Current Enforcement Trends

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Enforcement Trends

- Food and Drug Administration
  - Impact of COVID-19
  - "It has come to our attention" letters and other informal correspondence
  - Warning letters
- Federal Trade Commission
- State Regulators

Telehealth Enforcement Trends Under Title 18 the Food, Drug, and Cosmetic Act And Other Statutes

John Claud
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Consumer Protection Branch

Consumer Protection Branch

- **Main Justice component of approximately 95 prosecutors.**
- **Office in Washington; travels to and works with all 93 USAOs.**
- **Leads DOJ efforts to enforce criminal and civil laws that protect Americans' health, safety, economic security, and identity integrity.**
  - **Titles 18 and 21 Offenses**
  - **Primary DOJ authority over FDCA and FTCA (JM 4-1.313.8-9)**
- **Represents the FTC, FDA and other consumer protection agencies in defensive litigation.**
- **https://www.justice.gov/civil/consumer-protection-branch**

Consumer Protection Branch

Food, Drug, and Consumer Products

- Criminal and Civil Enforcement
  - Pharmaceuticals and Medical Devices
  - Food and Dietary Supplements
  - Compounding Pharmacies
  - Consumer Products
- Justice Manual § 4-8.000 Requirements
- Defense of FDA/CPSC

Opioids

- PIL Task Force
- Criminal and Civil Enforcement
  - Manufacturers
  - Distributors
  - Pharmacies/Prescribers
- CSA Injunctions – 21 U.S.C. § 843(f)
- National Prescription Opiate MDL
- Injection Site Litigation
- Data Analytics/Leads

Complex Consumer Fraud

- Transnational Elder Fraud Strike Force
- Criminal Enforcement
  - Telemarketing Fraud
  - Mass-Mailing Fraud
  - Tech-Support Scams
- Civil Fraud Injunctions – 18 U.S.C. § 1345
- Interagency Coordination
- Data Analytics/Leads

Deceptive Practices/ Identity Integrity

- Unfair/Deceptive Practices
- Privacy/Data Breaches
- Robocalls/Do Not Call Violations
- U.S. Servicemember Fraud

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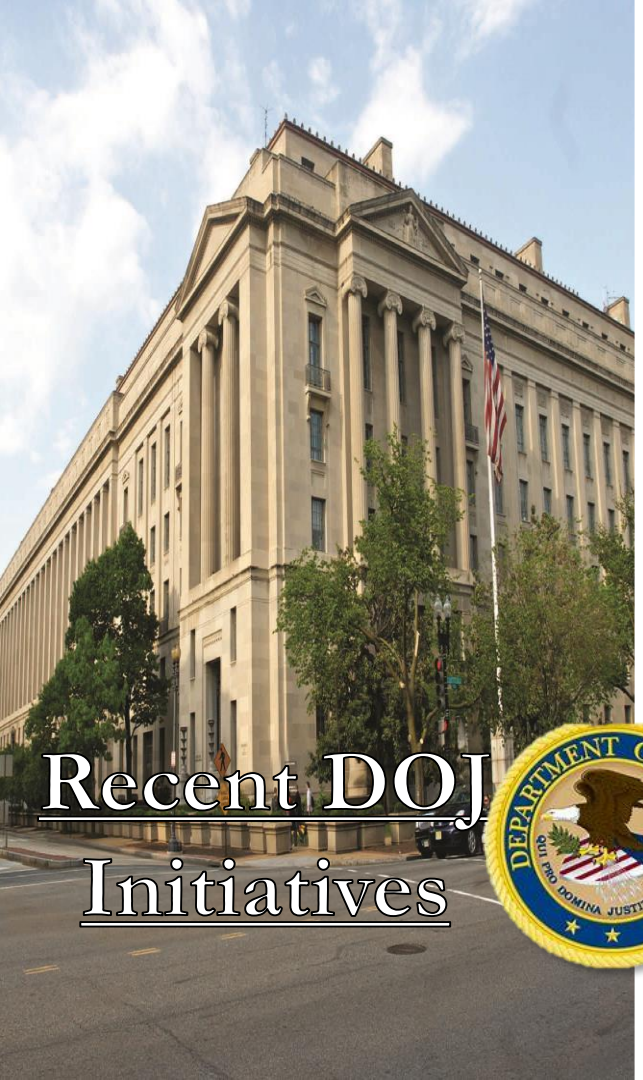
www.justice.gov/civil/consumer-protection-branch

What is "telemedicine fraud?"

Analogue to wire fraud statute:

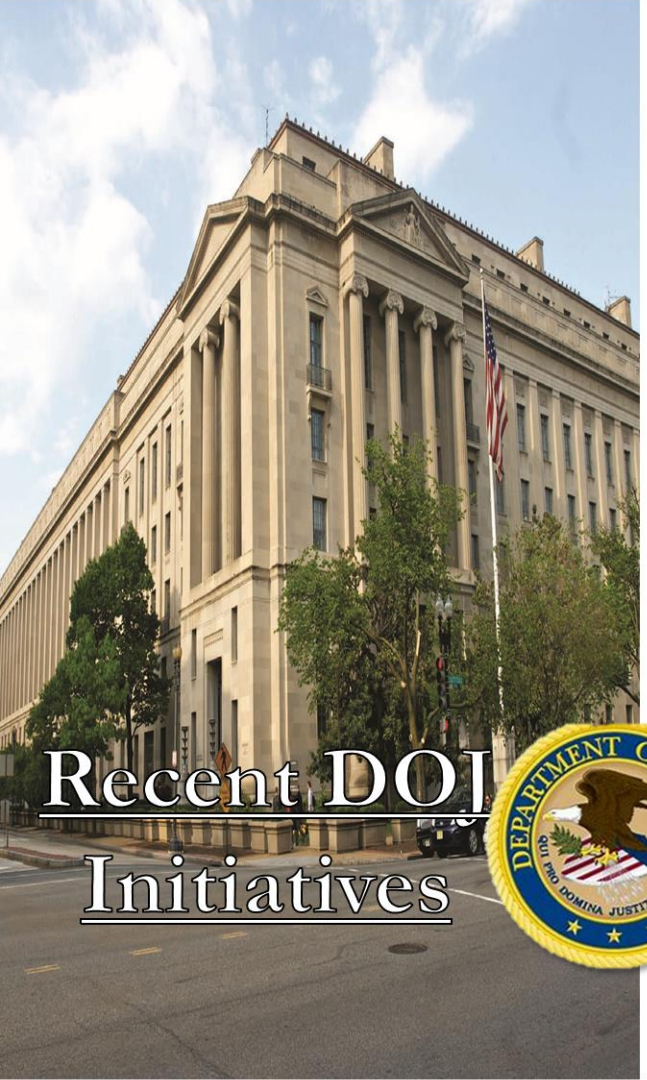
Whoever, having devised or intending to devise **any scheme or artifice to defraud**, or for obtaining money or property by means of false or fraudulent pretenses, representations, or promises, **transmits or causes to be transmitted by means of wire, radio, or television communication in interstate or foreign commerce**, any writings, signs, signals, pictures, or sounds for the purpose of executing such scheme or artifice, shall be fined under this title or imprisoned not more than 20 years, or both.



Recent DOJ Initiatives

Operation Double Helix

- Led by Health Care Fraud Strike Force
- Criminal Division's Fraud Section,
- Fraudulent genetic cancer testing and the use of telemedicine that has resulted in charges against dozens of defendants associated with telemedicine companies and cancer genetic testing laboratories.



Recent DOJ Initiatives

- Uncovered an alleged genetic testing scheme valued at over $1.7 billion in fraudulent Medicare claims.
- Paid illegal kickbacks to telemedicine companies and practitioners in exchange for expensive cancer genetic test referrals for people on Medicare.
- Often, the Medicare patients never received their test results, the results were worthless to their doctors, and the tests were not medically necessary.

DME/Durable Medical Equipment

Telemedicine company executives are alleged to have paid doctors and nurse practitioners to order unnecessary durable medical equipment, genetic and other diagnostic testing, and pain medications, either without any patient interaction at all, or with only a brief telephonic conversation with patients they have never met or seen.

Benscome (S.D.Fl., 2021)

- Licensed medical doctor & site director who served as the primary investigator for clinical trials purportedly conducted at Unlimited Medical Research.
- Admitted that they participated in a scheme to defraud an unnamed pharmaceutical company by fabricating the data and participation of subjects in a clinical trial at Unlimited Medical Research.
- The clinical trial was designed to investigate the safety and efficacy of an asthma medication in children between the ages of four and 11.

Tellus Clinical Research (S.D.Fl., 2021)

- Sub-investigator and assistant study coordinator.
- As part of their plea agreements, defendants admitted that they conspired with others to falsify data in connection with two clinical trials
- Fabricating medical records to make it appear as though subjects were participating in the clinical trials when, in truth, they were not.

Clinical Trial Fraud –

- Control the data
- Know the subcontractors, how they control the data

United States v. Peter Bolos

- **Defendants indicted for using telemarketer to sell prescriptions via cold calls, and then filled through defendant's compounding pharmacies.**
- **No valid doctor/patient relationship – doctors "approved" prescriptions without ever meeting patients.**

An indictment is merely an allegation. The defendant is presumed to be innocent until proven guilty beyond a reasonable doubt in a court of law.

United States v. Peter Bolos

- Telemarketers provided patient information to doctors. No visit or virtual assessment.
- Billed repackaged prescriptions pain creams to private insurers at exorbitant markups.

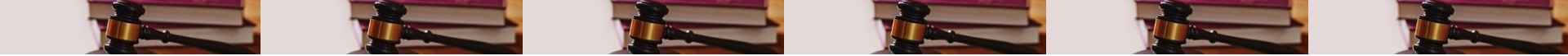
An indictment is merely an allegation. The defendant is presumed to be innocent until proven guilty beyond a reasonable doubt in a court of law.

Data Privacy and Telehealth – Potential Statutory Enforcement Basis

- FTC Act (UDAP)
- False Claims Act
- CFAA
- HIPAA
- FDCA

Possible FDCA Concerns and Triggers

- 21 U.S.C. § 352(f)(1) - Adequate directions for use.
- 21 U.S.C. § 353(b)(1) – dispensing drugs w/o valid prescription



Considerations When Pharma Companies Integrate General Wellness Products into Clinical Trials

- "[T]he healthcare industry — including pharmaceuticals — is primed to drive the next shift in healthcare: decentralization of clinical trials." Tom Moon, "Decentralization Presents A Leap Forward For Clinical Trials," Forbes.com.
- Decentralized clinical trials involve focusing the study on the patient rather than the site. One way this can happen is remote monitoring – monitoring the patient at home instead of, or in addition to, at the site.
- Benefits of remote monitoring can include convenience to the patient, exposure to fewer people during the coronavirus pandemic, and the potential for many more data points than traditionally garnered.

FDLI

Device Regulatory Status of General Wellness Products

- FDA has stated that it does not intend to regulate "low risk general wellness products." "General wellness" includes "'fitness' or 'activity' trackers." *General Wellness: Policy for Low Risk Devices Guidance for Industry and Food and Drug Administration Staff*, 2019.

- Designation as a general wellness product depends on the product's intended use – generally not "related to the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition." *Id.*

- A product that is commonly used for general wellness could become an investigational device if it is used as a remote monitoring tool in a clinical trial.

Challenges When Advising Clients on Use of General Wellness Products in Clinical Trials

- Pharma company employees are not as familiar with device regulatory concerns.
- Remote monitoring device used initially in an exploratory context (e.g. to determine patient willingness to use the device) might evolve into an investigational role.
- If data are shared with investigators, higher risk that data will be used for clinical decision-making purposes.
- Software developed with limited functionality initially, might expand and change device regulatory status.

Risks When Using General Wellness Products in Clinical Trials

- Part 11 compliance issues, even if the product is not a device.
- Reliance on third party manufacturer of product.
- Downstream concerns with usability of data for potential regulatory filings.
- In extreme cases, potential patient harm or regulatory action.