

Bridging Legal Frontiers: Navigating the Intersection of Luxury, Wellness, and Technology

Melanie Howard

Chair, Intellectual Property Protection

Chair, Luxury Brands

Deputy Chair, Advanced Media and Technology

Kristen Klesh

Partner

David G. Mallen

Co-Chair, Advertising Disputes

Chair, Retail & Consumer Brands



We're all connected.



LOS ANGELES
NEW YORK
CHICAGO
NASHVILLE

WASHINGTON, DC
SAN FRANCISCO
BEIJING
HONG KONG

loeb.com

The opinions expressed in this presentation do not necessarily reflect the views of Loeb & Loeb LLP or its clients. This document was created for purposes of teaching and commentary, and should not be posted to the Internet, or otherwise used for any commercial purposes, without prior written approval from Loeb & Loeb LLP. The information in this document is not intended to be and should not be taken as legal advice.

Panel Speakers



The Wellness Economy: Resilience and Growth



What is the “Wellness” Product Industry?



Wellness Is A Priority For U.S. Consumers

82% of US consumers consider wellness a top or important priority in their everyday lives.

Today's consumer views wellness across six dimensions.



Better health

Extends beyond medicine and supplements to include medical devices, tele-medicine, and remote healthcare services, as well as personal health trackers



Better fitness

Was steadily increasing over time before experiencing some upheaval over the past year, with many consumers struggling to maintain pre-COVID-19 fitness levels



Better nutrition

Has always been a part of wellness, but now consumers want food to help them accomplish their wellness goals in addition to tasting good



Better appearance

Primarily relates to wellness-oriented apparel ("athleisure") and beauty products (skincare and collagen supplements), but also includes service-oriented offerings like nonsurgical aesthetic procedures



Better sleep

Now goes beyond traditional sleep medication, like melatonin, to app-enabled sleep trackers and other sleep-enhancing products



Better mindfulness

Has gained mainstream consumer acceptance relatively recently, with meditation-focused apps and meditation-oriented offerings

McKinsey
& Company

Trends In The Wellness Market

Natural / Clean
Products

More
Personalization

Shift to Digital
Channels

Influencers
Drive
Purchasing

*{ Consumers want **effective, data-driven, science-backed** health and wellness solutions. (McKinsey) }*

Key Federal Regulators – Health & Wellness Advertising

- Claim substantiation
- Health & Safety Claims – Competent and Reliable Scientific Evidence
- Influencer engagements

FTC



- Claims establish the “intended use” of the product
- Intended use determines how the product is regulated by FDA
- Implying a product acts as a medical device or drug, absent FDA authorizations, presents enforcement risk

FDA



FDA vs FTC Regulatory Focus



- **Memorandum of Understanding**
 - FDA will look to advertising as evidence of “intended use”
 - FTC has taken to evaluating whether claims are appropriate for product
 - **Practically speaking**, the FDA and FTC will each assert jurisdiction over all forms and media for product
- **Rule of Thumb:**
 - FDA: “*Form over Function*”
 - FTC: “*Peels Back the Onion Layers*”

Wellness Devices & Apps: FDA Considerations



When is a product a “medical device”?

A medical device is “...an instrument, apparatus.... intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease.. or intended to affect the structure or any function of the body” Section 201(h) FDCA

It's a Very Broad Definition!

Wellness Devices & Apps : FDA Considerations

GENERAL WELLNESS PRODUCTS

- Not actively regulated by FDA
- Low safety risk
- Intended use to either:
 - ✓ Promote a general state of health
 - ✓ Help living well with certain chronic conditions



vs.

REGULATED MEDICAL DEVICES

- Requires FDA registration/listing
- Compliance with various FDA requirements:
 - Labeling/Claims
 - GMP
 - Adverse Events
 - Potential FDA *pre-market authorization*



Cosmetics & Supplements: FDA Considerations

Cosmetics

- Avoid claims to suggest a *physiological* change to the body
- Focus on outward surface level appearance and beautification
- “Appearance of fine lines”
- “Promotes thicker-looking hair”



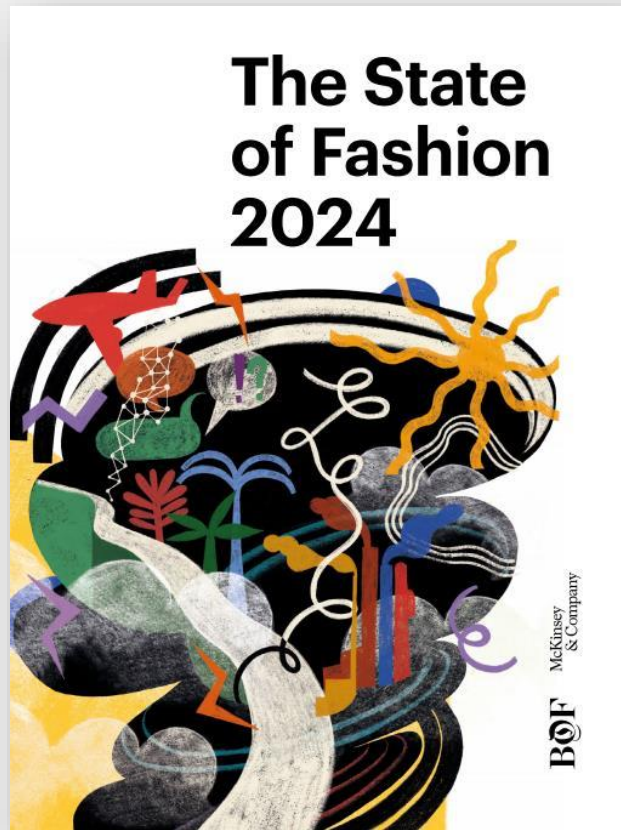
Supplements

- Keep healthy people healthy
- Do not make sick people well
- Do not prevent ‘diseases’
- “Supports immune function”
- Not “reduces risk of a cold”

Wellness Products: Advertising Watch Outs



Parallel Trends In The Luxury Market



Sustainability

Vacation /
Outdoor /
Lifestyle

(Re)New(ed)
Focus on
Influencers

Potential of
Generative AI

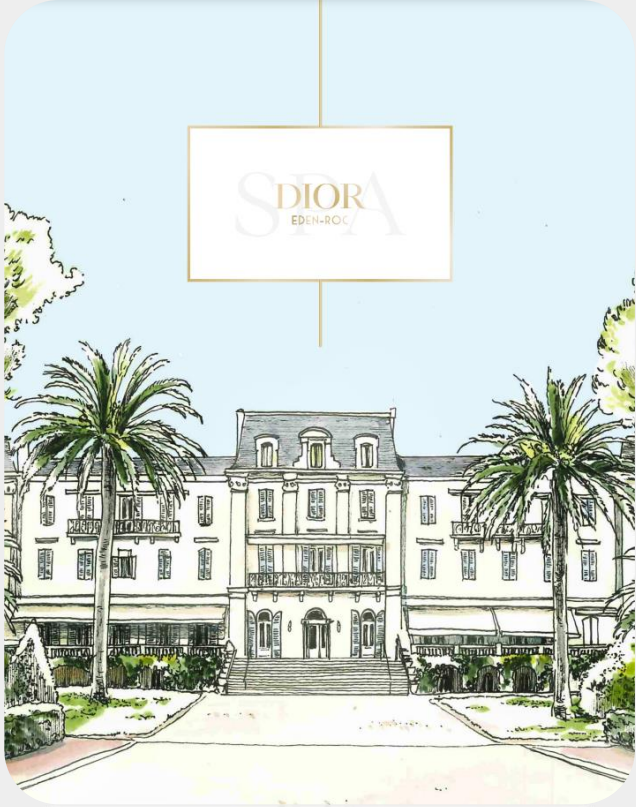


“Luxury is no longer confined to the tangible goods alone; it has expanded to encompass real and genuine experiences, travel, and cherished moments.”

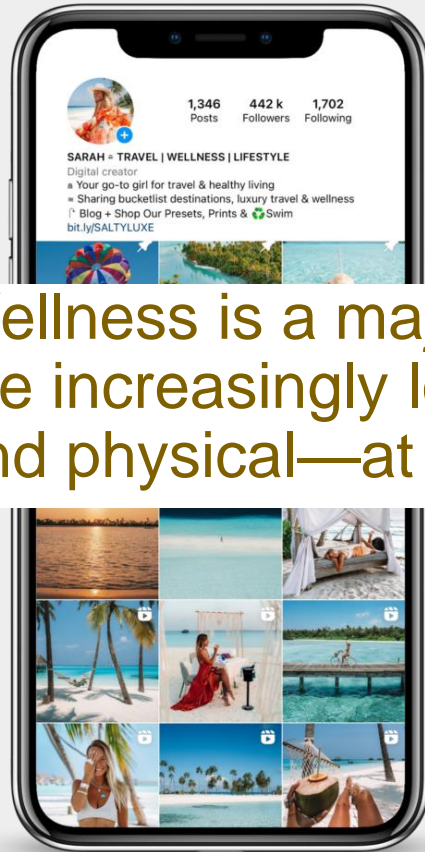
Belmond



Luxury x Hospitality



Luxury x Wellness x Hospitality



Wellness Travel: A Growing Trend In Personal Transformation

In recent years, the concept of wellness travel has grown significantly, with more individuals seeking experiences that foster personal growth, healing, and mindfulness.

Forbes

Wellness is a major, ongoing, global trend, and luxury tourists are increasingly looking for ways to put their health—both mental and physical—at the center of their travels (McKinsey)

Can these ultra-exclusive luxury destinations help extend your life? They'd certainly like to try

CNN style

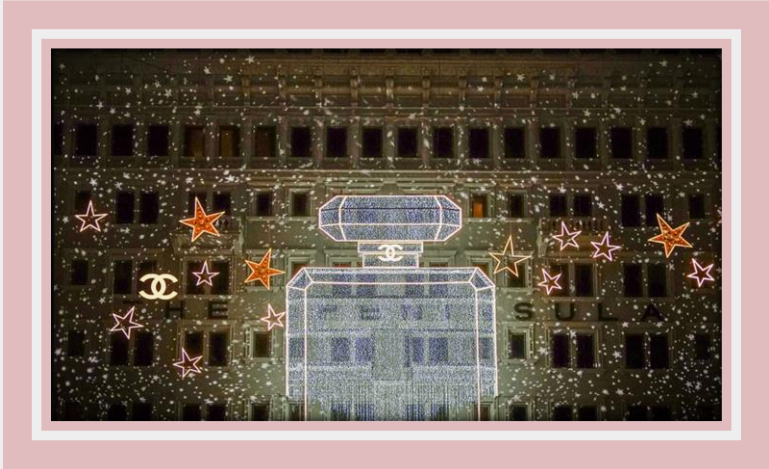


"Living well is the ultimate luxury."

The Four Seasons



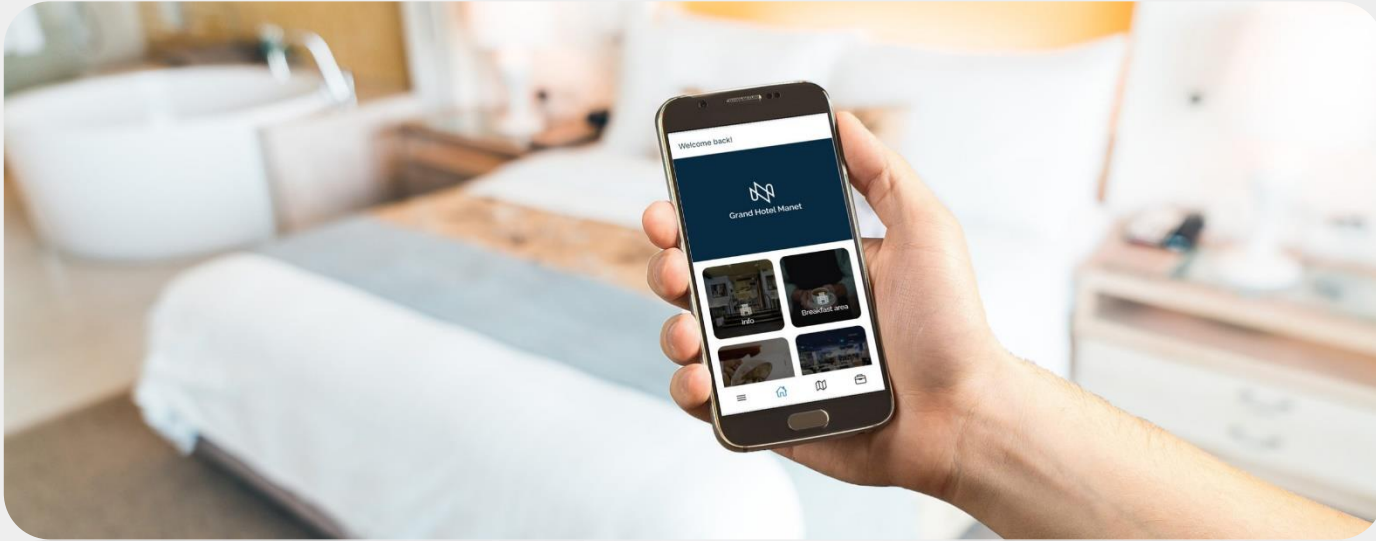
Luxury x Hospitality x Wellness





Case Study: A Luxury Wellness Retreat

Before Arrival



Before Arrival: Claims

“Our welcome prescreening mobile app...

- ✓ analyzes your eye movements to identify any balance disorders and then create a catered yoga program to address these issues*
- ✓ enables us to recommend a “coping skill of the day” you have self-identified with a mental health condition*
- ✓ evaluates voice and breathing patterns to identify stress so that we can recommend relaxation techniques as part of your stay*

In The Elevator



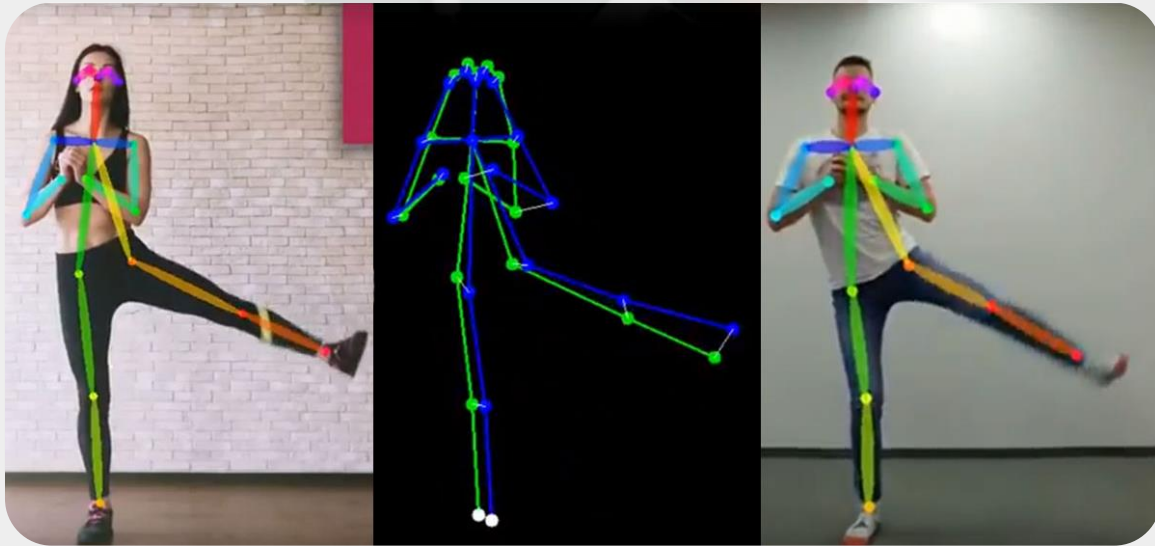
In The Room



On The Menu



In The Gym



At The Spa





Avoiding Pitfalls

Avoiding Pitfalls

- Appreciate the different functions and priorities of each applicable regulatory body
- Think early and often of the claims you want to make about the products
- Take advantage of areas of FDA enforcement discretion for general wellness products
- Develop a robust substantiation and safety dossier for novel technology uses
- Implement a plan to communicate requirements around claims with advertising community

Questions?



Melanie Howard
mhoward@loeb.com
+1.310.282.2143

Kristen Klesh
kklesh@loeb.com
+1.202.524.8488

David G. Mallen
dmallen@loeb.com
+1.212.407.4286