bioenergy Corvalen 2010 – fibromyalgia, chronic fatigue syndrome, or cardiovascular disease

Nestle's Boost Kid Essentials 2009 – "failure to thrive"

Efficas 2007 – allergies or asthma

Ganeden 2006 – lactose intolerance, psoriasis, constipation arthritis, Crohn's Disease, irritable bowel syndrome

Metagenics 2003 – type 2 diabetes, arthritis, psoriasis, eczema, chronic fatigue, and migraine headaches

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FDA: Dietary Management of Disease Can be achieved by modification of the diet

Pan American 2009 – Vitamin deficiency throughout pregnancy, postnatal and lactating periods

Garden of Life 2004 – abnormally functioning immune system

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Looking Ahead

- Enforcement – "bursts" of interest by FDA, focus on products being marketed to broad populations
- Applicability of FDAAA §912*/ - no sale of food containing an approved drug
  - July 2008 Federal Register Notice, "Request for Comments" (73 Fed. Reg. 43937)
- Substantiation standard – Recent "ratcheting" up of expectations by FTC (Iovate, Dannon, Nestle Healthcare consent decrees and POM case)

*/FDC Act § 301(ll)

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Questions?

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OVERVIEW

Sebastián Romero Melchor is a partner in the firm's Brussels office. He focuses his practice on food and nutrition law matters in the European Union and EU member states. He represents a wide variety of multinational firms and trade associations on such matters as EU regulatory law and policy (free movement of goods), food labeling and advertising issues (health and nutrition claims), product registration (novel foods, food supplements, food for special medical purposes, cosmetics, etc.), and product liability (withdrawals, recalls), among others, with special focus on functional foods and drinks.

PROFESSIONAL BACKGROUND

Mr. Romero Melchor has practiced as a lawyer at English and Spanish top law firms and in the European Commission. Mr. Romero Melchor is a visiting professor in nutrition law at the UIB – Universidad de las Islas Baleares.

PUBLICATIONS

In 2001, Mr. Romero Melchor founded a pioneering online journal on food law, the the *Boletín Europeo de Derecho Alimentario*, which established itself as the leading reference in food law issues in Spain. In 2005, the publication became a monthly newsletter, *the Revista de Derecho Alimentario*. He contributes to several top food publications such as *EU Food Law*, *Agra Europe*, *Agrafood Biotech*, *World Drinks Report*, and other European leading journals. He is also in charge of the legal analysis section of *World Food Regulation Review*. He contributes with longer feature articles to Spanish legal journals such as *Gaceta Jurídica de la CE y de la Competencia*, *Comunidad Europea Aranzadi*, *Alimentaria*, etc.

PROFESSIONAL/CIVIC ACTIVITIES

- President, Asociación Española para el Derecho Alimentario
- Deputy secretary-general, Asociación Iberoamericana para el Derecho Alimentario
- Member, European Food Law Association
- Member, Food Lawyers' Network Worldwide

Sebastián Romero Melchor (continued)

ADMISSIONS

- Brussels
- Santa Cruz de Tenerife
- Spain

EDUCATION

LL.M., College of Europe, Belgium, 1998 (European Legal Studies)

Law Degree, University of Deusto, 1994

LANGUAGES

- English
- French
- Italian
- Spanish

REPRESENTATIVE WORK

In the *botanical extracts* field, he represented the Spanish food supplement industry in the seminal case C-88/07 Commission v Spain, of March 5, 2009, whereby the CJEU condemned the Spanish authorities for not implementing the mutual recognition principle to herbal food supplements legally marketed in other Member States. This ruling opened the Spanish market to food supplements from around the world and represented a significant clarification of the borderline between foods and medicines in EU law.

He has developed significant expertise in the field of health and nutrition claims and the interpretation of Regulation 1924/2006.

In the novel food sphere, we have prepared applications for substantial equivalence for several clients and we regularly advise novel food producers on questions of legal interpretation and practical application of Regulation (EC) 258/97 on novel foods and novel food ingredients. Some applications are public and can be viewed at the following webpage: http://www.food.gov.uk/multimedia/pdfs/thechiacompany.pdf.

In the *vitamins and minerals* sphere, following his action before the European Commission, Spain dropped the maximum limits of vitamins and minerals present in food supplements and has adopted a flexible approach towards the application of the mutual recognition principle.

He has extensive experience in the legal assessment of *food labels* and regularly advises food business operators on questions of legal interpretation and practical application of Regulation 1169/2011 on food information to consumers, category-specific legislation and the national rules complementing this framework.

He has developed significant expertise in the *notification of food supplements in the EU Member*

Sebastián Romero Melchor (continued)

States. Together with his team, he has obtained thousands of registration letters for manufacturers worldwide willing to benefit from the mutual recognition principle, and he is regularly in contact with the national officials in charge of these matters.

Legal and regulatory services provided include:

- Drafting legal opinions on the compliance status of food supplements, foods for special nutritional purposes, botanical extracts, novel foods and ingredients, functional foods, organic products, cosmetics, borderline products and regular foods;
- Applying for regulatory clearance for the use of these products in the EU and Member States;
- Advising on food labeling and advertising issues, with a special focus on the possibility of using nutrition and health claims;
- Providing general EU food law advice, etc.

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OVERVIEW

Mr. Gu's practice includes cross-border business transactions, private equity investments, general corporate matters, foods regulations, corporate compliance matters and overseas public offerings.

PROFESSIONAL BACKGROUND

Mr. Gu combines his hands-on practice experience in the United States and China, together with his extensive experience having worked in-house at a world-leading diversified healthcare and nutrition foods company as their Senior Counsel primarily responsible for nearly 50% of the company's USD1 billion business in China.

Mr. Gu has seen business operations in China under the microscope as an in-house counsel, at which position, he was heavily involved the regulations and enforcement of food safety issues, and received academic training in earlier years on business management. Those business experiences give him the capability of appreciating the financial/business impact of legal issues as businesses appreciate them and offering insightful on-the-ground advice regardless of whether clients are seeking to invest in China through capital movement or operate a business in China.

Mr. Gu has also been a legal advisor for Chinese companies seeking to invest overseas or to tap into the overseas stock markets.

PRESENTATIONS

- Wuxi Cleantech Seminar, Wuxi (March 2010)
- Jilin Financial Group – Capital Market in US Seminar, Chicago (November 2009)
- AON Food Safety Seminar, Shanghai and Beijing (August 2009)
- Grant Thornton China Seminar, Chicago (November 2005, November 2006 and November 2007)
- International Housewares Association – Legal Forum, Chicago (March 2006)

ADMISSIONS

- Illinois
- China

Max Gu (continued)

EDUCATION

J.D., Chicago-Kent College of Law, Illinois Institute of Technology (2006) (Dean's List, CALI Excellence for the Future Award)

M.B.A., University of Illinois (2001) (*Beta Gamma Sigma*)

LL.B., East China University of Politics and Law (1998) (with high honors, International business law)

LANGUAGES

- Mandarin
- English

RECENT REPRESENTATIVE WORK

- Served as senior in-house position in China for a world-leading diversified healthcare and nutrition foods company with primary responsibilities over all aspects of the company's business operations in China.
- Currently represents multinational corporations in the food industry in their labeling/packaging compliance projects in China as well as adversarial proceedings before the several regulatory agencies in China.
- Represented a good number of offshore private equity funds in their investments in China through obtaining preferred shares of offshore vehicles in the industries of agrochemical products, medical devices, building materials, auto parts, consumer products and consulting services, etc.
- Represented a China-based marketing solution company and a China-based automobile equipment manufacturer which sought to go public in Hong Kong.
- Represented a China-based fine chemicals manufacturer which sought to go public in US.
- Represented a US sport brand in their merger and acquisition in China.
- Represented a US aviation consulting company in their negotiation with airport authorities in China.
- Represented a Hong Kong investment group in the establishment of their car dealerships of imported cars in China.
- Represented a publicly traded Chinese construction equipment company to set up assembly facilities in the United States.
- Represented a U.S. manufacturer of point-of-sales materials for brewery industry in their establishment of manufacturing facilities, litigation matters in China and offshore restructuring for financing purposes.
- Represented a U.S. data mining software developer to set up a wholly-owned subsidiary in China.

Max Gu (continued)

- Represented a U.S. supplier of Wal-Mart in sourcing products and intellectual property litigation matters in China.

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AREAS OF PRACTICE

Ms. Onel practices FDA law with a primary focus on regulatory issues involving medical devices, foods, dietary supplements, over-the-counter drugs, cosmetics and consumer products. She regularly advises international and domestic manufacturers, distributors, and researchers on market entry strategies, labeling and promotional activities, regulatory compliance, recalls and field corrections, and enforcement defense. Ms. Onel assists clients with the preparation of FDA submissions, including 510(k) premarket notifications, premarket approval applications (PMAs), food additive petitions, GRAS self-affirmations and notifications, food contact notifications, new dietary ingredient notifications, and adverse event reports. Ms. Onel's experience includes representing clients before the U.S. Food and Drug Administration; the Federal Trade Commission; the U.S. Department of Agriculture; the Bureau of Alcohol, Tobacco, and Firearms; the National Advertising Division of the Better Business Bureaus; and similar international and state bodies.

Ms. Onel's practice also includes FDA due diligence investigations and advising companies and private equity/venture capital investors on transactional matters involving life science company acquisition, divestment and capital growth as well as supplier contracts and clinical research agreements. Additionally, she counsels clients on trademark and copyright protection, unfair competition, the Lanham Act, trade dress, and Internet-related issues.

PROFESSIONAL BACKGROUND

Ms. Onel regularly speaks and writes on FDA issues including medical device software, food regulation, and dietary supplement/functional food. She has written articles and chapters in compilations published by the Food and Drug Law Institute, the Regulatory Affairs Professionals Society, the Medical Device & Diagnostic Industry, and others. Ms. Onel is also co-editor of the PLI treatise, "Medical Devices Law and Regulation Answer Book 2013."

PUBLICATIONS

- Chapter 8, "Cosmetics Regulation Revisited," *Food, and Drug Law and Regulation, 2nd Ed.*, Food and Drug Law Institute, December 2011.
- Co-Editor and contributing author, *Medical Devices Law and Regulation Answer Book,* published by the Practising Law Institute (PLI), September 2011.
- "Cultured Stem Cells for Autologous Use: Practice of Medicine or FDA Regulated Drug and Biological Product?," K&L Gates Food, Drugs, Medical Devices and Cosmetic Alert, September, 19, 2011.

Suzan Onel (continued)

- "Reducing FCPA Risks for Pharmaceutical and Medical Device Companies Through Cost-Effective Compliance Strategies," *FDLI Update,* Fall 2009.
- "Reducing FCPA Risks for Pharmaceutical and Medical Device Companies Through Cost-Effective Compliance Strategies," *K&L Gates Foreign Corrupt Practices Act (FCPA)/Food, Drugs, Medical Devices and Cosmetics Alert,* June 11, 2009.
- "Regulating the Conduct of Medical Device and Drug Manufacturers: Beware the Massachusetts Health Care Practitioner," *K&L Gates Life Sciences Alert,* April 22, 2009.
- "FDA to Review Classification of 25 Medical Device Categories," *K&L Gates Food, Drugs, Medical Devices and Cosmetics Alert,* April 16, 2009.
- Chapter, "Cosmetics Regulation Revisited," *Food and Drug Law and Regulation, 1st Ed.,* Food and Drug Law Institute, December 2008.
- "Building and Retaining Trust in the Biomedical Community," *Cleveland Clinic Journal of Medicine*, written for Dick Thornburgh. March 2007.
- Chapter, Postmarket Requirements for Significant Risk Devices," *Clinical Evaluation of Medical Devices, Principles and Case Studies* (2nd Ed., 2006).
- "Dietary Supplements: A Definition that is Black, White and Gray," *American Journal of Law and Medicine*, vol. 31, 2005.
- "FDA Regulation of Medical Device Software: A Delicate Balancing Act," *Journal of BioLaw and Business*, Volume 6, Number 4, 2003.
- "Sponsor Responsibilities and Liabilities for Clinical Investigator Fraud," American Lawyers Media, *Pharmaceutical & Medical Device Law Bulletin*, October 2002.
- "FDA Finalizes Rule that Could Expand OTC Drug Marketplace," *Food and Drug Law Institute (FDLI) Update,* September/October 2002.
- "Functional Foods, Nutraceuticals, Designer Foods: What Are They and How Are They Regulated?" *Regulatory Affairs Professionals Society (RAPS) Focus Magazine*, April 2001.
- "Copyright and Trademark Compliance on the Web: Are Device Makers Vulnerable?" *Medical Device and Diagnostic Industry Magazine*, June 2000.
- "Dietary Supplement Makers, Sellers Must Guard Against Liability Suits," *Leader Publication: Product Liability Law and Strategy*, April 2000.
- "FDA Regulation of Dietary Supplements: A Work in Progress," *RAPS Focus Magazine*, May 1999.
- "Copyright and Trademark Compliance on the Web: Is your Association Vulnerable?" *Association Law and Policy Newsletter*, April 1999.
- "Medical Device: Y2K Problem," *International Commercial Litigation*, June 1998.
- "Draft Revision of FDA's Medical Device Software Policy Raises Warning Flags," *MDDI Magazine*, Oct. 1997.

Suzan Onel (continued)

- "Cosmetic Regulation Revisited," Chapter 11, *Food and Drug Law Institute (FDLI), Fundamentals of Law and Regulation,* 1997.
- "Pharmaceuticals and Cosmetics," *Kirk-Othmer Encyclopedia of Chemical Technology*, 4th Ed., 1997.
- "Recent Enforcement Activity Under the PDMA," *Pharmaceutical Distribution Marketing Audit Update*, 1994.
- "FDA's Administrative Procedures," *FDLI Compilation*, 1993.
- "Legal Trends in Bioethics," *Journal of Clinical Ethics* (quarterly column), 1991-1992.
- "The Medical Waste Tracking Act of 1988: Will it Protect Our Beaches?" *Virginia Environmental Law Journal*, 1989.

PRESENTATIONS

- "Health-Related Foods: Claims, Marketing, Labeling and Expectations," 2012 RAPS Conference - The Regulatory Convergence, Seattle, WA, October 2012
- "What Medical Device Stakeholders Are and Should Be Talking About," FDLI Medical Device Regulation and Litigation Conference, Washington, DC, June 2012.
- "Seventh Annual Neurotech Industry Investing and Partnering Conference," NeuroInsights, Boston, MA, May 2012.
- "Navigating Regulatory Pathways in Neurology and Psychiatry," Sixth Annual Neurotech Industry Investing and Partnering Conference, NeuroInsights, San Francisco, CA, May 2011.
- "Medical Device Regulatory Compliance," 3-day Conference for CfPA, New Brunswick, NJ, April 2011.
- "FDA's 510(k) Premarket Notification Program: What It Is and Where It's Going," CfPA Webinar, March 2011.
- "FDA's MenaFlex Decision and Its Potential Impact on the Device Clearance Process," OCTANe, Irvine, CA, February 2011.
- "FDA's MenaFlex Decision and Its Potential Impact on the Device Clearance Process," K&L Gates Life Sciences Breakfast Briefing, Boston, MA, November 2010.
- "Navigating Regulatory Pathways in Neurology and Psychiatry," Fifth Annual Neurotech Industry Investing and Partnering Conference, NeuroInsights, Boston, MA, May 2010.
- "FDA Update," NIO Policy Tour, Washington, D.C., March 2010.
- "Clinical Investigations: Investigational Device Exemption (IDE), Institutional Review Boards (IRBs) and Informed Consent," FDA Commissioner's Fellowship Program, FDA Campus, Silver Spring, MD, January 2010.
- "FDA: Is there Any Hope?" Fourth Annual Life Science CEO Summit sponsored by Morgenthaler Ventures, San Francisco, CA, November 2009.

Suzan Onel (continued)

- "Medical Device Regulatory Compliance," 3-day Conference for CfPA, New Brunswick, NJ, November 2009.
- "Clinical Investigations: Investigational Device Exemption (IDE), Institutional Review Boards (IRB's) and Informed Consent," FDA Commissioner's Fellowship Program, FDA Campus, Silver Spring, MD, July 30, 2009.
- "Navigating the Global Regulatory Market and Effective Clinical Trial Designs," Fourth Annual Neurotech Industry Investing and Partnering Conference, NeuroInsights, San Francisco, CA, May 2009.
- "Impact of Change in Administration on FDA," NIO Policy Tour, Washington, DC, February 2009.
- "Introduction to Medical Device Law and Regulation: A Program on Understanding How the Government Regulates the Medical Device Industry," The Food and Drug Law Institute (FDLI), Washington, DC, February 26-27, 2009.
- "How Does the CPSIA Affect FDA-Regulated Industries?" K&L Gates Webinar, January 29, 2009.
- "Medical Device Regulatory Compliance," 3-day conference for CfPA, New Brunswick, NJ, November 3-5, 2008.
- "Views from the Center: Implementing the FDA AA in an Age of Rapid Scientific Advancement," Food and Drug Law Institute (FDLI) Annual Conference, Washington, DC, March 2008.
- "Public Policy and Neurotech," Third Annual Neurotech Industry Investing and Partnering Conference (NeuroInsights), Boston, MA, May 2008.
- "Medical Device Regulator Compliance," 3-day conference for CfPA, New Brunswick, NJ, November 2007.
- "Special Concerns for Manufacturing and Marketing Functional Foods," ACI, San Francisco, CA, May 2007.
- "Medical Device Regulatory Compliance," 3-day conference for CfPA, New Brunswick, NJ, October 2006.
- "Introduction to Medical Device Law & Regulation," FDLI, Washington, DC, January 2006.
- "Medical Device Regulatory Compliance," 3-day conference for CfPA, Millbrae, CA, September 2005.
- "Introduction to Medical Device Law & Regulation," FDLI, Washington, DC, May 2005.
- "Medical Device Regulatory Compliance," 3-day conference for CfPA, Northbrook, IL, October 2004.
- "Patent Protection for Medical Devices, Law and Strategy," Minnesota State Bar Association, May 17, 2004.
- "Food Allergens: Thresholds, Labeling, Manufacturing, and Consumer Issues," 47th Annual Conference of FDLI, Washington, DC, April 16, 2004.

Suzan Onel (continued)

- "Medical Device Regulatory Compliance," 2-day conference at Steris Corporation, October 2, 2003.
- "FDA Regulation of Electronic Records under Part 11," Biotechnology Industry Organization (BIO) Annual Convention, Washington, DC, June 2003.
- "The Role and Impact of Government Entities on Herbal Supplement Regulation and Litigation," Mealeys' Ephedra Litigation Conference, Pasadena, CA, April 2003.
- "US Regulatory and Market Considerations for the Medical Device Industry," videoconference simulcast to Austrade Australian Chamber of Commerce in Sydney and Melbourne, Washington, DC, March 2003.
- "Medical Device Regulatory Compliance," 3-day conference for CfPA, New Brunswick, NJ, March 2003.
- "Introduction to Medical Device Law and Regulation," FDLI, Washington, DC, October 2002.
- "Overview of Dietary Supplement Labeling and Advertising Claims," RAPS Annual Conference, Baltimore, MD, November 2001.
- "FDA Regulation of Computer Software," Biopharmaceutical Division of the Institute for International Research (IIR), Philadelphia, PA, March 2001.
- "The Internet: Intellectual Property Points to Consider," National Center for Non-Profit Law, Washington, DC, November 2000; October 1999.
- "Dietary Supplement Claims: Current Issues," Regulatory Affairs Professionals Society (RAPS) Annual Conference, Washington, DC, October 1999.
- "The Regulation of Dietary Supplements," 2-Day RAPS Conference, Washington, DC, August 1999.
- "Medical Device Regulation," CfPA, New Brunswick, NJ, March 1999; March 1998.
- "Trademark and Copyright Compliance on the Internet," Arts and Culture on the Net: Legal Issues of Fundraising and Marketing (multiple sponsors including American Association of Museums, Washington Area Lawyers for the Arts, and the Smithsonian), Washington, DC, November 1997.
- "Sunscreens: Evaluating Ingredients, Regulatory Landscape, and New Products on the Horizon," Global Business Research, Ltd., Philadelphia, PA, July 1997.
- "Interacting with the FDA," CfPA, New Brunswick, NJ, March 1995.

PROFESSIONAL/CIVIC ACTIVITIES

- Chair, K&L Gates FDA Practice Group
- Co-Chair, K&L Gates Hiring Committee, Washington, DC Office, 2005-2009
- Chair, Food, Cosmetics and Nutraceuticals Committee, ABA Section of Science & Technology Law
- Co-Chair, FDLI Medical Devices Committee

Suzan Onel (continued)

- FDA Counsel, Neurotechnology Industry Organization (NIO)
- UVA Law Class Manager, Annual Giving Program, 2005-2009
- Former Chair, Food and Drug Law Institute *Update* Editorial Advisory Board
- Member, Food and Drug Law Institute (FDLI) and Regulatory Affairs Professionals Society (RAPS)

ADMISSIONS

District of Columbia

Pennsylvania

EDUCATION

J.D., University of Virginia, 1990 (Notes Editor, *Virginia Environmental Law Journal*)

B.A. (Neurobiology and European Intellectual History), University of Pennsylvania, 1986 (Honors)

K&L GATES

FDA PRACTICE

K&L Gates' FDA practice, focusing on food, drug, device, and cosmetic regulatory and compliance matters, is an experienced and integrated team with a proven track record in all areas the FDA regulates. We help clients navigate the regulatory process throughout the life cycle of their products—from planning and development, to approval and marketing, to enforcement and ongoing compliance.

In addition to addressing regulatory issues after companies have funding and patents in hand, we assist with regulatory due diligence and other transactional needs. Our clients include domestic and international manufacturers and distributors of food, dietary supplement, pharmaceutical, biological, medical device, tobacco, personal care, and cosmetic products, as well as trade associations, individuals, and institutions involved in preclinical and clinical research of FDA-regulated products.

We offer clients multidisciplinary, global, regulatory, and transactional advice to help address FDA, Federal Trade Commission (FTC), Environmental Protection Agency (EPA), Consumer Product Safety Commission (CPSC), and other agency hurdles. We have excellent working relationships across the government agencies that regulate life science companies.

We Understand the Science

Our FDA team not only has significant legal and regulatory experience, but many of us have scientific degrees in areas such as biology, molecular biology, neuroscience, and engineering, as well as first-hand experience with biomedical research. As the scientific landscape continues to evolve, we have the knowledge necessary to assist clients with the regulatory challenges affecting new drugs, monograph drugs, alternative medicines and therapies, medical devices, radiological products, food, nutraceuticals, dietary supplements, medical food, cosmetics and other personal care and "combination" products.

We offer clients multidisciplinary, global, regulatory, and transactional advice.

Our Global Platform

K&L Gates' global platform allows our FDA team to offer domestic, international, and multinational companies 24/7 availability and a unique position from which to advise on research, approval, registration, import, export, and recall matters involving FDA-related issues on the East and West coasts of the U.S., as well as throughout Canada, the European Union (EU), Japan and the Pacific Rim, Latin America, and other markets.

Our practitioners in the EU and Pacific Rim, specifically, have significant experience in the area of food and nutrition law in the EU and EU member states.

Areas of Practice

Drugs and Biologics

We provide strategic direction on research and development and market entry pathways for clients seeking to enter the drug and biologics market. We assist with the IND, NDA, ANDA, NADA, ANADA, BLA, and Biosimilar approval and orphan designation processes. The value we provide to our clients does not stop when the FDA issues an approval letter. We also work with our clients to maintain compliance with FDA post-approval requirements, including labeling, advertising, cGMPs, and inspectional issues, and we help clients respond to enforcement issues and numerous other regulatory matters before FDA,

Drug Enforcement Agency (DEA), FTC, and state agencies. Our lawyers understand our clients' businesses and often play a major role in strategic decisions concerning life-cycle management, Hatch-Waxman (paragraph IV) patent challenges or defenses, and related competitive marketing activities.

We also advise on the medical therapies that do not require FDA preapproval, such as products subject to over-the-counter monographs, the DESI program, homeopathic rules, and grandfather statutes. We counsel clients on the risks, limitations, and legal boundaries for marketing claims for such products. Our lawyers also handle regulatory due diligence investigations and review contractual language for joint venture, investment banker, and venture capitalist transactions.

Medical Devices, In Vitro Diagnostics, and Biotechnology

We advise established and emerging companies engaged in developing, manufacturing, and marketing medical devices, in vitro diagnostics, medical equipment, eHealth/mHealth/medical software, combination products, and biotechnology. We counsel on issues throughout the product life cycle, including market entry strategies, premarket submissions (510(k)s, PMAs, IDEs), product development plans, clinical research, labeling and promotional activities, competitor strategy/trade complaints, adverse event reporting, recalls, and enforcement defense.

We provide customized strategic advice for FDA-regulated devices positioned at the cutting edge of science, regulation, and public health policy. This includes conducting compliance audits, drafting regulatory SOPs, advising investors and underwriters, and developing regulatory strategy for clients in most therapeutic areas including clinical chemistry and clinical toxicology, cardiovascular, general hospital, radiology, physical medicine, and neurological devices. Our device practice also includes a strong transactional focus. We conduct FDA regulatory due diligence investigations; assist with the preparation of reports and disclosures to the SEC; draft supplier, manufacturer, and distributor agreements; prepare clinical research agreements; and conduct in-house regulatory and executive training sessions.

Food, Dietary Supplements, and Medical Food

Consumers insist upon effective food safety regulation. Businesses seek clarity and predictability. The process is increasingly complicated by the industry's global scope. Our FDA team has decades of experience, in effectively addressing the issues and problems that arise for growers, manufacturers, associations, cooperatives, technology providers, and other interests in this area. We provide crisis management in recall situations; counsel on ingredient, labeling, and advertising matters; regulatory strategies for conventional food, functional food, dietary supplements, and medical food; compliance with dietary supplement GMPs; representation in enforcement proceedings; and a comprehensive range of other services for the food sector.

Our food practice also helps prepare Generally Recognized As Safe (GRAS) and food contact notifications, GRAS self-affirmations and safety evaluations, and new dietary ingredient notifications for dietary supplements. In the inspection area, we have extensive experience on issues involving the application of cGMPs, HACCP, and other compliance mechanisms to FDA-regulated products.

EU Regulatory: Food and Nutrition

Our EU Regulatory food practice offers strategic legal advice to a broad array of clients in the food and drink industry. We have experience in a wide variety of areas including EU regulatory law and policy (free movement of goods, customs classifications, quotas), food labeling and advertising issues (health and nutrition claims, geographical indications and designations of origin), product registration (novel foods, food supplements, food for special medical purposes, cosmetics, etc.), and product liability (withdrawals, recalls), among others, with particular focus on innovative foods and drinks

For clients that are seeking to expand their products into the EU we help to navigate them through all aspects of the EU regulatory process. With more than 1,500 nutritional supplements and functional foods registered in the EU countries during the last 8 years, we provide global clients with legal advice, creative solutions and specific strategies for products being imported or marketed into the EU.

Cosmetics and Personal Care

Technology advances often blur the cosmetic/drug/device distinction and have fostered a reevaluation of cosmetic safety and intended purposes. Our lawyers routinely advise companies on the critical definitional distinctions between cosmetics or personal care products and drugs/medical devices. We also assist clients in crafting labeling claims that comply with FDA and FTC requirements, including scientific substantiation and safety. Our lawyers are attuned to company and user concerns and to the innovation that is key to the industry. We counsel manufacturers, retailers, marketers, importers, exporters, and formulators on these and other issues such as "organic" claims, testing and claim support, inspections, import detentions, and product recalls. We also help clients identify and meet related state, federal, and international requirements, such as limits for volatile organic chemicals, labeling under California's Proposition 65, reporting requirements under California's Safe Cosmetic Act, and the EU's REACH requirements.

Tobacco

Our FDA practice closely follows the FDA's expanded authority over the manufacturing, distribution, and marketing of tobacco products. Our lawyers have extensive knowledge of all aspects of tobacco regulation, and advise clients with regard to

labeling, substantial equivalence submissions, listings and registration, and dissolvable tobacco products. We also follow the deliberations of the FDA's Tobacco Product Scientific Advisory Committee closely and advise industry and investors on jurisdictional and policy matters.

Combination Products/Regulatory Strategy

With the rapid advancement of materials science as well as biotechnology and pharmacology, the classification of a product as a drug, device, biological product, or combination of these product categories is becoming a significant issue in relation to marketing approval/clearance as well as market strategy for regulated industry. Our lawyers counsel clients on product category placement strategy, including whether a product is subject to the FDA's jurisdiction. We also help frame issues related to how a product achieves its primary mode of action and prepare formal requests for designation.

Advertising and Promotion

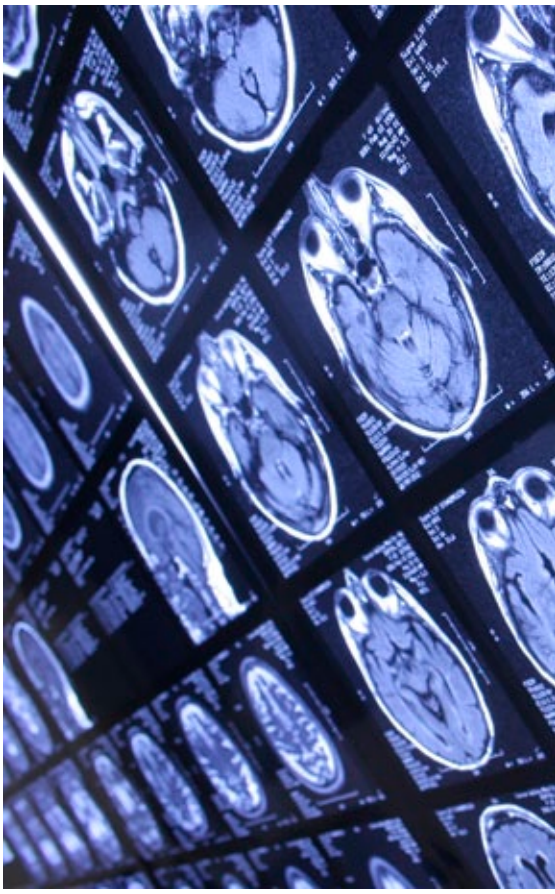
Industry has become increasingly creative and competitive in its labeling, advertising, and promotional activities related to FDA-regulated products, which has resulted in intensified FDA and FTC scrutiny. To assist clients in navigating this often confusing and treacherous area, we advise on acceptable promotional claims and claim substantiation for all product types in all promotional venues, from traditional print ads to new social media spaces. We have extensive and successful experience defending against FDA, FTC, and industry enforcement, including NAD inquiries, FTC investigations, and consumer actions. We also counsel clients on FDA, FTC, DDMAC, and Health and Human Services Office of the Inspector General enforcement trends and conduct compliance reviews of promotional copy, labeling, and launch materials.

HIPAA and Clinical Research

Our FDA lawyers advise clients on all aspects of preclinical and clinical research. We also provide integrated advice on compliance with human subject protection regulations, IND/IDE and GLP/GCP requirements, clinical trial billing and reimbursement, HIPAA, tissue repositories, stem cell research, financial conflicts of interest, research misconduct, and response to BIMO inspections. Additionally, we assist clients on transactional matters, including drafting and negotiating research agreements with U.S. and international sites, and government grants and contracts. Our client base is diverse and includes industry, academic medical centers, research hospitals, nonprofit research organizations, IRBs, and investigators.

Enforcement and Inspections

Enforcement issues are at the core of any regulatory practice. This is particularly true within the FDA-regulated community with the agency's publicly stated intent to leverage its resources through more aggressive use of the wide range of enforcement tools at its disposal. Our FDA team has extensive, successful experience representing product manufacturers, distributors, and marketers in matters ranging from informal compliance issues and negotiations with agency staff to investigations, formal administrative proceedings, and litigation in state and federal courts. More importantly, our ongoing counseling activities are geared toward the identification and mitigation of potential enforcement issues before they occur.



For more information about our FDA Practice, please visit klgates.com or contact one of our lawyers:

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K&L GATES

FOOD REGULATORY PRACTICE

K&L Gates provides a broad array of legal services to organizations and individuals representing all segments of the food industry. Our clients are engaged in the production, marketing, import, export, and distribution of products including meat, poultry, produce, organic, and natural products, processed foods, cheese and other dairy products, seafood, spice, flavors and food additives. The firm's lawyers counsel clients on compliance with the requirements of federal and state agencies, including regulation of food ingredients, labeling, advertising, food safety and security, animal health, and products of new technologies such as irradiation, and various forms of genetic modification.

When problems arise we can also assist clients with the intricacies of food product recalls, administrative, civil and criminal litigation and other enforcement proceedings. We pride ourselves on our ability to not only address the client's immediate needs, but also consider its long-term business objectives.

Deep Government Experience

We are particularly proud of our substantial government experience, which gives our clients an important edge in dealing with the various regulatory agencies. As a practical matter, we understand the underlying culture of the food regulatory system, which helps us to facilitate matters which can become stalled within the bureaucracy and prevent unwarranted forms of interference. We regularly assist clients in compliance issues with the Food Drug and Cosmetic Act, Federal Meat Inspection Act, Poultry Products Inspection Act, Packers and Stockyards Act, and Perishable Commodities Act, among others.

Global Perspective

In the global marketplace, where ingredients, raw materials, and animals cross borders, significant issues arise around food security, quality controls, food defense, and bioterrorism. Contaminants such as melamine, salmonella, listeria, and e.coli are the subject of increasing scientific and regulatory focus. In addition, we have found that concerns surrounding allergens and their proper labeling are posing a growing challenge on the global stage. Such risks require companies to be more conscientious about both the safety and the proper labeling of all of the products they market.

Our food lawyers regularly counsel clients on how to successfully market their food process in the global environment. We have worked with U.S. and non-U.S. based clients importing food from Canada, Mexico, Australia, New Zealand, Eastern and Western Europe, Central and South America, and China. We also consider the trade, public policy, and food security issues, as well as the client's overall business strategy, when developing strategies to protect the client from risk and insure compliance.

What We Work On

Examples of the firm's work in the food industry include:

- Participation in rulemaking and other public proceedings
- Organic/natural products and labeling
- International trade issues
- Food safety and product recalls
- Customer relations and public communication
- Animal disease outbreaks and related regulatory restrictions
- Additives and ingredients
- Claims, labeling, and advertising
- Transgenic crops and GMOs
- Safety evaluation of food ingredients
- New product formulations and new ingredients
- Detention or seizure of adulterated or misbranded products
- Criminal enforcement investigations
- Insurance coverage issues
- USDA and FDA enforcement
- Supply chain management and food security
- School lunch and other government food procurement
- Injunctive proceedings challenging agency actions
- New technologies
- Public policy and advocacy

Learn more about our Food Regulatory practice at www.klgates.com.

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For more information, please contact the lawyers included in this proposal, or visit www.klgates.com

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