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WORKSHOP 2: Consumer and Product Compliance

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1. INTRODUCTION

Many countries enforce stringent legal regulations to protect consumers in product sales and service provision. Regulations differ between jurisdictions, covering topics such as product liability, general contractual terms, advertising and promotion, as well as sustainability. As this paper will show, the specific topics covered, as well as the scope of legislation on seemingly similar topics, can vary greatly. This paper looks closer at the laws of the European Union, India, and the United States of America. Because of the breadth of the subject matters covered, it is beyond the scope of this workshop and paper to cover all laws and regulations on this topic. Consequently, the paper represents only a selection of the laws that a practitioner needs to be aware of when delving in to product liability issues in any of the jurisdictions covered.

2. THE EUROPEAN UNION

2.1. The European Union – An Introduction

The European Union (the "EU") is a political and economic union of 27 member states ("MS") sharing common values, policies and institutions. The EU creates a system of supranational law, which operates in the MS. However, the EU does not enjoy general competence to legislate in each and every domain. It has the so-called conferred legislative powers, which means that it can only legislate to the extent that it has received mandate from the EU treaties. The EU can adopt legislation in the areas of, e.g., consumer protection, products safety and environment. Yet, it must rely on MS for its enforcement and sanctioning.

The legal acts of the EU are created by a variety of legislative procedures involving the popularly elected European Parliament, the Council of the European Union (which represents the MS governments) and the European Commission (a cabinet which is elected jointly by the Council and Parliament), and where only the Commission has the right to propose legislation. The legal system is composed of primary and secondary law, as well as general principles and case law.

Primary law consists of the treaties that establish the EU and define its objectives, competences and decision-making procedures. The treaties are binding on all MS and have supremacy over national law. Secondary law comprises the legal acts adopted by the EU institutions in accordance with the treaties. The main types of secondary law are regulations, directives and decisions.

Regulations are general and directly applicable rules that have the same force and effect in all MS. Directives are binding on the MS as to the result to be achieved, but leave them some discretion as to the form and methods of implementation. Once adopted at EU level, MS are called to adopt measures to incorporate the directive into national law (transpose) by a deadline contained by the directive (generally within two years). Decisions are specific and binding on the addressees, which can be MS, individuals or other entities.

2.2. Overview of the Legal Framework in the EU

2.2.1. Product Compliance

The legal framework in the EU for product compliance aims to ensure that products can freely circulate within the EU single market of circa 500 million consumers in the 27 MS and that

they are “safe” and, since recently, “sustainable”. Products are subject to the requirements of a series of legislation and standards, covering various aspects of their design, manufacturing, testing, labelling, packaging, distribution, and disposal, as well as the obligations and responsibilities of economic operators, such as manufacturers, importers, distributors, and retailers. These legislations are either “horizontal”, applying to all products, such as, for example, the General Products Safety Regulation, or “vertical”, applying to a specific group of products, such as, for example, the rules for toys, foods, cosmetics (all discussed below) and many others.

2.2.1.1. General Product Safety Regulation (EU) 2023/988 (“GPSR”)

The GPSR, applicable since December 2024, is a regulation of a horizontal nature, which aims at ensuring the safety of consumer products placed or made available on the EU market. Products entering the EU from abroad should comply with the safety requirements in the GPSR as if they had been manufactured within the EU. The GPSR is said to provide a “safety net”, as it applies where there are no product-specific EU requirements covering the same safety aspects.

The GPSR sets out a general safety requirement whereby economic operators should place only safe products on the market. Safety of products is assessed with regard to different factors and elements and can be presumed if the product conforms to some EU published standards. Economic operators are subject to tailored safety obligations depending on their role in the supply chain. Distance sales and the product safety obligations of online marketplaces are also regulated under the new GPSR.

The GPSR also organizes the exchange of information within the EU about products placed on the market that may prove to be unsafe so that appropriate measures can be taken, such as market withdrawals and product recalls. This requires producers to notify authorities of unsafe products and to cooperate with authorities.

One aspect of product safety is the chemical composition of the products. Chemicals are regulated in the REACH Regulation (concerning the Registration, Evaluation, Authorisation, and Restriction of Chemicals) and the CLP Regulation (concerning the Classification, Labelling, and Packaging of substances and mixtures), ensuring that they are safe for use and bear sufficient information for their users.

2.2.1.2. Toy Safety Directive 2009/48/EC

The Toy Safety Directive regulates the safety of products designed or intended for use in play by children under 14 years of age (Toys) in the EU market. It lays down safety requirements and conformity assessment procedures for Toys. Manufacturers can choose self-verification by applying harmonised standards, or external verification by a notified body. They must issue an EC declaration of conformity and affix the CE marking on the toy.

A new Regulation on Toy Safety will soon replace the Toy Directive ensuring uniformity of new provisions in the EU market. Moreover, the proposed Regulation broadens the definition of health to include children’s psychological and mental health, wellbeing and cognitive development.

2.2.1.3. General Food Law Regulation (EC) 178/2002

Food safety in the EU is generally and broadly regulated by the General Food Law Regulation, which ensures that food placed on the EU market is safe for consumption, covering all stages of the food chain (production, processing and distribution).

A key element of the Regulation is the requirement for traceability throughout the food chain. In fact, every food producer must be able to trace the origin of their products. The General Food Law established also the European Food Safety Authority (EFSA), an independent agency entrusted with the provision of scientific counsel and the dissemination of information pertaining to the safety of food products.

The General Food Law is the legal basis for Regulations that were subsequently adopted by the European Commission, and which regulate specific topics, such as: Novel Foods[1] (e.g., Antarctic Krill oil, chia seeds, noni fruit juice), Hygiene of Foodstuff,[2] Additives[3] and labelling.[4] Food legislation is supplemented by specific rules on food contact materials, including food packaging, utensils and culinary tools.[5]

2.2.2. Cosmetic Products Regulation (EC) 1223/2009

The primary legislation governing cosmetics in the EU is the Cosmetic Products Regulation, which harmonises the rules for cosmetic and personal care products intended to be placed in contact with the external parts of the human body or the teeth and mouth to clean, perfume, protect them, etc. The aim of the Regulation is to facilitate the free movement within the EU internal market of cosmetic products and to ensure a high level of protection for human health.

Safety is a key topic, and every cosmetic product must undergo a safety assessment documented with a detailed safety report, kept available at the disposal of authorities. Each cosmetic product made available on the EU market must have a designated "responsible person" within the EU that shall ensure compliance with the safety, labelling and notifications requirements of the Regulation.

Certain substances, such as those classified as carcinogenic, mutagenic or reprotoxic in Category 1A and 1B under the EU Chemicals legislation, cannot be used in cosmetics, and only authorized colorants, preservatives and UV-filters can be. These lists of substances are updated to account for scientific progress.

2.2.3. Eco-design for Sustainable Products Regulation (EU) 2024/1781 ("ESPR")

Along with safety, another key topic on which the European Commission is focusing on since recently is sustainability. The ESPR provides a general framework on the basis of which more specific requirements will be set for different product groups, to make them more environmentally sustainable. Most products are in scope of the ESPR, but product-specific requirements will need to be set via the Commission's delegated acts, following a prioritization

[1] Regulation 2015/2289 on Novel Foods, addressing Novel Foods and their authorization and placing on the market within the HU;
[2] Regulation 852/2004 on the Hygiene of Foodstuff, setting out general hygiene requirements for food businesses;
[3] Regulation 1333/2008 that sets out rules for the use of food additives including definitions, conditions of use, labelling, and procedures;
[4] Regulation 1169/2011 on the provision of Food information to Consumers, which mainly focuses on ensuring that consumers have access to complete and accurate information about the food they purchase, in line with food labelling requirements;
[5] Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC.

approach. The first working plan is scheduled for April 2025 and is expected to cover iron, aluminium, textiles, furniture, etc.

Delegated acts will impose, for a given product category, performance and/or information requirements to improve certain product aspects such as durability, reusability, reparability, possibility of maintenance and refurbishment, possibility of remanufacturing and recycling, resource use or resource efficiency, recycled content, presence of hazardous chemicals or expected generation of waste.

Additionally, the ESPR provides for the annual disclosure of information on the unsold consumer products that were discarded during the preceding year, and prohibits the destruction of certain unsold consumer goods.

2.2.4. Packaging and Packaging Waste Regulation (EU) 2025/40 ("PPWR")

The PPWR recently entered into force (February 2025) and will apply from August 2026. From that date, food packaging containing PFAS above specified thresholds will be prohibited. The PPWR sets new design-for-recycling (DfR) criteria and recyclability performance grades for January 2028.

Plastic packaging will have recycled content targets of 30% by 2030 and 50% by 2040, with exemptions for compostable packaging and any part of the packaging that makes up less than 5% of the total weight. Packaging must be reduced to essentials by 2030, with overpackaging banned and empty space limited to 50%. Certain single-use plastic packaging will be banned from 2030.

Businesses must participate in re-use systems, and food distributors must accept consumer-owned containers by February 2027 and offer reusable take-away packaging by February 2028.

The PPWR establishes packaging labelling requirements, including material composition labels, QR codes for reusability and waste sorting, and QR codes identifying substances of concern, ensuring EU-wide harmonisation while permitting MS-specific EPR and DRS labels. To harmonise extended producer responsibility (EPR) obligations, the PPWR defines economic operators' responsibilities, mandates national producer registration, and requires the European Commission to standardize registration formats.

2.3. Consequences of Violation: Sanctions, Remedies and Consumer Claims

In principle, because of the specific nature of the EU legal order, penalties for violating EU product safety and sustainability rules are established at the national level in the individual MS. It is the competence of the MS to determine these penalties when transposing the EU legislation into their domestic law. MS then report the national penalties to the European Commission.

While EU legislation does not specify the exact penalties, it typically requires that they are effective, proportionate, and dissuasive, taking into account the type of infringement and the nature and severity of the injury suffered by the consumer. Additionally, MS are required to take all necessary measures to ensure the implementation of these penalties.

However, there are some EU rules which harmonise various aspects related to sanctions and remedies.

2.3.1. Consumer Rights Directive 2011/83/EU and right of withdrawal

The Consumer Rights Directive harmonises several key aspects of national legislation on contracts between consumers and traders,[6] covering sales and services contracts concluded in shops, off-premises or at a distance (online). The Directive also stipulates which specific information traders must provide the consumers before concluding a contract. More specific information is required from online marketplaces for contracts concluded online.

One of the most important features of the Directive is the right of withdrawal, allowing consumers to withdraw from most distance and off-premises contracts within 14 days of conclusion, without providing any reason or incurring any costs. If the consumers are not made aware of these rights, the withdrawal period is extended by 12 months. This right does not apply to contracts for goods made to the consumer's specifications, goods that deteriorate or expire rapidly, and sealed goods unsuitable for return due to health or hygiene reasons once unsealed. Digital service providers are required to offer a clear and accessible withdrawal mechanism on their interfaces, ensuring that consumers can easily exercise their right of withdrawal. Regarding contracts concluded at a distance, providers are required to ensure that their interfaces offer an easy-to-find withdrawal function.

2.3.2. Right to Repair Directive (EU) 2024/1799 ("R2RD")

The R2RD aims to encourage consumers to use their goods longer by promoting their repair. It notably introduces an obligation to repair certain goods (i) for which repairability requirements already exist in EU law, and (ii) which are not under warranty anymore, i.e., for which the two-year legal warranty has expired. Upon request and within a reasonable time, companies must repair the above products or have them repaired by a third party, except where repair is impossible. Companies must inform consumers about the available repair services (whether in-house or sub-contracted) so that consumers can invoke their right to repair.

The R2RD also tries to incentivize the repair of products that are still in warranty, so that consumers consider asking for a repair over replacement of the defective product. Notably, the R2RD extends the legal warranty period of repaired products for 1 year.

The Directive entered into force in July 2024, and MS have until July 2026 to transpose it into national law.

2.3.3. Product Liability Directive (EU) 2024/2853 ("PLD")

The PLD establishes the principle of liability without fault (strict product liability) applicable to products in the EU, including for intangible products such as digital manufacturing files and software. Where a defective product causes damage to a consumer, the manufacturer (or representative) may be liable even without having committed a negligence or fault. A recent update (recast) seeks to simplify damages reparation, responding to digital advancements and global supply chains. This may lead to increased product liability litigation.

[6] In this paper, "trader" refers to any natural person or legal person who is acting for purposes of relating to that person's trade, business, craft or profession. It would typically include manufacturers, distributors, and resellers.

The PLD defines a number of entities that are potentially liable for products and components, including companies and importers, setting out a series of situations where a product is presumed to be defective or a causal link between the damage and the defectiveness is presumed to exist.

Product liability claims, including those filed collectively, necessitate that disclosure be accessible to claimants. The PLD enables national courts to order the disclosure of a company's evidence to be used in support of a claim for damages.

The PLD traditionally exonerated manufacturers from responsibility if they were able to show that their products were "state of the art" and the defect was not discoverable with the scientific and technical knowledge at the time of production. However, with the recast, this became optional for MS.

The Directive entered into force in December 2024, and MS will have until 9 December 2026 to transpose this directive into national law.

2.3.4. EU Collective Redress Directive (EU) 2020/1828 ("CRD")

The CRD aims to enhance consumer protection across the EU by introducing a harmonised framework for representative actions. It enables qualified entities representing consumers' interests to bring representative actions before courts or administrative authorities against domestic or cross-border infringements of EU laws that (may) harm collective interests, e.g., rules on data protection, medicines, medical devices, food, and the protection of passengers. The Directive was adopted on 20 December 2020, and its requirements had to be applied by 25 June 2023.

The representative actions can be actions seeking injunctive measures (to stop or prohibit a practice) or redress measures (such as compensation, repair or price reduction) or both, for the protection of collective interests of consumers or the interests of a group of consumers.

Qualified entities, such as consumer organizations and public bodies, are designated by MS to bring representative actions. These entities must meet certain criteria for designation, including being non-profit and independent organizations, having a legitimate interest in protecting consumer interests and demonstrating a history of activity in consumer protection.

The CRD sets safeguards for preventing abusive litigation, such as requiring transparency in the funding of representative actions or allowing the courts to dismiss manifestly unfounded actions at an early stage.

2.4. False Claims Regulations

2.4.1. The Directive on Unfair Commercial Practices 2005/29/EC ("UCPD")

The UCPD regulates unfair business practices in the EU by strengthening consumer confidence; facilitating cross-border trade, particularly for small and medium-sized enterprises; and harmonising legislations against deceptive and aggressive business tactics. It applies to business-to-consumer transactions before, during, and after a sale, prohibiting misleading claims, false information, and coercive marketing that could distort consumer decisions.

It clearly defines the unfair business-to-consumer commercial practices that are prohibited in the EU as those that are contrary to the requirements of professional diligence, and are likely to materially distort the purchasing behavior of the average consumer. Unfair practices fall into two categories under the Directive: misleading commercial practices (by action or omission) and aggressive commercial practices.

Annex I of the Directive contains a list of all the commercial practices that are always considered misleading, and MS are the ones in charge of ensuring that consumers have the right to individual remedies when harmed by those practices, and impose penalties with fines of at least 4% of the trader's turnover.

2.4.2. The Consumers Empowerment Directive (EU) 2024/825 ("CED")

The Consumers Empowerment Directive, which revised and supplemented the UCPD since March 2024, plays a crucial role in creating a specialized regime to govern environmental claims. It provides a new definition of environmental claim and certification scheme, mandating traders to provide clear, relevant and reliable information on the sustainable nature of the product. Generic and overstated environmental claims such as "environmental friendly", "energy efficient", "biodegradable", and "made with recycled plastic" are prohibited in the absence of excellent environmental performance, or precise information on the product ("wholly or partially made with recycled plastic").

The CED also prohibits sustainability labels not based on a certification scheme, when sustainability labels refer to unreliable voluntary sustainability logos referring to products' environmental characteristics. Use of environmental claims related to future environmental performance without clear, objective and verifiable commitments and targets and without an independent monitoring system is also prohibited.

The Directive entered into force in March 2024 and must be transposed into national law by March 2026, and applied from September 2026.

2.4.3. The Green Claims Substantiation Directive

Alongside with the CED, the EU is in the process of adopting a Green Claims Directive that will establish minimum requirements on the substantiation and communication of explicit environmental claims made voluntarily by traders about products in business-to-consumer commercial practices.

Explicit environmental claim is defined as "an environmental claim made in written form or orally, including through audiovisual media, […] excluding environmental labels". This will force companies to ensure that any green claim is verified by third-party independent experts before being published or appointed by the MS. Companies should base their environmental labels and claims on current scientific evidence and clear criteria. They should use simple language and specify the environmental characteristics they address, such as durability or recyclability. Businesses will also be required to prove climate-related claims, including those involving carbon credits.

The text is still going through the legislative process and is therefore not final. It should be adopted by Q2 of 2025 before national transposition by the MS.

2.4.4. The Comparative Advertising Directive 2006/114/EC ("CAD")

The CAD has the purpose of protecting traders against misleading advertising, laying down the rules under which comparative advertising is permitted. Unlike the Unfair Commercial Practices it applies B2B.

The Directive considers advertisements misleading when they deceive or are likely to deceive consumers about the essential aspects of the goods or services they promote. These aspects include the characteristics, results, price, supply conditions, and identity and rights of the advertiser. They can create false expectations about the product's performance, misrepresent the cost or availability, and obscure the true nature of the advertiser's qualifications or legal rights. It is crucial for advertisements to provide accurate and clear information to ensure consumers can make informed decisions.

Comparative advertising is when they refer to a competitor or their products, either directly or indirectly. This type of advertising highlights the differences between competing products to help consumers make informed choices. It can be a valid way of informing consumers, but it must not be misleading or unfair. It should compare products that are similar, relevant, verifiable and objective, and should not confuse, discredit or copy the competitor's brand.

3. INDIA

3.1. India – An Introduction

India's consumer protection and advertising landscape has become highly regulated recently, with a web of laws governing product safety, marketing claims, and fair-trade practices. From food and cosmetics to medical devices and automobiles, businesses must navigate strict labeling rules, advertising guidelines, and liability provisions.

3.1.1. Legal Framework

The Consumer Protection Act, 2019 ("CP Act") is the primary legislation governing consumer protection in India. The CP Act protects consumers who purchase goods and services for consideration or use them with the approval of the actual buyer. However, it does not protect persons who obtain goods or services for resale or commercial purposes.

In addition to the CP Act, various product-specific regulations outline the liabilities of manufacturers, importers, packagers, sellers, and distributors.

While the CP Act addresses product liability in general, it does not prescribe specific product safety standards. Instead, product-specific laws govern safety standards across different industries. For instance, dedicated regulations set specific standards for food products, drugs, cosmetics, medical devices, electronic items, and several other products.

Additionally, both general and product-specific laws regulate labeling and packaging to ensure transparency, accurate consumer information, and compliance with safety standards.

3.2. Product Liability

3.2.1. Product liability under the CP Act

The CP Act holds manufacturers and sellers accountable for defective products that cause harm. "Harm" includes property damage (excluding the product itself), personal injury, illness, death, and emotional distress, but excludes commercial losses.[7] A "defect" is any fault, imperfection, or shortcoming in quality, quantity, or standard as per law or seller claims.[8]

Manufacturers are liable if a product has a manufacturing defect, design flaw, fails to meet specifications, violates an express warranty, or lacks adequate warnings or usage instructions.[9]

Sellers, which are not manufacturers, may also be liable if they control product design, testing, packaging and labelling; or if they modify the product; issue an independent warranty; sell a product from an unknown or inaccessible manufacturer; or fail to ensure proper handling, inspection, or warnings.[10]

[7] Consumer Protection Act, § 2(22), No. 35, Acts of Parliament, 2019 (India).
[8] Consumer Protection Act, § 2(10), No. 35, Acts of Parliament, 2019 (India).
[9] Consumer Protection Act, § 84, No. 35, Acts of Parliament, 2019 (India).
[10] Consumer Protection Act, § 86, No. 35, Acts of Parliament, 2019 (India).

A consumer forum, an adjudicatory body under the Consumer Protection Act, 2019, may order a party to provide one or more of the following remedies: removal of defects, replacement of defective goods, refund with interest, compensation for negligence or product liability, and punitive damages if deemed necessary. It may also ban the sale of hazardous goods to protect consumers.[11]

3.2.2. Product liability for food products

The Food Safety and Standards Act, 2006 ("FSSA") is the primary legislation on food safety and regulation in India. The Food Safety and Standards Authority of India ("FSSAI"), established under the FSSA, sets scientific standards and regulates manufacture, storage, packaging, labelling, distribution, sale, and import of food products, including advertisements and consumer safety.

FSSA holds manufacturers, distributors, and sellers accountable for defective or unsafe food products.

3.2.3. Liability on Food Business Operators ("FBO")

FBOs, which include persons by whom businesses are carried on or owned, must ensure that all food products comply with the FSSA at every stage of production, processing, import, distribution, and sale. FBOs cannot manufacture, store, sell, or distribute food that is unsafe, misbranded, sub-standard, or prohibited under the applicable law, or that violates licensing conditions prescribed by FSSAI. FBOs must not employ persons with contagious diseases.[12]

If unsafe food is found in a batch or consignment, it is presumed that the entire lot is unsafe unless proven otherwise. Authorities can impose market restrictions or recalls, even if food meets certain standards, if there is reasonable suspicion of safety concerns.

3.2.4. Liability of manufacturers, packagers, wholesalers, distributors and sellers of food products

A manufacturer or packer is liable if a food product fails to meet legal safety standards.[13]

A wholesaler or distributor is liable if they supply expired, unsafe, or misbranded food, violate storage or safety instructions, or fail to identify the manufacturer.[14]

A seller is liable for selling expired, misbranded, or unhygienic food, or if they cannot identify the manufacturer or distributor. Liability also applies if food is received with knowledge of being unsafe.[15]

3.2.5. Violations of FSSA

Violating FSSAI food safety standards can result in monetary penalties and imprisonment, depending on the nature of the offence and the severity of harm caused. For example, unsafe

[11] Consumer Protection Act, § 39 (1), No. 35, Acts of Parliament, 2019 (India).
[12] Food Safety and Standards Act, § 26, No. 34, Acts of Parliament, 2006 (India).
[13] Food Safety and Standards Act, § 27 (1), No. 34, Acts of Parliament, 2006 (India).
[14] Food Safety and Standards Act, § 27 (2), No. 34, Acts of Parliament, 2006 (India).
[15] Food Safety and Standards Act, § 27 (3), No. 34, Acts of Parliament, 2006 (India).

food causing minor injury can result in a monetary penalty of INR 0.1 million (approximately USD 1,200) and imprisonment for up to one year, whereas serious injury can attract life imprisonment along with INR 1 million (approximately USD 12,000) in monetary penalties.[16]

While consumers cannot seek compensation under the FSSA, they can report violations to trigger regulatory action. If consumers suffer financial loss or health issues, they can claim compensation under the CP Act through the appropriate consumer forum.

3.2.6. Product liability for drugs, cosmetics, and medical devices

The Drugs and Cosmetics Act, 1940 ("DC Act") regulates the manufacture, sale, distribution, and quality control of drugs, cosmetics, and medical devices in India. It prescribes the products' safety, and quality standards, while holding manufacturers and sellers accountable for defective or harmful products.

Manufacture or sale is permitted only with a valid license under the DC Act, which also prohibits any person from manufacturing, selling, stocking, or distributing the following:

a. substandard, misbranded, adulterated, or spurious drugs or cosmetics;
b. patent or proprietary medicines without properly displaying the formula or active ingredients;
c. drugs with false or misleading claims regarding disease prevention, cure, or effects;
d. cosmetics with harmful ingredients that make them unsafe for use;
e. drugs or cosmetics violating any legal provisions under this Act or related rules; and
f. imported or locally manufactured drugs or cosmetics that violate regulatory requirements. [17]

Consumers cannot seek compensation under the DC Act, but can report violations to regulatory authorities for enforcement action. For personal compensation, they must approach the Consumer Forum under the CP Act.

3.3. Laws on Product Safety Standards

Different laws govern product safety based on the specific products they regulate. Each legislation sets standards and requirements to ensure consumer protection and compliance within its domain.

3.3.1. Products Standards under the Bureau of Indian Standards Act, 2016.

The Bureau of Indian Standards ("BIS"), established under the Bureau of Indian Standards Act, 2016 ("BIS Act"), is India's National Standards Body responsible for standardization, conformity assessment, and quality assurance.

[16] Food Safety and Standards Act, § 59, No. 34, Acts of Parliament, 2006 (India).
[17] Drugs and Cosmetics Act, § 18, No. 23, Acts of Parliament, 1940 (India).

BIS publishes standards for various products, with compliance being voluntary unless mandated under the (i) BIS Certification Scheme[18] for varied products, such as toys, cement, steel, electrical appliances, packaged drinking water, etc., or (ii) BIS Registration Scheme[19] for electronic products. Products covered under these schemes must meet prescribed standards and comply with the BIS Act.

Currently, about 688 products are covered under the mandatory BIS Certification Scheme and about 73 products are covered under the BIS Registration Scheme.

No person or entity is permitted to manufacture, import, distribute, sell, hire, lease, store or exhibit for sale any product(s) covered under the mandatory certification scheme or mandatory registration scheme without conforming to the prescribed Indian standards and without a valid certificate and license from BIS.

3.3.2. Products standards for drugs and cosmetics

The DC Act provides for specific standards for drugs and cosmetics. All drugs and cosmetics in India must comply with prescribed standards, which may be updated periodically to ensure safety, efficacy, and quality. The Government of India, upon providing a three-month notice in the Official Gazette, has the authority to amend or update drug standards, ensuring they remain current and aligned with evolving regulatory requirements.[20]

3.3.3. Products standards for medical devices

The Government of India, under the Medical Devices Rules, 2017, mandates that all medical devices must comply with standards prescribed by the BIS or as notified by the Ministry of Health and Family Welfare. If no such standards are specified, the device must adhere to international standards, such as those set by the International Organization for Standardization (ISO) or the International Electrotechnical Commission (IEC), or any other recognized pharmacopoeia standards. If none of these standards exist, the device must conform to the manufacturer's standards.[21]

3.3.4. Products standards for food products

Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011 ("Food Standards Regulation") framed under the FSSA prescribe standards for food products in India. In addition, under the Food Standards Regulations, FSSAI has framed specific standards for (a) vegan foods,[22] (b) ayura foods (excluding ayurveda medicines),[23] (c) foods

[18] Bureau of Indian Standards (BIS). (1986). Bureau of Indian Standards Certification Scheme. Government of India.

[19] Government of India. (2012). The Electronics and Information Technology Goods (Requirements for Compulsory Registration) Order, 2012. Ministry of Electronics and Information Technology (MeitY).

[20] Drugs and Cosmetics Act, § 8, No. 23, Acts of Parliament, 1940 (India).

[21] Medical Devices Rules, Rule 7, Gazette of India, Ministry of Health and Family Welfare, 2017 (India).

[22] Food Safety and Standards (Vegan Foods) Regulations, Gazette of India, Food Safety and Standards Authority of India, 2022 (India).

[23] Food Safety and Standards (Ayurveda Aahara) Regulations, Gazette of India, Food Safety and Standards Authority of India, 2021 (India).

for infant nutrition,[24] (d) fortification of food,[25] (e) alcoholic beverages,[26] (f) organic foods,[27] and (g) health supplements, nutraceuticals, food for special dietary use, food for special medical purposes, functional food and novel food.[28]

Non-specified food includes any food other than proprietary food or food ingredients, including additives, processing aids, and enzymes for which standards have not been specific under the FSSA.[29] Food Safety and Standards (Approval for Non-Specific Food and Food Ingredients) Regulation, 2017, prohibits manufacture or import of any non-specified food or food ingredients, as the case may be except for the prior approval of the Food Authority.[30]

3.3.5. Safety standards for motor vehicles and their components

The Motor Vehicles Act, 1988 ("MV Act") is the primary legislation that regulates vehicle safety, design, manufacturing, and roadworthiness. MV Act requires that vehicles and their components must comply with the standards prescribed under the Central Motor Vehicles Rules, 1989 ("CMV Rules").[31] CMV Rules mandate compliance with Bharat Stage emission norms for all motor vehicles and specifies emission limits, testing procedures, and fuel quality requirements for vehicles.[32]

CMV Rules prescribe safety standards for motor vehicles and components and have referenced several of the standards framed by BIS and Automotive Industry Standards ("AIS") for mandatory compliance.[33] CMV Rules also prescribe standards for build quality of vehicles.[34]

3.4. False claims

The CP Act broadly regulates misleading advertisements, unfair trade practices, and deceptive claims. It defines advertisements expansively, encompassing labels, wrappers, invoices, and endorsements, making them subject to consumer protection laws. In addition to the CP Act, product-specific regulations also establish guidelines for advertisements and product claims to ensure transparency and accuracy.

3.4.1. Misleading advertisements and unfair trade practices under the CP Act

An advertisement is misleading if it:

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[24] Food Safety and Standards (Foods for Infant Nutrition) Regulations, Gazette of India, Food Safety and Standards Authority of India, 2020 (India).

[25] Food Safety and Standards (Fortification of Foods) Regulations, Gazette of India, Food Safety and Standards Authority of India, 2018 (India).

[26] Food Safety and Standards (Alcoholic Beverages) Regulations, Gazette of India, Food Safety and Standards Authority of India, 2018 (India).

[27] Food Safety and Standards (Organic Food) Regulations, Gazette of India, Food Safety and Standards Authority of India, 2017 (India).

[28] Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food, and Novel Food) Regulations, Gazette of India, Food Safety and Standards Authority of India, 2016 (India).

[29] Rule 2 (d) of Food Safety and Standards (Approval for Non-Specific Food and Food Ingredients) Regulation, 2017.

[30] Rule 3 of the Food Safety and Standards (Approval for Non-Specific Food and Food Ingredients) Regulation, 2017.

[31] Motor Vehicles Act, § 110-111, No. 59, Acts of Parliament, 1988 (India).

[32] Central Motor Vehicles Rules, Rule 115, Gazette of India, Ministry of Road Transport and Highways (1989).

[33] Central Motor Vehicles Rules, Rules 123-127, Gazette of India, Ministry of Road Transport and Highways, 1989 (India).

[34] Central Motor Vehicles Rules, Rule 126, Gazette of India, Ministry of Road Transport and Highways (1989).

a. Falsely describes a product or service,
b. Provides false guarantees,
c. Misleads consumers about quality, quantity, or benefits,
d. Conceals important information, or
e. Promotes unfair trade practices through deceptive claims.[35]

The burden of proof lies on the advertiser if a product claim is challenged.

3.4.2. Regulatory oversight – the Central Consumer Protection Authority and advertisement guidelines

The Central Consumer Protection Authority ("CCPA"), set up under the CP Act, regulates misleading advertisements and unfair trade practices. In 2022, it issued Guidelines for Prevention of Misleading Advertisements ("CCPA Advertising Guidelines"), requiring advertisements to be truthful, verifiable, and not misleading.[36]

3.4.3. Penalties for misleading advertisements under the CP Act

Violations related to misleading advertisements under the Consumer Protection Act, 2019 can result in the following penalties and punishment:

a. fines up to INR 1 million (USD 12,000) and imprisonment up to two years for first-time violators; and
b. fines up to INR 5 million (USD 60,000) and imprisonment up to five years for repeat offenses.[37]

3.4.4. Role of Advertising Standards Council of India

The Advertising Standards Council of India ("ASCI") is a self-regulatory body monitoring advertisements in India. While it cannot enforce penalties, TV advertisements must mandatorily comply with ASCI's Code under the Cable Television Networks Rules, 1994.

3.4.5. Product claim guidelines[38]

Product claims must be truthful, verifiable, and evidence-based as per the CP Act, CCPA Advertising Guidelines, and ASCI Code. All descriptions, comparisons, and numerical claims must be substantiated with reliable data. Claims about usefulness, performance, or research-based findings must indicate sources and dates. Comparative claims with competitors must be accurate and factual.

Environmental claims like "eco-friendly" or "sustainable" require credible certification and cannot mislead consumers. Awards or rankings must come from independent, recognized bodies. Aspirational claims about future goals should be backed by clear action plans. Misleading disclaimers or vague superiority claims are prohibited.

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[35] Consumer Protection Act, § 2(28), No. 35, Acts of Parliament, 2019 (India).
[36] Consumer Protection Act, § 21, No. 35, Acts of Parliament, 2019 (India).
[37] Consumer Protection Act, § 89, No. 35, Acts of Parliament, 2019 (India).
[38] Guidelines for Prevention of Misleading Advertisements and Endorsements for Misleading Advertisements, Gazette of India, Central Consumer Protection Authority, 2022 (India).

3.4.6. Product claims under FSSA

The FSSA prohibits false or misleading food product claims. Claims about health benefits, ingredients, or nutrition must be scientifically validated. False claims may result in:

a. Fines up to INR 10 lakh (USD 12,000), and/or
b. Product recall or ban by FSSAI.[39]

3.4.7. Product claims under the DC Act

The DC Act regulates misleading claims about medicinal efficacy. False claims about a drug's ability to cure or prevent diseases are punishable with:

a. Fines and imprisonment (up to life for serious violations), and/or
b. Product seizure or cancellation of manufacturing license.[40]

3.5. Labelling Requirement

3.5.1. Labelling of pre-packaged commodities in general

In general, all "pre-packaged commodities" for sale in India must be labeled in compliance with the Legal Metrology (Packaged Commodities) Rules, 2011[41] ("Packaged Commodity Rules").

"Pre-packaged commodities" means a commodity which without the purchaser being present is placed in a package of whatever nature, whether sealed or not, so that the product contained therein has a pre-determined quantity.

Packaged Commodity Rules apply across India. There are no separate city/state specific labelling requirements. Mandatory labelling requirements under the Packaged Commodity Rules include the manufacturer's/importer's details, country of origin, product name, net quantity, manufacture date, best before and use by date, MRP, size/dimensions, consumer complaint address, and unit price.

3.5.2. Labeling requirements for drugs, cosmetics, and medical devices

Labelling of drugs, cosmetics, and medical devices in India is governed by the DC Act, the Medical Devices Rules, 2017, and the Packaged Commodity Rules. These regulations ensure consumer safety, proper usage, and regulatory compliance.

3.5.3. Labeling requirements for drugs

Drug labels must include brand and generic name, active ingredients, and dosage; manufacturing & expiry date, batch number, storage conditions; and schedule drugs warning (e.g., "Schedule H drug – To be sold by retail on prescription only").[42]

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[39] Food Safety and Standards Act, § 53, No. 34, Acts of Parliament, 2006 (India).
[40] Drugs and Cosmetics Act, §§ 18, 27, No. 23, Acts of Parliament, 1940 (India).
[41] Additional labelling compliances may apply in respect of drugs, foods and other regulated products. However, we have not covered labeling requirements for such products. [this footnote uses both the US and UK spellings of "labelling/labeling" ~ US Proofreading]
[42] Drugs and Cosmetics Rules, Rule 96, Gazette of India, Ministry of Health and Family Welfare (1945).

3.5.4. Labeling requirements for cosmetics

Cosmetic labels must display the product name, manufacturer details, batch number, expiry date, directions for use, and warnings for specific ingredients.[43]

3.5.5. Labelling requirements for medical devices

Medical device labels must include device name, intended use, manufacturer details, and import license number, date of manufacture, expiry (if applicable), batch number, and Unique Device Identification ("UDI") for traceability.[44]

3.6. Labelling of food products

Labelling of food products are governed by the FSSA and its associated regulations. The Food Safety and Standards (Labelling and Display) Regulations, 2020 ("FSS Labelling Regulations") prescribe mandatory labelling requirements for all packaged food products. In addition to the FSS Labelling Regulations, specific conditions are prescribed for special foods categories under the respective regulation, such as, for example, vegan foods, organic foods, infant foods, and fortified foods.

[43] Drugs and Cosmetics Rules, Rule 148, Gazette of India (1945).
[44] Medical Devices Rules, Rule 44, Gazette of India, Ministry of Health and Family Welfare (2017).

4. THE UNITED STATES

4.1. The US – An Introduction and Overview of the Legal Framework in the USA

The United States has both federal and state laws covering consumer protection and manufacturer, distributor, and reseller compliance and enforcement. This creates a complex legal environment with manufacturers, distributors, and resellers needing to be aware not just of federal requirements, but also about the state requirements for the products and services they are marketing and selling. In some instances, even local laws may be relevant. Aside from a brief introduction, this paper will focus on a couple key areas that franchisors in certain industry segments must address and deal with in their franchise systems.

Several federal agencies are formed to protect consumers. While some regulations are overreaching and apply to all product and service sales, oftentimes which agency's regulation is relevant will depend on the type of product or service being offered. The U.S. Consumer Product Safety Commission (the "CPSC") administers the Consumer Product Safety Act and many other statutes that apply throughout the U.S., including statutes intended to protect children, or that are intended to protect the general public from hazardous substances.[45] The CPSC publishes regulations and standards, and also issues voluntary standards and certification information. While most consumer products fall within the purview of the CPSC, not all do. For example, cars, trucks and motorcycles, as well as food products and drugs do not. Cars, trucks and motorcycles are regulated by the Department of Transportation and other agencies, while food, drugs, and cosmetics are regulated by the Food and Drug Administration.[46] Another agency that plays an important role is the Federal Trade Commission (the "FTC"), which, pursuant to the Federal Trade Commission Act (the "FTC Act"),[47] enforces consumer protection laws to prevent fraud and unfair business practices, for example, by regulating truth in advertising. Advertising guidelines from the FTC include the Green Guides,[48] which are intended to help marketers ensure that environmental claims in advertising are not in violation of the FTC Act. Likewise, the FTC has published guides regarding the use of endorsements and testimonials in advertising.[49]

On the state level, there is some uniformity around product liability, as, except for Louisiana, all 50 states have adopted Article 2 of the Uniform Commercial Code, which includes general provision about express and implied product warranties (the implied warranty of merchantability and the implied warranty of fitness for a particular purpose).[50] Otherwise, product liability has often developed under common law and will to some degree vary by state, even if there are a lot of similarities.

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[45] *See* https://www.cpsc.gov/Regulations-Laws--Standards/Statutes for a list of statutes enforced by the CPSC.
[46] For a list of different U.S. federal agencies that are involved in different ways in product safety and consumer protection, with information about what agency covers what area, *see* https://www.cpsc.gov/Regulations-Laws--Standards/Products-Outside-CPSCs-Jurisdiction.
[47] 15 U.S.C. §§41-58, as amended.
[48] https://www.ftc.gov/sites/default/files/attachments/press-releases/ftc-issues-revised-green-guides/greenguides.pdf
[49] https://www.ecfr.gov/current/title-16/chapter-I/subchapter-B/part-255
[50] Each state must implement the UCC into its state law, and proper citations to Article 2 of the UCC will therefore differ by state. The text of Article 2 of the UCC can be found here: https://www.law.cornell.edu/ucc/2.

4.1.1. Restaurant and Food Service Industry

The restaurant and food service industry makes up a large segment of the franchisor and franchise system population. While most franchise attorneys focus on the offer and sale of the franchise, and matters relating to the franchise relationship, restaurant and food service franchisors need to keep abreast of industry-specific laws, rules and regulations. Below is an overview of several key laws and related rules and regulations that effect franchised restaurant and food service systems.

The Affordable Care Act of 2010 and regulations issued by the U.S. Food and Drug Administration ("FDA") (the so-called "menu labeling rule") require covered retail foodservice establishments, including those that are part of a chain of 20 or more units, to disclose to consumers, on menu boards, online ordering platforms, and otherwise, certain nutritional information regarding menu items.

Other laws have particular applicability to restaurants and other retail foodservice establishments, including food safety and health and sanitation laws and liquor license laws, liquor liability, and dram shop laws (if alcoholic beverages are offered or sold on the premises). Many states and municipalities also require specific licensure or training in sanitation and safety laws before permitting a restaurant to serve the public.

Recently, some cities have enacted laws that impose specific burdens targeted on restaurants and other retail foodservice establishments that serve foods or beverages that are high in sugar and/or salt. Such cities may require restaurants operating in their jurisdiction to pay additional taxes on the sale of sugar-sweetened beverages and/or may require restaurants or other retail foodservice establishments to warn consumers of high-sodium menu items.

Some states and cities also require that restaurants and other retail food establishments provide information to consumers about food allergens.

Many states and cities also regulate foodware and foodservice packaging items. Some cities ban plastic straws and other single-use items. Some states also now require a certain amount of post-consumer recycled content or restrict or prohibit the use of certain types of Styrofoam and plastic. Additionally, state extended producer responsibility laws could ultimately place reporting and other obligations on restaurant chains that distribute branded items.

Additionally, in January 2026, many restaurants will be required to keep certain key data elements when such restaurants receive food that is on the FDA's food traceability list. If a restaurant must keep such key data elements, it must keep the specific data required by FDA and must be able to make such information available to FDA via an electronic sortable spreadsheet.

By way of example of state legislation in this area, in 2025, the Texas Senate passed SB 25, which would require food manufacturers to add warning labels to packaged food products offered for sale in Texas starting as early as January 1, 2027.

SB 25, as currently drafted, contains several initiatives inspired by the Make America Healthy Again (MAHA) movement, such as:

- Daily physical education for Texas children, along with a prohibition on the removal of recess, physical education, or sports practice for disciplinary reasons;
- Nutrition education for Texas students and nutrition training for Texas physicians; and
- The establishment of an independent nutrition advisory council.

If SB 25 passes as written, the law would also require new warning labels to be applied to a wide swath of processed foods sold in Texas. The law would apply to any food manufacturer who sells a food product or ingredient intended for human consumption in the state of Texas. However, "prepared food" or "food ready for immediate consumption," which are defined to include restaurant-type foods, would be exempt from the proposed warning label requirements. As currently drafted, SB 25 would require "a warning label disclosing the use of any" of the 50 specific ingredients listed in the bill (list provided below). A manufacturer who sells food using any of those ingredients also would need to include a similar statement or warning on the manufacturer's website. Notably, some of the ingredients on the Texas Legislature's list are already unlawful in the U.S., such as melatonin (which FDA has repeatedly warned is not generally recognized as safe (GRAS) for use in conventional food), partially hydrogenated oil (aka, trans fat, also not GRAS), or dimethylamylamine (DMAA) (which FDA has cautioned consumers is an unsafe food additive).

If a food "contains an artificial color, chemical or food additive," it would have to be labeled with the following statement:

"WARNING: This product contains an artificial color, chemical or food additive that is banned in Australia, Canada, the European Union or the United Kingdom."

4.1.2. Medical, health and wellness industry

The health and wellness services industry is heavily regulated in the United States by federal, state, and local governments, as are franchise systems that operate health and wellness franchises.

Key aspects of certain healthcare regulatory rules and regulations include without limitation: (i) state corporate practice of medicine laws and regulations; (ii) telehealth and prescribing laws and regulations; (iii) data privacy laws such as HIPAA; (iv) anti-kickback, fee-splitting, and physician self-referral laws and regulations; (v) physician and provider licensing and registration laws; (vi) regulations pertaining to medical devices and healthcare equipment; (vii) rules and regulations promulgated by esthetician boards, nursing boards, pharmacy boards and medical boards; (viii) laws governing marketing claims and commercial speech; (iv) employment laws related to wage and hour requirements; and (x) laws related to workplace safety such as those promulgated by the Occupational Safety and Health Administration.

CPOM Doctrine and State Medical Practice Laws

State laws and regulations vary from state-to-state and may significantly affect or restrict the operations of medical or health and wellness franchised businesses, regardless of whether medical or health and wellness franchised businesses is providing non-medical products and services or is operating as an administrative management company for a physician practice.

CPOM Rules – Many states restrict or prohibit ownership and control of medical practices by unlicensed persons or corporations. These restrictions are commonly referred to as the corporate practice of medicine ("CPOM") doctrine. A state's CPOM doctrine can include a wide range of restrictions such as prohibiting an unlicensed person or corporation from owning or controlling a medical practice, employing a physician for the provision of medical services, collecting professional fees related to the physician practice, serving in management positions of a physician practice, or engaging in certain activities, such as controlling or directing the hiring or firing of clinical personnel, fixing medical revenues, or otherwise influencing or interfering with a medical provider's professional medical judgment or discretion.

Telehealth Laws – The practice of telehealth is governed by Federal and state laws. Telehealth laws regulate the delivery of medical services via telecommunication technologies. These laws regulate who can provide telehealth services, what types of technology can be used, and the requirements for establishing a physician-patient relationship. Telehealth laws may also limit the prescription of controlled substances absent an in-person examination of the recipient. Providers must comply with both federal and state telehealth laws, including as they may relate to privacy and security under HIPAA.

Scope of Practice, Delegation and Supervision – State laws and licensing board regulations and guidelines may also impact whether a licensed professional is required to perform certain activities or procedures, the scope and type of activities and procedures the licensed professional is permitted to perform, how many providers a physician may supervise at a given time and how that supervision and collaboration must occur. For example, states may require certain providers, such as a physician, nurse practitioner (subject to appropriate supervision), or physician assistant (subject to appropriate supervision) to perform the initial evaluation and diagnosis for a customer of a medical or health and wellness franchised business and/or to order certain treatment or procedures.

Fee Splitting – Many states also restrict or prohibit a lay person or corporation from splitting or sharing the professional fees received in connection with the provision of professional medical services by Authorized Care providers. These regulations may restrict or limit the flow of funds between the medical practice or Authorized Care Providers and third parties (including the entity providing administrative services). For example, these laws may prohibit compensation that is based on a percentage of revenues of the medical practice or otherwise restrict or limit the compensation structure or arrangements with non-medical entities and individuals and classify such arrangements as illegal fee splitting or improper payments to induce or reward the referral of patients.

Fraud and Abuse Regulations

Federal Anti-Kickback Statute –The Federal Anti-Kickback Statute (42 U.S.C. §1320a-7b) is a criminal statute that prohibits any person from knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any discount, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind, to any person, in return for or to induce such person to: (1) refer an individual to a person for the furnishing or arranging for the furnishing of an item or service for which payment may be made in whole or in part under Medicare, Medicaid, TRICARE or any other Federal Health Care Programs (as defined by 42 U.S.C. § 1320a-7b(f)); or (2) purchase, lease, order or arrange for or recommend the purchasing, leasing or ordering of any good, facility, service or item for which payment may be made in whole or in part under any Medicare, Medicaid, TRICARE or any other Federal Health Care Programs.

The Federal Anti-Kickback Statute has been broadly interpreted to cover any arrangement where just one purpose of the remuneration is to induce or reward the referral of patients or generate Federal Health Care Program business. Remuneration includes anything of value, not just payment of money.

The U.S. Department of Health and Human Services Office of Inspector General ("OIG") has enacted certain "safe harbors" to protect those transactions it deemed unlikely to result in abuse of the Medicare program. Transactions that satisfy every element of a particular safe harbor are protected and will not be considered to violate the statute. Failure of an arrangement to meet every element of a safe harbor does not render the arrangement per se illegal, but the arrangement will be subject to scrutiny by the OIG. Although elements of the safe harbors vary, a common and important element is to ensure that any compensation paid is consistent with fair market value for items or services actually provided and is not determined in a manner that takes into account the volume or value of referrals or other business generated between the parties.

While the services a medical or health and wellness franchised business offers may not be reimbursed by Federal Health Care Programs, many states have similar anti-kickback statutes and/or have incorporated the federal safe harbors, so it is important to understand and be aware of this statute and its regulations. Further, as discussed below, activities that may violate the Federal Anti-Kickback Statute may be prosecuted under other mechanisms, such as the Federal Travel Act.

Federal Stark Law – The Physician Self-Referral Law, commonly referred to as the "Stark Law," prohibits physicians from referring patients for certain "designated health services" payable by Medicare or Medicaid to entities with which the physician or an immediate family member of the physician has a financial relationship, unless an exception applies. The Stark Law is a strict liability statute, which means specific intent to violate the law is not required. While certain products or services offered by medical or health and wellness franchised businesses may not be designated health services (e.g., if there is no reimbursement from Medicare or Medicaid), the Stark Law may still have implications for physicians and their practices if any other services an Authorized Care Provider renders are designated health services.

Federal Travel Act – Federal prosecutors have recently used the Travel Act to transform violations of state commercial bribery laws into violations of federal law. The Travel Act generally provides that it is a federal crime to engage in interstate commerce with the intent to promote or carry on any unlawful activity – which includes violation of a state bribery law, such as those addressing improper payments in connection with patient referrals.

Disclosure Law – Some states require that physicians make certain disclosures to their patients regarding their affiliation with a person or entity if they will receive, directly or indirectly, remuneration for securing or soliciting the patient.

Commercial Bribery Statute – Some states have a commercial bribery statute that applies regardless of payor source. Typically, a person commits an offense if he or she intentionally or knowingly solicits, accepts, or agrees to accept any benefit from another person on agreement or understanding that the benefit will influence the conduct of the fiduciary in relation to the affairs of his beneficiary. A "fiduciary" may include a physician or other healthcare provider.

State Anti-Kickback and Self-Referral Statutes – Most states have their own anti-kickback statutes, and some have self-referral prohibitions. These statutes can be broader than their federal counterparts and can apply regardless of the payor (i.e., regardless of whether any Federal Health Care Program beneficiaries are involved). Further, while certain products or services offered by medical or health and wellness franchised businesses may not be considered "designated health services" for purposes of the federal Stark Law (unless provided in a certain setting and used to treat certain specific conditions), some states have self-referral prohibitions that can broadly apply regardless of payor.

Licensing and Notifications – Depending on the nature and structure of the healthcare business, some states may have licensing requirements for the medical practice or its location. In addition, some states (such as California, Massachusetts, Minnesota, Nevada, and New York) have imposed or are considering laws requiring disclosure and/or approval of certain transactions involving healthcare entities, which may include entering into administrative services agreements with organizations providing administrative services similar to the services provided by or through a management company for a medical or health and wellness franchised business.

Health Insurance Portability and Accountability Act of 1996 ("HIPAA") and State Health Information Privacy Laws – HIPAA and state health information privacy laws protect the privacy and security of health information and may impose requirements on the ability to use, disclose, collect, share, store, transmit and retain this information.

Advertising and Promotion and Sale of Medical Devices and Equipment – There are extensive federal, state and local laws, rules and regulations that regulate the type of marketing and advertising that a medical or health and wellness business may or may not engage in as to the products and services offered by a medical or health and wellness franchised business, the results that a customer seeking services from a medical or health and wellness franchised business may or may not achieve, whether or not products or services offered by medical or health and wellness franchised businesses are authorized, cleared and/or approved by any government agency or authority, and the authorized care provider that may or may not be administering, supervising and/or performing products or services offered by medical or health and wellness franchised businesses. In addition, state and federal regulations relating to medical devices and equipment may apply, such as the Federal Food, Drug, and Cosmetic Act and equivalent state statutes. Certain state statutes may require registration or licensing related to distribution of medical devices and equipment.

4.1.3. Federal and state False Claims Acts

The United States is perhaps at the forefront of direct customer to manufacturer, distributor or reseller lawsuits and liability. But the federal government has redress as well. The False Claims Act ("FCA")[51] protects the federal government from being overcharged or sold deficient goods or services. The FCA provides that any person who knowingly submits, or causes to submit, false claims to the federal government is liable for three times the government's damages plus a penalty.

In addition to allowing the federal government to pursue fraud on its own, the FCA allows private citizens to file suits on behalf of the government (so-called "qui tam" suits) against

[51] 31 U.S.C. §3729-3733.

those who have allegedly defrauded the federal government. Importantly, private citizens who successfully bring qui tam actions may receive a portion of the federal government's recovery. 32 US states have their own False Claims Acts, mostly mirroring the federal FCA, allowing whistleblowers to report fraud and receive a portion of any recovered funds.