FDA Enforcement during COVID-19

What We Know and What We Can Expect

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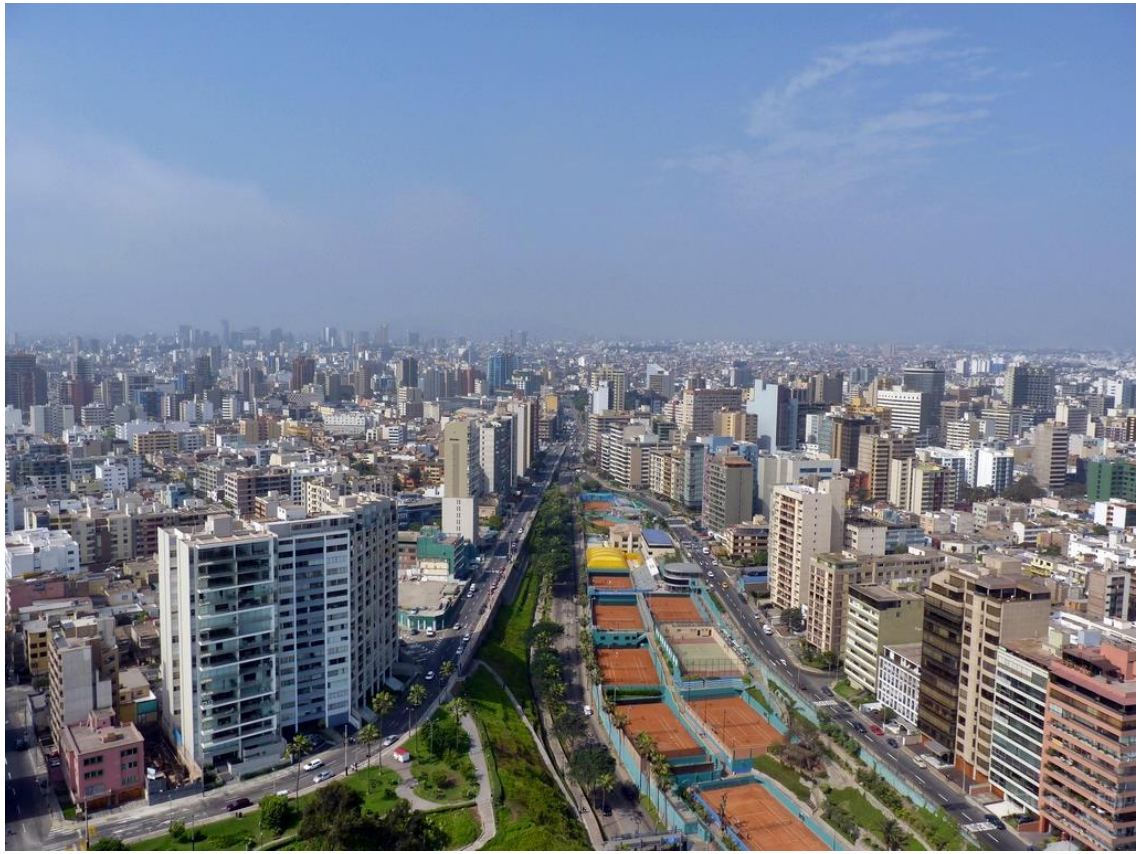
FDA Regulation During Normal Times

- Approval process usually required to sell medical products
- Devices (diagnostic tests, masks)
  - Premarket approval, 510(k)
- Therapeutics (drugs)
  - NDA, ANDA, OTC Monographs



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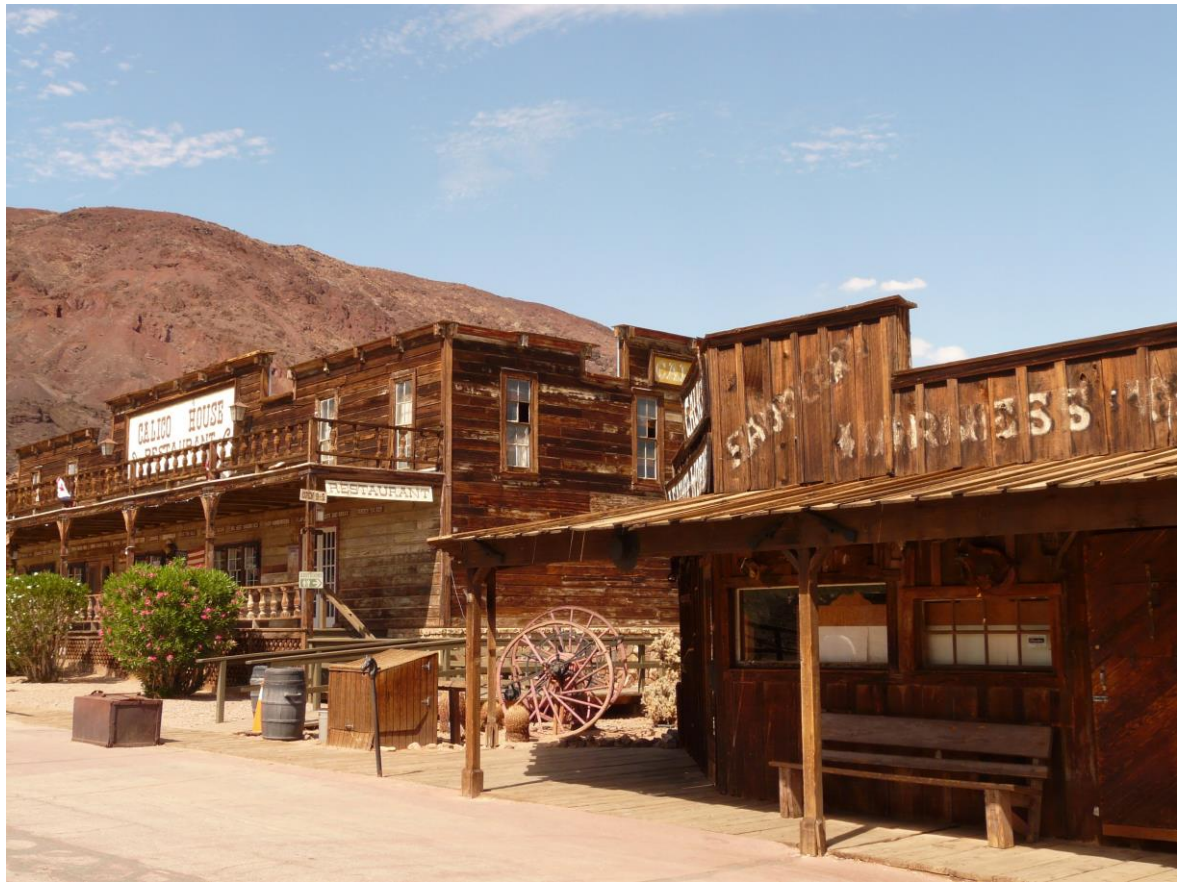
FDA Regulation During COVID Pandemic

- Traditional pathways still available
- FDA uses a system of regulatory authority to allow products to be marketed more quickly
  - Emergency Use Authorizations
  - Enforcement Policies
- FDA is rapidly revising the system as it gathers more information
  - Since March 17, FDA has issued 49 new guidance documents related to COVID-19



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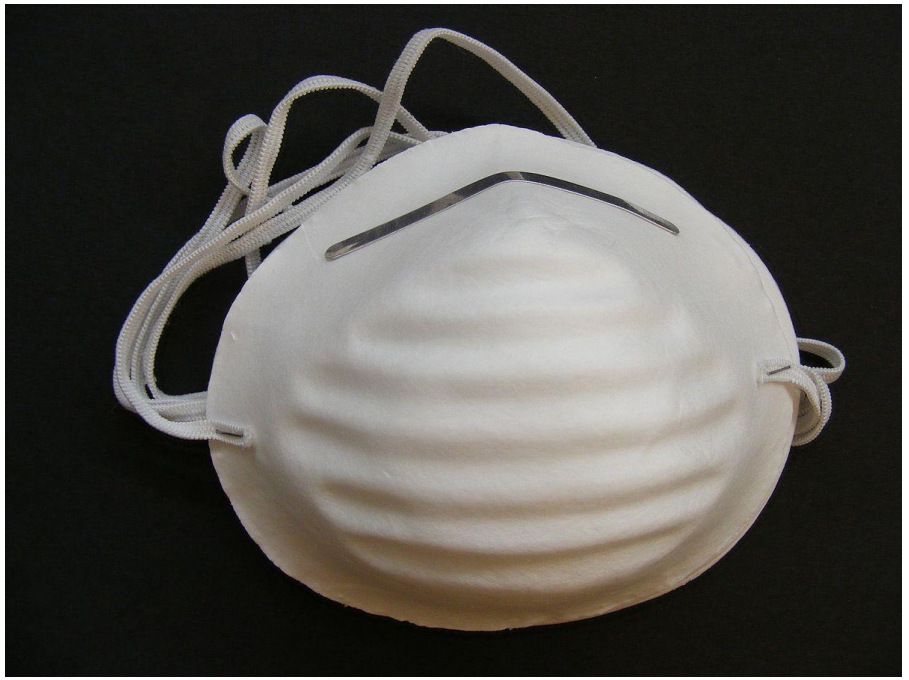
Emergency Use Authorizations

- Granted when FDA determines that the known and potential benefits of authorizing the use of a product outweigh the known and potential risks
- Even if granted, FDA includes many conditions for marketing the product
- General vs. Device-Specific EUAs
  - "Authorized" status
  - "Listed" status

Enforcement Policies

- Guidance + Enforcement Discretion
- Describes conditions under which "FDA does not intend to object" to marketing a product
  - Conditions usually include requirement for language that hedges efficacy of product
- Little to no interaction with FDA



Selling Under EUA vs. Enforcement Policy

	EUA	Enforcement Policy
Legal Status	FDA-authorized	"FDA does not object"
Time to market	After FDA review	Immediate if conditions are met
Quality assurance	Seller submits performance data to FDA	Seller responsible for ensuring product meets performance indications
Marketability after pandemic	Unknown, but likely longer than products sold under Enforcement Policy	Unknown

- FDA Enforcement: Operation "Quack Hack"

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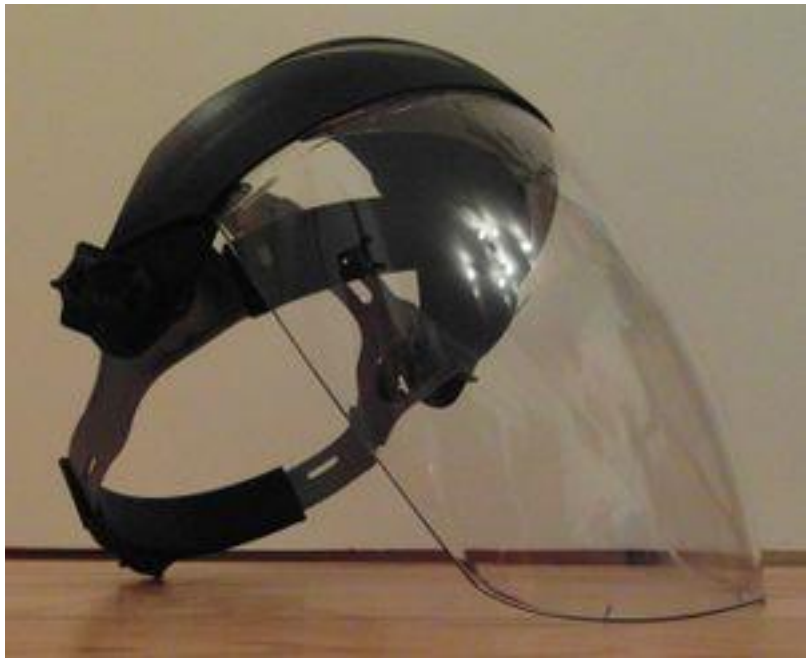
FDA Reissuance of KN 95 EUA

- News coverage about underperforming mask products
  - WSJ: “Low-Quality Masks Infiltrate U.S. Coronavirus Supply”
- EUA is for all respirator products imported from China, but KN 95 is most known
- Changes
  - Removed respirators from authorized list that were authorized under test report criterion
  - Added Chinese National Medical Products Administration as a body that can provide certification basis for EUA
  - Only manufacturers can submit EUA requests (no more importers/sellers)

Other EUAs for Personal Protective Equipment

- Face Shields
  - Do not need to take any action to sell under EUA (other than meeting conditions)
- Imported Respirators
  - Must have marketing authorization in a foreign jurisdiction and prove that to FDA
- Face Masks
  - Also includes conditions for advertising and promotion
  - IMPORTANT: This EUA is for face masks used as source control, not as PPE



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Changes to Enforcement Policy for Respirators

- Covered categories of products
  - Mask/Shield/Respirators not intended for medical purpose
  - Masks for medical purpose not intended for liquid barrier protection
  - Masks for medical purpose intended for liquid barrier protection
  - Face Shields
  - New Category: Respirators listed on CDC site
    - FDA will not object to marketing of respirators identified in CDC recommendations
      - Note: no conditions except “identified”
      - “Because FDA cannot confirm the authenticity of the respirators described above, FDA recommends that importers take appropriate steps to verify the authenticity of the products they import”
- Enforcement Policy also includes guidance on how to submit EUAs for Face Masks and Respirators

FDA and CBP Enforcement at the Ports

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FDA Enforcement at the Ports

- No change to import procedures
- FDA actively using same enforcement tools currently available:
  - Import screening, examinations, and sampling
  - Import alerts
  - Looking to a firm's compliance history and information from foreign governments
- FDA focus at ports likely to increase during suspension of routine foreign inspections
- Shipment release times at ports may be impacted

- **Recommendation: Be careful to follow all administrative/paperwork requirements to avoid delays**

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FDA Enforcement at the Ports

- Continue to use PREDICT to flag higher-risk import shipments
  - Based on confidential algorithm, which could be adjusted to account for any issues of heightened concern during pandemic (this would not be made public)
- Particularly on the lookout for port shopping
  - FDA's existing protocols will be used
  - **Recommendation: If you choose a different port than usual, have justification readily available for review in case it is flagged by FDA**
- Closely monitoring International Mail Facilities
  - FDA remaining vigilant in this area.
  - **Recommendation: Ensure the contents of packages are accurately declared**

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CBP Team for PPE Imports

- CBP is encouraging importation of medical supplies and PPE into the United States, and has set up a dedicated "COVID-19 Cargo Resolution Team" (CCRT) to coordinate inquiries.
- Goal of the CCRT is to coordinate with ports and other government agencies to ensure that legitimate shipments of PPE and other supplies are not unnecessarily delayed.
- CCRT is accepting general inquiries about the import of these items, as well as facilitation requests from other government agencies and private industry.

FEMA Ban on PPE Exports - Overview

- In early April, FEMA issued a rule that prohibited export of "commercial levels" of certain types of PPE from the United States.
- CBP enforces this export ban at the federal border, and has the power to seize shipments for investigation and potential detainment.
- In mid-April, FEMA formalized 10 exemptions to the export ban, summarized on the following slide.

FEMA Ban on PPE Exports - Exemptions

1) Shipments to U.S. Commonwealths and Territories, e.g. Guam, Puerto Rico, *etc.*;
2) Exports of covered materials by non-profit or non-governmental organizations that are solely for donation to foreign charities or governments for free distribution (not sale) at their destination(s);
3) Intracompany transfers of covered materials by U.S. companies from domestic facilities to company-owned or affiliated foreign facilities;
4) Shipments of covered materials that are exported solely for assembly in medical kits and diagnostic testing kits destined for U.S. sale and delivery;
5) Sealed, sterile medical kits where only a portion of the kit is made up of one or more Covered Materials that cannot be easily removed without damaging the kits;
6) Declared diplomatic shipments from foreign embassies and consulates to their home countries, shipped from and consigned to foreign governments;
7) Shipments to overseas U.S. military addresses, foreign service posts (*e.g.* diplomatic post offices), and embassies;
8) In-Transit Merchandise: Shipments in transit through the United States with a foreign shipper and consignee, including shipments temporarily entered into a warehouse or temporarily admitted to a Foreign Trade Zone (FTZ);
9) Shipments for which the final destination is Canada or Mexico; and,
10) Shipments by or on behalf of the U.S. federal Government, including its military.

Cross-Border Supply Chain Issues

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Border Closures by CBP

- As of March 21st, the northern and southern U.S. borders have been closed to non-essential traffic, through at least June 21, 2020.
- "Lawful cross-border trade" not intended to be affected.
  - CBP reports that its operations at land ports are running smoothly.
  - Decreased fee revenues have led to reduced personnel, but this has been counterbalanced with decreased trade flows across the border.
- A U.S. suspension on travel from some EU countries is also in effect, but does not include commercial trade from EU.
- Supply chain issues will be front and center for the next several months.

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Key Takeaways

- Modified regulatory requirements do not mean there are no longer any regulatory requirements.
- Choosing the best marketing pathway depends upon business needs.
- Determining compliance with Enforcement Policy/EUA requirements is highly fact-specific.
- Alternative marketing pathways will not last forever.
- Resources are available to facilitate the importation and, to a lesser extent, exportation of PPE and other medical supplies.
- Keep in mind cross-border logistics and supply chain issues.

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Questions?

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