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**NEWS** RULINGS VERDICTS**SPECIAL REPORT****20 Under 40**

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Thursday, January 29, 2015

## FDA's general wellness guidance is welcome news

**Michael H. Cohen** is founder of the Michael H Cohen Law Group, providing legal strategy for the health and wellness industry. He also served as director of Legal Programs at the Harvard Medical Division for Research and Education in Complementary and Integrative Medical Therapies, and as an assistant professor of Medicine at Harvard Medical School and adjunct assistant professor at Harvard School of Public Health.



The FDA just issued a draft guidance titled "General Wellness: Policy for Low Risk Devices." This sounds like good news for manufacturers and distributors of what the FDA now calls, "low risk products that promote a healthy lifestyle (general wellness products)."

But what exactly are those products and is the FDA really lowering the barrier for industry?

Start with the "intended use" doctrine. The FDA considers not

only to what the product is or does, but also at what the manufacturer or distributor says the product is or does. This means reviewing the product labeling, which includes not only the physical labels on and inside the package, but all the marketing materials.

For example, the federal Food Drug and Cosmetic Act (FDCA) defines a "medical device" as "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is ... 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" (emphasis added). Similarly, the FDCA defines drugs, in part, by their intended use, as "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease."

The FDA's definition of "general wellness products" begins with the criterion that the products: (1) "are intended for only general wellness use, as defined in this guidance," and (2) "present a very low risk to users' safety."

There are two types of general wellness intended uses outlined: first, one "that relates to a maintaining or encouraging a general state of health or healthy activity" - which means no disease claims can be made - and second, one "that associates the role of healthy lifestyle with helping to reduce the risk or impact of certain chronic diseases or conditions" - which can mean helping either to reduce the risk of a condition or to live well with a condition.

Whether a device is low risk depends on whether the product: (1) is invasive; (2) involves an intervention or technology that may pose a risk to a user's safety if device controls are not applied (e.g., lasers); (3) raise novel questions of usability; or (4) raise questions of biocompatibility. Any one of these four may cause the FDA to categorize the product as not "low risk."

### Medical Devices vs. Drugs

Medical devices are subject to a host of FDA rules but drugs are subject to even more significant regulatory hurdles. As such, when deciding how to position a product for market, the intended use is critical. For example, the FDA notes that a mobile app that plays music to "soothe and relax" and help the user "manage stress," would be considered a low risk general wellness product. On the other hand, the guidance is clear that if the intended use is disease care - such as to mitigate anxiety - then it fails

Friday, January 30, 2015

### Judges and Judiciary

#### OC prosecutor appeals 'not qualified' rating by judge selection committee

Allegations and a judge's findings last year that some members of the Orange County district attorney's office misused jailhouse informants to violate suspects' rights now may be preventing local prosecutors from becoming judges.

### Litigation

#### Environmentalists launch another attack against growth of crude by rail

Local air regulators failed to give environmental scrutiny to the Bakersfield Crude Terminal, a lawsuit alleges.

### Criminal

#### Public defender arrest exposes dubious doctrine

Tuesday's arrest of San Francisco Public Defender Jami Tollefson crystallized much of the unrealism and absurdity surrounding the post-Warren courts' approach to police-citizen encounters. By **Hadar Aviram**

### Ethics/Professional Responsibility

#### VIDEO: Dos, don'ts for lawyers on social media

Emphasis on the use of social media within the practice of law has increased. But ignorance of the rules, no matter how new or infrequent your use of social media, will not cut it. By **Shawn Shaffie**

### Government

#### New SEC enforcement director is San Francisco office veteran

Erin E. Schneider, an SEC insider who has overseen accounting fraud cases involving CEO bonuses, actions against hedge fund managers and a jury trial for stock options backdating, was promoted to regional director of enforcement.

### California Courts of Appeal

#### In case of dubious prosecutorial conduct, state appeals court upholds conviction

A state appeals court on Thursday reluctantly upheld the conviction of a man even though it concluded the deputy district attorney threatened to bring criminal charges against a defense investigator and possibly a defense lawyer.

the low risk general wellness product test - and medical device regulation would likely apply. This position follows that taken by the FDA in its earlier guidance on "mobile medical apps" - apps that the FDA will regulate as medical devices. Clearly, language is critical.

Technological aspects of the product and safety issues also play a role. For example, if an exfoliating product also enhances the delivery of a topically applied product containing active pharmaceutical ingredients, the product presents inherent safety risks and may be considered a drug. Here, the technology itself moves the product out of the guidance and into the more burdensome regulatory category of a drug.

### Takeaways

Many industry commentators are heralding the guidance as a new swing by the FDA toward more permissive regulatory of wearable health technology and other health-oriented consumer products.

The reality is the document merely carves out products that do not make disease claims, where the intended use is general wellness, and the product is considered low risk. This follows FDCA definitions of medical devices and drugs, and the FDA's long-standing enforcement focus on unlawful disease claims.

There are other important caveats. First, if a product fails the criteria in the guidance, it will probably fall within a regulatory category (such as medical device or drug) that is subject to more burdensome regulatory requirements. Second, the guidance does not establish "legally enforceable responsibilities." Rather, guidance documents merely "describe the Agency's current thinking on a topic." That thinking could change tomorrow - with changes in staff, in technology, in enforcement priorities, or in safety data.

Third, that a consumer product meets the definitions under the guidance does not establish that the product has been shown to be "safe, effective, and not misbranded for its intended use." In other words, if a product is shown to be unsafe or ineffective, or if the manufacturer or distributor makes unsubstantiated claims for the product, then the FDA will probably exercise enforcement discretion against the manufacturer or distributor. The FDA may start with a warning letter, but its enforcement remedies include seizure and civil and criminal penalties.

Finally, even if the guidance signals perhaps greater FDA tolerance for products focused on general wellness and healthy lifestyle - so long as they are generally safe - epistemological chaos still results from the slippery slope between promoting wellness and mitigating disease. Companies still face enforcement peril, and will benefit from astute legal review of their product positioning and claims.

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### Litigation

#### Boy Scouts trial settles

After just a few days of trial proceedings, the Boy Scouts of America settled a lawsuit Thursday brought by the family of a man molested by a volunteer.

#### Uber sued in San Francisco federal court over attack in India

A passenger sued Uber Technologies Inc. Thursday for alleged lax background checks and inadequate safety measures after she was assaulted and raped by a driver in India in December.

### Corporate

#### Mikhail Gorbachev to headline ACC Southern California gala

The former and final leader of the Union of Soviet Socialist Republics will deliver the keynote speech at the Association of Corporate Counsel Southern California chapter's 20th annual gala dinner in early May.

### Judges and Judiciary

#### Veteran San Francisco judge to retire

James J. McBride, a longtime judge on the San Francisco County Superior Court bench, will retire in about two weeks, he announced Thursday.

### Solo and Small Firms

#### Personal injury firm succeeds with little to no advertising

Steven B. Effres grew up in the inner city of South Philadelphia and was only 14 when his father, a union worker, passed away, but one of the last conversations they had shaped his career.

### Alternative Dispute Resolution

#### N. Denise Asher

Judicate West San Diego and Santa Ana

### Discipline

#### Disciplinary Actions

Here are summaries of lawyer disciplinary actions taken recently by the state Supreme Court or the Bar Court, listing attorney by name, age, city of residence and date of the court's action.

### Litigation

#### State Bar moves to send fired executive director's suit to arbitration

The bar also claims Joseph L. Dunn's lawsuit should be tossed because he failed to follow proper procedures in suing a governmental agency and because the bar president has qualified immunity.

### Law Practice

#### Vacating judgments when service fails

When can a default judgment be vacated for claimed lack of service of the summons and complaint? By **Daniel Brenner**

### Family

#### Digital age divorces spawn civil litigation

Traditionally, family law practitioners and civil litigators existed in separate worlds with little

overlap between the two practice areas. That has changed in recent years. By **Erik Syverson**

#### **Ethics/Professional Responsibility**

##### **Buyer's remorse breeds buyer's recourse**

Having consented to a settlement, a settling party who later develops buyer's remorse cannot simply back out of the agreement. But they can sue their lawyer. By **Louie Castoria**

#### **Government Contracts**

##### **New laws change landscape for public projects**

The expansion of the law shows a continued legislative policy to close any loops that may have enabled construction to proceed without the payment of prevailing wages. By **Michael Maurer**

#### **Ethics/Professional Responsibility**

##### **What's new in updated e-discovery ethics opinion?**

In April 2014, the State Bar's professional responsibility committee released an opinion on e-discovery ethics. And just this month, they revised that opinion. By **Wendy Wen Yun Chang**

#### **Litigation**

##### **Alarming self-inflicted mootness ruling**

A recent decision represents a minority approach to a common pleading defect but, should this approach become common practice, it would result in unfairness and inefficiencies in the legal system. By **Amy Lally and Emily Culbertson**

#### **Judicial Profile**

##### **Rocky L. Crabb**

Superior Court Commissioner Los Angeles County (Pomona)

#### **California Supreme Court**

##### **State high court reverses itself, but new justices could keep case alive**

In an unusual move, the state Supreme Court on Thursday reversed one of its own decisions from just eight years ago, ruling that adults who have oral sex with minors can be punished more harshly than those who have intercourse.