Chambers
Global Practice
Guides

Definitive global law guides offering
comparative analysis from top-ranked lawyers

Medical Devices & Consumer Health Products 2021

USA: Law & Practice
Dan Kracov, Mahnu Davar and Phillip DeFedele
Arnold & Porter

USA: Trends & Developments
Mahnu Davar, Abeba Habtemariam
and Elizabeth Trentacost
Arnold & Porter

practiceguides.chambers.com

USA

Law and Practice

Contributed by:
Dan Kracov, Mahnu Davar and Phillip DeFedele
Arnold & Porter see p.19

CONTENTS

Trends and Developments

Contributed by:
Mahnu Davar, Abeba Habtemariam and Elizabeth Trentacost
***Arnold & Porter** see p.28*

Introduction

Increasingly, consumer products include health or wellness components, and more technology-oriented, over-the-counter medical devices are entering the consumer health marketplace (referred to as "digital health tools" for the purposes of this article). Smartphones, tablets and other internet and Bluetooth-enabled, software-based consumer products are foundational to the growth in consumer health and wellness products, some of which are app-enabled/supported medical devices regulated by the U.S. Food and Drug Administration (FDA). Indeed, the COVID-19 pandemic has accelerated adoption and adaptation of more complex medical device functions and technologies for consumer healthcare use. However, the trend of expansion and growth in digital health tools predates the pandemic.

In particular, the marketplace for digital health tools and other consumer health products directed at young women and parents – "femtech", "babytech" and "famtech" – has experienced significant growth and innovation in recent years. In 2019, Forbes estimated the US babytech market size at around USD46 billion, while Allied Market Research, a market research agency, estimated that the global baby monitor portion of this sector could reach USD1.9 billion by 2027. Companies catering to this demographic are marketing a variety of tech-enabled medical devices and wellness products, including smartphone-enabled fertility trackers and breast pumps, app-enabled infant sleeping systems, baby monitors that measure infant breathing and vitals and at-home fertility tests.

A core consideration for companies developing and launching a femtech or babytech product is whether the product could be subject to regulation by the FDA as a medical device. Given the time and resources that achieving compliance with FDA requirements can require, there are many companies in this space that aim to position and market their products in a manner that exempts them from FDA oversight. Moreover, regulatory agencies, self-regulatory bodies, competitors and consumers are all attentive to what companies are promising in terms of efficacy and attributes for products in the femtech and babytech sectors. Accordingly, regulatory compliance and truth-in-advertising are critical considerations for companies marketing products in this lucrative market, both of which demand careful development of strategies for bringing products to market and associated product advertising and promotion.

Although this article focuses on femtech and babytech products, it may be noted that, in many respects, the same issues and risks apply in other consumer technology areas of focus in digital wellness and health.

The first part of this article provides an overview of the regulatory framework for digital health products marketed in the femtech and babytech spaces, the second part provides illustrative examples of these products, and the third part speaks to the risk environment and enforcement climate for these products, addressing recent regulatory enforcement, advertising challenges and consumer litigation.

Regulatory framework

Whether a femtech or babytech product marketed for a health-related use is subject to FDA oversight as a medical device turns on whether the product meets the statutory definition of a device. The Federal Food, Drug, and Cosmetic Act (FDCA) defines the term "device" in relevant part, as an "instrument, apparatus, implement, machine, contrivance, implant in vitro reagent or other similar or related article, including any component, part, or accessory [that is] (1) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or (2) intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes" (21 U.S.C. § 321(h)).

Significantly, the FDA determines the intended use of a product by looking at the objective intent of the person responsible for marketing the device, as reflected by, for example, the labelling, promotional materials, product website or oral statements by the company or its representatives. Thus, two companies can market essentially the same consumer digital health product in the USA, but one be considered a device and the other not a device because of the difference in claims made for the products. Therefore, if a company markets a wearable device for infants that detects heart rate, respiration and sleep movements for sleep tracking or sleep management, the product could potentially be considered a general wellness tool that is not subject to FDA regulation. If, however, the company, in addition to promoting the wearable device for sleep management, also makes statements about use of the wearable in assessing whether an infant shows signs of (or for monitoring) sudden infant death syndrome (SIDS), sleep apnea or other sleep or breathing disorders, then that same wearable could be considered a regulated medical device.

The FDA has long maintained that the device definition encompasses software-based products, such as mobile applications, in the same manner in which it encompasses traditional hardware-based products. However, because of the ways in which they differ from more traditional medical devices, the FDA has struggled with how to apply its device authorities to software-based digital health products. The agency's regulatory approach to digital health devices, including consumer digital health devices, has evolved significantly over the last decade, culminating in a December 2016 statutory amendment to the FDCA device definition to carve out certain software functions through enactment of the 21st Century Cures Act (Cures Act).

In the years leading up to the Cures Act, the FDA had adopted a risk-based approach to regulation of digital health tools where the agency decided to focus its regulatory oversight on higher-risk digital health tools, while exercising enforcement discretion over lower-risk tools even if the lower-risk tools technically meet the definition of a device. This risk-based approach to regulation was reflected in various agency guidance documents, including draft FDA guidance on mobile medical applications and general wellness tools. The agency has tried to solicit and respond to medical technology developer feedback when shaping these proposals, particularly those around multi-use software applications.

As amended in December of 2016 by the Cures Act, the FDCA device definition now excludes certain enumerated categories of low-risk software functions – for example, certain administrative support tools, general wellness tools, electronic patient records, medical device data

systems and certain clinical decision support (CDS) tools; see 21 U.S.C. § 360j(o). Although the Cures Act carve out largely codified FDA's existing policies on regulation of software products, they have helped to provide more certainty to those companies seeking to develop digital health tools. For example, certain women's health digital health tools are potentially marketed without FDA oversight pursuant to the Cures Act "general wellness" exemption for software functions that are intended for "maintaining or encouraging a healthy lifestyle and [are] unrelated to the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition". Other women's health digital health tools are potentially marketed pursuant to FDA enforcement discretion policies for additional low-risk general wellness tools as well as for certain low-risk mobile medical applications.

The Cures Act also excludes from the FDCA device definition certain software functions that provide recommendations to a healthcare professional (HCP) about prevention, diagnosis or treatment of a disease or condition provided certain conditions are met. Although this Cures Act CDS exemption does not apply to digital health tools intended for patients ("patient CDS"), the FDA in draft guidance announced that there are certain low-risk patient CDS for which the FDA intends to exercise enforcement discretion. Specifically, the FDA does not intend to enforce compliance with applicable FDCA requirements for patient CDS that are intended to inform clinical management for "non-serious situations or conditions" and that, in addition, are intended for the patient to be able to independently evaluate the basis for the software's recommendations.

In contrast, the FDA does intend to focus its regulatory oversight on patient CDS functions that are intended to inform clinical management for a non-serious situation or condition but that are not intended for the patient to be able to independently evaluate the basis for the software's recommendations. The FDA also intends to focus its regulatory oversight on device patient CDS functions that are intended to inform clinical management for a serious or critical situation or condition, whether or not the software is intended for the patient to be able to independently evaluate the basis for the software's recommendations.

If a digital health tool does meet the definition of a medical device (and does not fall under an enforcement discretion policy), the requirements applicable to manufacturing and marketing of the product would turn on the device classification under which the product falls: Class I – low risk; Class II – moderate risk; Class III – high risk. If a product meets the FDCA definition of a "device", but no FDA device classification exists under which the product would fall (or the product potentially falls under an existing Class II classification but no suitable legally marketed predicate exists to which the manufacturer could demonstrate substantial equivalence for purposes of a Section 510(k) pre-market notification), the product would by default be considered a Class III device, subject to approval through a pre-market approval (PMA). This can occur, for example, when a product is a novel device (eg, certain software-based technologies). The FDA's de novo classification process can potentially be used to down-classify devices in this category to either Class II or Class I, depending on risks posed by use of the device. For example, Natural Cycles®, the first pregnancy contraception mobile medical application to receive FDA marketing authorisation, was reviewed and classified through the de novo process.

If a proposed product has device functions as well as non-device (eg, exempt) software functions, the FDA may assess the impact that the software non-device function has on the device function when assessing the safety and

effectiveness of the device function as further detailed in FDA guidance on multiple function devices. In addition, as it relates to certain diagnostic femtech products, also relevant is the FDA's enforcement discretion policy for certain types of in vitro diagnostic devices referred to as laboratory developed tests (LDTs).

In terms of advertising and promotion, for most over-the-counter medical devices, the FDA and FTC exercise joint regulatory authority over product labelling and advertising. The FDA has primary jurisdiction over labelling for all medical devices and advertising for restricted devices (typically Class III), while FTC has primary jurisdiction over advertising of "unrestricted" medical devices (Class I and most Class II devices). The FDCA prohibits the distribution or receipt in interstate commerce of a misbranded medical device, which includes a device bearing false or misleading labelling. Claims in device labelling, including product websites, that are outside the scope of the devices' cleared uses can misbrand, and even adulterate the device, another prohibited act under the FDCA.

Similarly, FTC's enabling statute, the Federal Trade Commission Act, prohibits unfair or deceptive acts or practices in or affecting commerce as well as the dissemination of any false advertisement that is likely to induce the purchase of medical devices. The FDA takes a broad view of what types of materials are considered labelling, and, ultimately, promotion of these products on platforms such as websites and social media may come within both agencies' purview. Additionally, advertising for products that are not regulated as medical devices is subject to FTC's truth-in-advertising laws. Firms marketing these products must take care to avoid expressly or by implication suggesting they are intended for use as medical devices, as this presents risk of enforcement action and advertising challenges.

Both agencies are known to collaborate when pursuing enforcement action, and issue joint warning letters in cases where claims violate the agencies' enabling statutes and implementing regulations. Furthermore, violations of FDA and FTC requirements can also lead to follow-on consumer, competitor or National Advertising Division of the Better Business Bureau (NAD) challenges. Thus, a key aspect of compliance and risk mitigation is ensuring that all product advertising and promotion is truthful, non-misleading and appropriately substantiated.

Digital health tools marketed in the femtech and babytech sectors, including as medical devices

An increasing number of femtech and babytech products are regulated as medical devices, and some companies marketing products that are not regulated as such are eyeing medical device applications as a way to expand their markets and uses. Common themes underlying the introduction of newer medical devices in the femtech market are offering women more insights into and control over their health. Babytech products are also heavily information-driven, and aim to give parents insights into infants' patterns, vitals and other wellness data. Femtech and babytech products cover a broad variety of consumer health and wellness interests, including fertility, conception, contraception, and infant sleep and monitoring, as discussed further below.

As noted, a number of femtech products concentrate on core areas of women's health – conception and contraception. For example, following the trend of expanding direct-to-consumer diagnostic test options, Modern Fertility launched an at-home fertility test system that culminates in issuing an app-enabled fertility profile based on the results of an at-home finger-prick blood test or in-laboratory hormone testing. Women seeking to become pregnant and non-hormonal contraception are also served by a growing market

of app-enabled and wearable medical devices. For example, Ava Sciences markets the Ava Fertility Tracker, an over-the-counter, 510(k)-cleared device comprised of a fertility tracking sensor bracelet and accompanying app. Natural Cycles offers a 510(k)-cleared (initially authorised under a de novo) web and mobile-based application that is intended for women 18 years and older to monitor fertility, and can be used for preventing a pregnancy (contraception) or planning a pregnancy (conception). The app monitors a woman's menstrual cycle by using information entered by the user – daily temperature measurements – and then a proprietary algorithm evaluates the data and provides the user's fertility status.

In the babytech space, infant sleep and monitoring products are a key focus, and companies are starting to consider subjecting their products to FDA regulation as medical devices, which could expand permitted uses, claims, and open up new customer markets. Happiest Baby®, for example, presently markets an app-enabled bassinet (cradle) called the SNOO Smart Sleeper® that bears claims of adding an additional one to two hours of sleep per night, preventing rolling, and giving piece of mind to parents by securing their baby safely on the back. For now, the product is not regulated as a medical device and does not bear SIDS-prevention claims, but that could change. In February 2020, the company announced that the SNOO® Smart Sleeper was accepted into the FDA's Breakthrough Device Program as a potential candidate for preventing or reducing SIDS.

Another veteran of the infant-care ecosystem marketplace, Owlet Baby Care, also recently announced intention to seek FDA clearance for new and existing products in its infant ecosystem portfolio (eg, the Smart Sock product that tracks a baby's heart rate, oxygen levels and sleep trends using pulse oximetry technology). The company's February 2021 Investor Presentation acknowledged that FDA authorisation for its products could allow for expanded claims, new markets and possibly telehealth opportunities.

Advertising and promotion enforcement and challenges

Regardless of whether the product at issue is an FDA-regulated medical device, regulatory agencies, the NAD, competitors and consumers pay close attention to product claims in the femtech and babytech space. Recent enforcement action and challenges reflect the heightened scrutiny applied to these products and are illustrative of the risks that marketers of these types of products face.

With respect to infant products, the FDA has historically scrutinised product marketing that expressly or by implication claims to prevent SIDS and has broadly notified industry of its stance that marketing a baby product with claims to cure, treat or prevent SIDS subjects it to regulation as a medical device. In addition to a 2010 warning letter to a firm marketing a 510(k)-cleared infant sleep mattress with SIDS-prevention claims – for which the product was not cleared – in 2011, the FDA sent letters to companies regarding SIDS-prevention claims for baby products. This letter cautioned that labelling, packaging or advertising containing claims to prevent or reduce the risk of SIDS violates the FD&C Act, a message echoed on FDA webpages centred on baby products with SIDS-prevention claims. Companies marketing infant sleep and monitoring products have to tread carefully in this area and refrain from suggesting or stating that their products can prevent or reduce the risk of SIDS, unless the FDA specifically approves or clears the products for that purpose.

More recently, the FDA's and FTC's enforcement priorities in the women's health space have

focused on therapeutic (drug) claims for products that are marketed as dietary supplements. On 20 May 2021, the FDA and the FTC jointly issued warning letters to five companies that were illegally selling dietary supplements claiming to cure, treat, mitigate or prevent infertility and other reproductive health conditions (eg, restoring fertility, replacing conventional fertility treatments, touting pregnancy within several months after using the supplement). Although targeted at marketers of purported dietary supplements, such regulatory enforcement attention on therapeutic claims creates risk for diagnostic or wellness products that recommend supplements or other interventions.

Aside from regulatory action, companies marketing femtech and babytech products also face the risk of challenge by or before the NAD and piggy-back or parallel consumer litigation arising out of allegedly false or misleading claims.

In 2019, Owlet both faced a challenge to advertising claims for its Smart Sock® monitor brought by the NAD as part of its ongoing monitoring programme, as well as consumer litigation alleging unlawful, false, misleading and deceptive marketing and advertising practices in connection with the sale of the Smart Sock. The NAD evaluated whether Owlet accurately communicated to consumers the nature of the product as an information-gathering device, "without overstating the extent to which the Owlet can actually prevent adverse medical events"; see Owlet Baby Care, Inc., Smart Sock Baby Monitor, NAD Case No 6282 (4 June 2019).

At issue were claims that the product would reassure parents that their baby is okay and provide notifications if his or her heart rate and oxygen levels leave pre-set zones, testimonials that the product gives parents peace of mind, and the content and placement of a disclosure communicating that the Smart Sock is not an FDA-approved medical device nor is it intended to diagnose, cure, treat, alleviate or prevent disease.

The NAD concluded that the Smart Sock advertising "reasonably conveyed" that it could prevent SIDS and save lives, which was unsupported by the available evidence. The NAD thus recommended that Owlet limit the scope of its advertising claims by using a clear and conspicuous disclosure highlighting the product's information-gathering function, and explicitly stating that the product does not prevent SIDS nor replace a medical monitor.

In the Owlet consumer litigation, plaintiffs alleged that the Smart Sock was defective – giving false alarms that cause parents to think their baby is ill, while also failing to detect abnormal oxygen levels and heart rates – allegedly the "exact purpose" for which the product was designed and advertised; see Ruiz and Marisela v Owlet Baby Care, Inc., Case No 2:19-cv-00252-HCN-DBP (D. Ut. 2019). Plaintiffs alleged that this material information was not disclosed to consumers before sale, the company actively concealed its knowledge of these defects, and that the company failed to disclose that the product can burn babies' feet, even when used as instructed. In June 2020, the court ruled on the defendant's motion to dismiss and gave plaintiffs leave to amend their complaint. Plaintiffs sought leave to file an amended complaint on 1 July 2020. Subsequently, on 3 August 2021, the court denied plaintiffs' motion for leave to file the proposed amended complaint and dismissed the case, having found that the amended complaint asserted essentially the same claims asserted in the previous complaint and dismissed by the court.

Ava Science, Inc. also faced a challenge regarding claims for its Ava Ovulation Bracelet arising out of NAD's routine monitoring programme. The

Contributed by: *Mahnu Davar, Abeba Habtemariam and Elizabeth Trentacost,* ***Arnold & Porter***

NAD focused on whether a "one-year guarantee of pregnancy" claim that hyperlinked to a money-back guarantee, and a social media post that displayed a picture of a pregnant woman next to "one year pregnancy guarantee" in a circle communicated a money-back guarantee message or a product performance claim (guaranteeing pregnancy); see Ava Science, Inc., Ava Ovulation Bracelet, NAD Case No 6348 (6 February 2020).

The NAD concluded that the pregnancy guarantee claim was tied to the "performance result" (pregnancy) rather than the refund which may be issued if the product does not perform as claimed, and recommended modifications to the claim and hyperlink. After Ava Science failed to confirm it would comply with NAD's recommendations, the NAD referred the matter to the FTC in March 2020. The FTC decided not to take additional action but reserved the right to take further action as the public interest demands.

Conclusion

Companies entering the market for digital health tools, especially femtech and babytech products, face a number of important considerations. These include whether the product is subject to regulation as a medical device, and whether to develop and position the product in order to seek regulation and clearance through the medical device pathway. Although medical device status carries particular regulatory compliance burdens, it can allow companies to lawfully promote their products for prevention, treatment and management of key aspects of consumers' health.

As recent announcements of intention to seek FDA clearance of babytech products not currently subject to regulation as a medical device suggest, companies in this sector see FDA regulation as a way to grow their markets. Overall, the femtech and babytech sectors and related product offerings are poised to continue expanding, and will continue to push the agencies' frameworks for regulation and oversight.

Arnold & Porter has 200 attorneys dedicated to serving its multinational life sciences clients across the firm's US and international offices. It provides globally integrated counselling to pharmaceutical, biotechnology, medical products and diagnostic companies, clinical laboratories, emerging growth and venture-backed companies, investors, non-profit institutions and universities around the world. Arnold & Porter currently has 94 attorneys who have held senior positions in US and European government and international organisations and over 100 attorneys with scientific degrees. Its team also includes healthcare professionals and public policy specialists. The firm's offerings in these fields cover regulatory matters, internal investigations, civil and criminal government investigations, domestic and global compliance programmes, patent procurement, structuring and fundraising, corporate transactions, mergers and acquisitions, tax and securities offerings, licensing and other partnering transactions, patent and commercial litigation, antitrust, product liability and government contracting.

AUTHORS

Mahnu Davar is a partner of Arnold & Porter. He is a trusted adviser to lawyers, compliance officers, regulatory professionals and business executives across the life sciences industry. Mahnu counsels clients on mission-critical FDA, CLIA, fraud and abuse, and state licensing regulatory matters, including compliance programme development and management. He routinely assists multinational companies with sensitive internal investigations, regulatory inspections, product quality and safety issues, data integrity concerns and government enforcement matters. He also assists clients, particularly in the diagnostics and medical technology fields, in developing regulatory life-cycle strategies.

Abeba Habtemariam advises life sciences companies on a range of regulatory, compliance and legislative matters, with a particular focus on counselling pharmaceutical and medical device manufacturers on compliance with the Federal Food, Drug, and Cosmetic Act. She routinely advises clients on the regulation of medical device software and healthcare IT, pre-market approval and clearance strategies, promotional review matters and cGMP compliance. Abeba also assists clients with responding to FDA and DOJ investigations and enforcement actions. Previously, Abeba worked as a legal fellow at the AAMC, and interned as a legal assistant to the President of Eritrea. Prior to attending law school, Abeba was a research analyst at the National Association of Public Hospitals, and a clinical researcher at Johns Hopkins Hospital and School of Medicine, focusing on Alzheimer's disease, maternal depression and breast cancer research.

Contributed by: *Mahnu Davar, Abeba Habtemariam and Elizabeth Trentacost,* ***Arnold & Porter***

Elizabeth Trentacost counsels life sciences, food and consumer products companies on a broad range of FDA regulatory, compliance, enforcement and strategic matters. She routinely advises on issues related to product and claims development, and provides guidance that encompasses FDA, FTC, NAD and litigation considerations and risks. Elizabeth also maintains an active pro bono practice. Prior to joining Arnold & Porter, she spent several years as a regulatory counsel in the Office of Regulatory Policy in the FDA's Center for Drug Evaluation and Research. At the FDA, Elizabeth was involved in a wide variety of policy issues involving drug approvals, responded to citizen petitions, developed guidance for industry and counselled on matters relating to Hatch-Waxman marketing exclusivities.

Arnold & Porter

601 Massachusetts Avenue NW
Washington
DC 20001
USA

Tel: +1 202 942 6172
Email: mahnu.davar@arnoldporter.com
Web: www.arnoldporter.com

Arnold&Porter