Future of medicine is just a tap away

Michael H. Cohen *is founder of the Michael H. Cohen Law Group, a law firm focused on 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.*

With the advent of wearable health technology, medicine moves into a new phase: one in which everyday health and wellness are becoming even more powerfully integrated into our overall vision of care.

The trend here is a gradual merger of self-generated information about fitness and personal wellness into medicine - with the concomitant recognition that health and healing occupy a spectrum: from diseases that require serious clinical care, to mind-body-spirit wholeness, whose pathways are often mysterious, and reserved to the individual's habits and decisions.

From a regulatory perspective, the last hundred years or so have seen the dichotomization of healthcare into public, technological, biomedical care on one hand, and private self-care on the other. Governments regulate access to therapies by licensing practitioners and setting regulatory hurdles before healthcare products can get to market.

Under the police power, states have required licensure to practice "medicine." The key to regulatory control here is the definition of medicine, typically in terms such as "diagnosis," "treatment," "operation," or "prescription" for any "disease," "illness," or "human affliction." Historically, these broad definitions were intended to consolidate the power of "regular" physicians and allow them to dominate the market for healthcare services; to purge "irregular" competitors from the public eye; and, to sweep non-MD practitioners into the maw of medical board investigators and prosecutors.

This theme runs through the regulatory history. In the landmark case of *Wilk v. AMA*, the 7th U.S. Circuit Court of Appeals found that the American Medical Association, through its "Committee on Quackery," had engaged in a "nationwide conspiracy to eliminate a licensed profession." In *People v. Amber*, 349 N.Y.S. 604, 612 (Sup. Ct. 1973), a New York court reviewed an acupuncturist's claim he is merely determining "the existence of a disharmony brought about by the disequilibrium of Yin and Yang," and held that "every means and method ... to relieve ... infirmity" constitutes the practice of medicine. In *U.S. v. Rutherford*, the 10th U.S. Circuit Court of Appeals held that patients who will "die of cancer regardless," cannot access unapproved cancer drugs. In *U.S. v. Burzynski*, 819 F. 2d 1301 (1987), the 5th U.S. Circuit Court of Appeals dismissed patient testimony that a cancer treatment was lifesaving, and quoted a 1952 case for the proposition that, "[w]hen the subject of investigation is the existence of cancer, the personal testimony of the lay sufferer is entitled to no weight."

Medical paternalism - the ethical position that "doctor knows best"" - ruled patient care and biomedical orthodoxy dominated the regulatory landscape.

In 1992, due in part to the efforts of Congressman Berkley Bedell, who was frustrated that he had to go overseas to obtain an alternative treatment for Lyme disease, Congress created what is now known as the National Center for Complementary and Alternative Medicine, (CAM) to fund research into complementary and alternative

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Criminal
Government loses pair of cases against banking executives
The government's campaign to crack down on U.S. taxpayers who hide money in secret overseas bank accounts has taken back-to-back hits with two separate juries acquitting high-level banking executives in the past several days.

California Supreme Court
State high court hints that company must pay workers for time spent on call
The state Supreme Court appears poised to rule that security guards who are required to be on site must be paid for all their time regardless of whether or not they actually worked.

Health Care & Hospital Law
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With the advent of wearable health technology, medicine moves into a new phase: one in which everyday health and wellness are becoming even more powerfully integrated into our overall vision of care By **Michael H. Cohen**

Litigation
Complex court judges, attorneys to share insight at symposium
Attorneys will have the rare opportunity to hear from more than a dozen complex court judges from across California at a Nov. 12 symposium in Los Angeles sponsored by the L.A. County Bar Association.

Administrative/Regulatory
FCC reinforces all fax ads need opt-out notices
The Federal Communications Commission ruled it had the authority to amend a law mandating companies to tell consumers how to stop receiving unsolicited advertisements via fax

Government
Life sciences company to pay $55 million to settle foreign bribery case
A California-based developer of life science and diagnostic tools will pay $55 million to settle claims its subsidiaries bribed government officials in Russia, Vietnam and Thailand, violating the U.S. Foreign Corrupt Practices Act.

Lawyers watching out for fraud on election day
Lawyers in the state are manning regional call centers set up by the nonprofit Election Protection. Reed Smith is providing facilities in Los Angeles. In San Francisco, Bingham McCutchen, Kirkland & Ellis and DLA Piper are on board.

medicine such as chiropractic, massage therapy, and acupuncture, among others.

CAM has also morphed into "integrative medicine" - integrating evidence-based CAM treatments into conventional care. Techniques such as mindfulness-based stress reduction (MBSR), have emerged out of CAM and entered the mainstream. Practitioners such as chiropractors and acupuncturists have widespread licensure, and many states allow non-licensed CAM practitioners to offer healthcare services to consumers, provided certain disclosure and other requirements are met.

What does all this have to do with wearable health technology?

The integrative medicine movement - which has morphed over the last 20 years from "unconventional" to "holistic" to "alternative" to "complementary and alternative" to "integrative" - represents the synthesis of the best of clinical care and self-care. Clinical care has the advantage of scientific power and carries the risk of being dehumanizing; self-care offers choice, autonomy, and the power of consumer-driven information, at the risk of sacrificing evidence to anecdote.

Enter wearable health technology apps - an unstoppable wave of health technology that will, for the first time in history, move the power historically given to medical doctors by scientific advantage and regulatory domination, back to the individual.

Medicine is moving from physical, to online, to mobile, to wearable (and ingestible), and ultimately to implantable healthcare.

This movement in turn gives federal regulators a significant role on the products side of healthcare. The Food and Drug Administration defines "drugs" and "medical devices" in terms that resonate with the states' regulatory definitions of "medicine." Significantly, if the intended use of the product is to diagnose or cure, mitigate, or treat disease, then the product falls within FDA jurisdiction. Recently, FDA has issued a guidance document on "mobile medical apps:" if the app's intended use is for diagnosis or cure/mitigation/treatment of disease, then the app is regulated as a medical device. FDA determines "intended use" from the claims the promoter makes, based on all the labeling (i.e., including website and other marketing materials) and has enforcement discretion.

If the app is a mobile medical app, then the manufacturer is subject to all the requirements of medical device regulations, including: medical device establishment registration and product listing, FDA labeling rules, quality system regulation, adverse event reporting, acceptance of legal prohibitions on adulteration and misbranding, and submission of a cybersecurity plan. This is leagues more burdensome and expensive than putting a calorie-tracker, for instance, out to market.

FDA's guidance document lays out types of apps that are not considered mobile medical apps (those that provide general information about a disease) versus those that, for instance, transform the mobile platform into a medical device, because they use a built-in feature to diagnose or treat disease. This still leaves considerable ambiguity for the mobile app maker. FDA regulation of medical devices can be more or less burdensome, depending on the classification of the medical device (Class 1, 2 or 3) and relevant regulations, and classification depends in part on risk/safety of the device, and on intended use. This has obvious implications for telemedicine, as many telemedicine companies are using apps for diagnostic purposes, as part of an overall mobile health (m-health) strategy.

Consider a mobile app using a smartphone's built-in camera to upload patient photos, which will then be outsourced diagnostic purposes. If the outsourced reader is not a physician, or is not licensed in the consumer's state, then issues of unlicensed and corporate practice of medicine arise; there are also privacy and security (including, possibly HIPAA) issues; and, the diagnostic function will bring the app into the mobile medical app category. Possibly, the manufacturer might take advantage of medical device data system (MDDS) regulation - a classification category, which involves only the electronic storage, transfer, or display of medical device data, or electronic conversion of medical device data from one format to another format under a preset specification. MDDS is Class 1 and exempt from the more burdensome filing requirement known as a 510(k) submission. However, when the app grows more sophisticated and in an update, itself contains an algorithm upon which patient prescriptions can be based - rather than outsourcing the photo to remotely based diagnosticians - the app may be a Class 2 medical device, and require a 510(k) submission with a showing that the app is substantially equivalent to a predicate device already on the market. Either way, the mobile app will be a mobile medical app, and will not escape FDA medical device regulation.

Telemedicine companies, mobile app developers, and manufacturers and distributors of wearable health technologies, all need a detailed understand of how FDA medical device regulation shapes the way they can market their product. In a thorough FDA

Corporate
General counsel joins health care tech company Castlight
San Francisco-based health care software developer Castlight Health Inc. announced Monday the appointment of its first general counsel and chief compliance officer, who joined months after the company's IPO.

States step in where federal government resists on investor crowdfunding
More than two dozen states have taken up the issue themselves in an effort to stimulate investment activity within their own borders.

Litigation
Tourist rental company sues San Francisco over ordinance
Tourist rental online platform HomeAway Inc. sued the city and county of San Francisco in the Northern District on Monday, claiming constitutional flaws mar its new ordinance regulating short-term rentals.

Corporate
West Coast M&A valuations hit recent record highs
A handful of mega-deals emanating out of California lifted West Coast merger and acquisition valuations to record-breaking levels through the first three quarters of the year, according to a recent report.

Obituaries
Former Santa Barbara district attorney, known for tenacity, dies at 73
Thomas W. Sneddon, the longtime Santa Barbara County district attorney best known for his tenacious style and 2005 prosecution of late pop star Michael Jackson, has died at the age of 73.

Law Practice
Stradling Yocca adds attorneys in Santa Monica
The Newport Beach-based firm is growing its Santa Monica office with the addition of five new attorneys in the past two weeks.

Bankruptcy
Legal tab in Stockton bankruptcy proceedings exceeds $14M
Orrick, Herrington & Sutcliffe LLP's portion of the legal fees, as of May, amounted to roughly $10.5 million for its services preparing for and fighting the city's bankruptcy battle. The total amount billed isn't yet known.

California Supreme Court
State Supreme Court may overturn 8-year-old ruling
Eight years ago, state Supreme Court Justice Marvin Baxter cast the lone dissenting vote in a decision invalidating a sex offender law. Now, he appears to be the driving force in the court's decision to potentially reverse itself.

Mergers & Acquisitions

regulatory review, FDA legal counsel projects the preferred, and likely, regulatory path to market, and advises the client on how to style claims for the product to maximize marketing potential, while minimizing potential regulatory burden.

Like CAM therapies, wearable health technologies also eviscerate the distance between patient and therapy, and move healthcare from the practitioner, to (literally) the consumer's fingertips.

The integration and synthesis of everything we know about health is occurring, not only through exploration of mind-body medicine, but also through exploration of self-data through wearable health technology. We are entering a sea change in integrative health care, in which attorneys and policymakers have an incredible opportunity to guide clients - and the market - into a space in which laws and regulations support innovative paths to healing on all fronts.

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Criminal
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New drug sentencing guidelines took effect this weekend, allowing federal judges to begin weighing prisoner petitions. District courts and attorneys have been readying for this change with new procedures and extra manpower.