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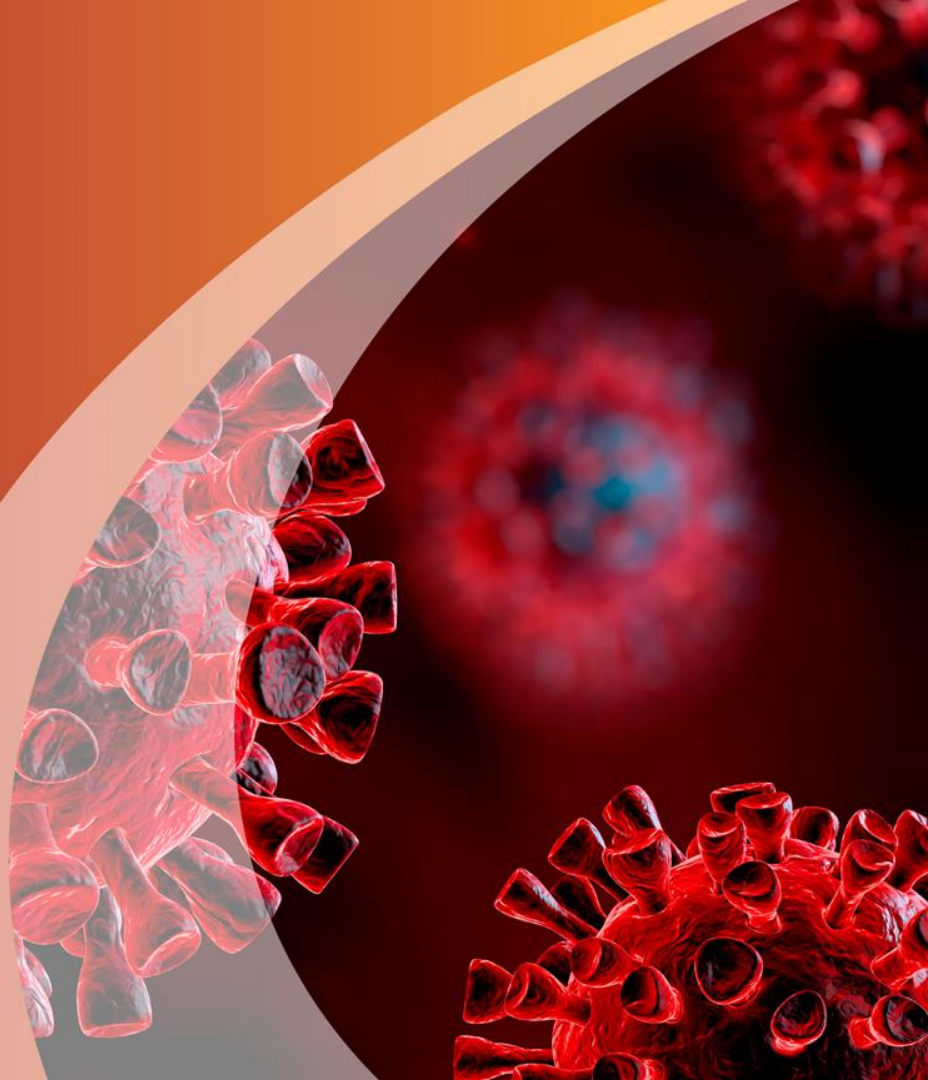
COVID-19 and Product Pivoting: Pitfalls and Opportunities

April 22, 2020



Introduction

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American Industry Declares War on Covid-19. Here's What That Means.

PPE Manufacturers & Suppliers Respond to COVID-19

Similar To WWII, Companies Are Repurposing To Fight The Coronavirus

Here's How Brands Have Pivoted Since The COVID-19 Outbreak

Product Pivoting - Answering the Call

- Corporate America is rising to the occasion in bold and dramatic fashion, entering new product lines to meet pandemic needs
  - hand sanitizers
  - ventilators
  - masks
  - PPE
  - medical devices
  - pharmaceuticals and therapies

Product Pivoting - Opportunities

- Keep the workforce productively engaged
- Do good
- Branding
- Gain

Product Pivoting - Challenges

- Vexing new regulation and regulators
- Unfamiliar territory when it comes to tort risk
- Needing to learn how the government, and government contracts, work

- Brand new risk management and mitigation needs in the worlds of
  - Regulatory
  - Contracting
  - Common Law (tort) Liability

FDA

John Fuson

You're an FDA Regulated Company

Or you're a large-scale purchaser of FDA-regulated equipment.

- COVID-19 has brought newfound awareness of FDA.
- FDA: a science-based public health agency.
- Gatekeeper of drugs, PPE for the health care setting, personal hand sanitizers, sanitizing equipment, ventilators, diagnostic tests, and more.
- The agency has struggled to balance quality control with meeting needs created by desperate shortages of critical equipment.
  - Medical masks, industrial masks, or just ordinary scarves and bandanas?
- "Expand availability": (1) enforcement discretion; (2) emergency use authorizations; and (3) compassionate use.

You're an FDA Regulated Company

Now What?

- Manufacturer
  - Is my product approved?
    - Cleared/Approved?
    - Authorized?
    - Subject to Enforcement Discretion?
  - Is my product properly labeled?
    - What can I say about my product?
  - What must I report to FDA?
    - Serious adverse health consequences
- Sophisticated Purchaser
  - Is this product approved?
    - How much oversight did FDA exercise?
  - What does this product do?
    - What *doesn't* this product do?
  - What should I expect of my FDA-regulated product manufacturer?

Importing Personal Protective Equipment (PPE) and other goods essential for the COVID-19 response

David Stepp

Importing PPE and other Goods for the COVID-19 Response

- **Changes to FDA Requirements**
  - As a result of COVID-19, the FDA has relaxed some of its regulatory requirements to help facilitate the importation of PPE
  - Some entry information for PPE no longer needs to be transmitted to the FDA
  - The FDA has provided guidance and broken down COVID-19 related medical supplies into three categories with relaxed regulatory requirements

- **Category 1: Non-FDA-regulated general purpose personal protective equipment (masks, respirators, gloves, etc.)**
  - These products include PPE for non-healthcare use
  - No longer require information to be transmitted to the FDA

Changes to FDA Requirements

- **Category 2: Products authorized for emergency use under an Emergency Use Authorization (EUA)**
  - EUAs are issued by the FDA in response to an emergency declaration by HHS. These products ordinarily would require FDA approval but have been exempted from that requirement. EUAs are granted for individual products.
    - These products currently include:
      - Diagnostic tests
      - N95 Masks and similar products
      - Ventilators
    - For these items, importers need only transmit an Intended Use Code of 940.000: *Compassionate Use/Emergency Use Device*, and an appropriate FDA product code.
      - FDA is regularly updating this list and a current list can be found on the FDA's website

Changes to FDA Requirements

- **Category 3: Products regulated by the FDA as a device, not authorized by an EUA, but where an enforcement declaration policy has been issued**
  - Need only transmit Intended Use Code 081.006: *Enforcement discretion per final guidance*, and an appropriate FDA product code.
    - This includes supplies such as thermometers, surgical face masks, respirators, ventilators and accessories, disinfectants, and air purifiers
    - This list is regularly being updated by the FDA

    - https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization

FEMA Export Ban

David Stepp

FEMA PPE Export Ban

- On April 10, FEMA issued a temporary rule which prevents five (5) different types of PPE from being exported from the United States.
  - The rule will be in effect from April 10 to August 8 (120 days)
  - The export ban affects certain masks and gloves:
    - N95 Filtering Facepiece Respirators;
    - Other Filtering Facepiece Respirators (e.g., those designated as N99, N100, R95, R99, R100, or P95, P99, P100), including single-use, disposable half-mask respiratory protective devices that cover the user's airway (nose and mouth) and offer protection from particulate materials at an N95 filtration efficiency level per 42 CFR 84.181;
    - Elastomeric, air-purifying respirators and appropriate particulate filters/cartridges;
    - PPE surgical masks, including masks that cover the user's nose and mouth and provide a physical barrier to fluids and particulate materials; and
    - PPE gloves or surgical gloves, including those defined at 21 CFR 880.6250 (exam gloves) and 878.4460 (surgical gloves) and such gloves intended for the same purposes.

FEMA PPE Export Ban

- On April 10, FEMA issued a temporary rule which prevents five (5) different types of PPE from being exported from the United States.
  - Under this temporary rule, before any shipments of such covered materials may leave the United States, CBP will detain the shipment temporarily.
    - FEMA will determine whether to 1) return for domestic use, 2) issue a rated order for, or 3) allow the export of part or all of the shipment. Such determinations will be made within a "reasonable time" of being notified of an intended shipment.
  - There is an exception for U.S. manufacturers with continuous export agreements with customers in other countries:
    - If the agreement has been in place since at least January 1, 2020; and
    - At least 80 percent of such manufacturer's domestic production of covered materials, on a per item basis, was distributed in the United States in the preceding 12 months.

FEMA PPE Export Ban

- On April 10, FEMA issued a temporary rule which prevents five (5) different types of PPE from being exported from the United States.
  - The final rule establishes penalties of a fine of not more than $10,000 or imprisonment for not more than one year, or both, upon conviction, pursuant to 50 U.S.C. § 4513.
  - The final rule contains a clause which allows FEMA to establish additional exemptions determined to be necessary or appropriate to promote the national defense. Such exemptions will be published in the Federal Register.
    - There is currently no formal process for making an exemption request.

FEMA PPE Export Ban

- On April 21, FEMA issued a Notice of Additional Exemptions in the Federal Register, pursuant to 44 C.F.R. 328.102(d)(2). The Notice identified nine (9) additional exemptions. Of particular note are:
  - 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)
  - Intracompany Transfers of Covered Materials by U.S. Companies from Domestic Facilities to Company-owned or Affiliated Foreign Facilities
  - Shipments of Covered Materials that are Exported Solely for Assembly in Medical Kits and Diagnostic Testing Kits Destined for U.S. Sale and Delivery

FEMA PPE Export Ban

- Additional exemptions of note:
  - Sealed, Sterile Medical Kits and Diagnostic Testing 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
  - 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
  - Shipments for Which the Final Destination is Canada or Mexico
- For certain categories of these exempt products, FEMA will require a letter of attestation to be submitted to FEMA via CBP's document imaging system and placed on file with CBP, certifying to FEMA the purpose of the shipment of covered materials.

Types of Products

John Fuson and Chalana Damron

Types of Products

- Hand sanitizer
- Surgical masks
- Ventilators
- Medical gloves
- In Vitro Diagnostic Tests
- Face shields
- Gowns
- Surgical suits
- Sterilization systems
- Remote monitoring devices
- Thermometers
- Infusion pumps
- Masks
- Respirators

Face Masks

- Face Masks NOT Intended to Provide Liquid Protection (not including respirators)
  - FDA will exercise enforcement discretion if masks does not comply with FDA's premarket notification ("510(k)") requirements, registration and listing, the quality system regulation, Unique Device Identification requirements, and certain reporting requirements.
  - Product Labeling must:
    - Describe product as face mask and include a list of body contacting materials
    - Make recommendations that would reduce sufficiently the risk of use (e.g., recommending against use in a clinical setting where infection risk level through inhalation exposure is high); and
    - Instruct that the product is not intended for use for antiviral protection or related uses for infection prevention or reduction and does not include particulate filtration claims

Face Masks

- Masks marketed to the general public for general, non-medical purposes
  - NOT regulated by the FDA
  - FDA will consider factors, such as labeling and promotional claims, intended users and modifications (e.g. anti-microbial agents), to determine whether face masks are intended for medical purposes.
- Limiting Risks – Appropriate Disclaimers
  - This article is intended for general, non-medical, purposes;
  - Not intended for use by health care professionals; and
  - Not intended for use in a health care facility or environment.

Face Masks

- Masks marketed to the general public (including Healthcare Professionals)
  - **EUA (4/18/2020)**:
    - Face masks are authorized under this EUA when they are intended for use by members of the general public, including HCPs in healthcare settings as PPE, to cover their noses and mouths, in accordance with CDC recommendations, to prevent the spread of SARS-CoV-2 during the COVID-19 pandemic.
    - Authorized face masks must meet the following requirements: (1) the product is labeled accurately as a mask, (2) the product is labeled so that it is not intended to provide liquid barriers or be used as a surgical mask, (3) not labeled to represent/imply it is intended for antimicrobial/antiviral protection or particulate filtration

Diagnostic Tests

What Is the Current State of Play for Testing?

- What are the types of tests? What do they tell us? What are the risks? What are the restrictions?
- Regulatory framework: FDA Emergency Use Authorization (EUA)
- Types of tests:
  - Polymerase Chain Reaction (PCR) Testing (detects the presence of active virus)
  - Serology Testing (detects immune system response – antibodies)
- New This Week: First At-Home Tests Authorized – more on the way?

PREP Act Immunity

Mariam Sarwar

PREP Act Liability Immunity

- The PREP Act provides immunity against claims of loss related to medical countermeasures against COVID-19
- Policy: To encourage the design, manufacture, testing, distribution and use of much-needed products
- Boxes to be checked (ALL conditions must be satisfied for immunity to attach):
  - ❑ The Product must be a “Covered Countermeasure”;
  - ❑ The Individual/Entity seeking immunity must be a “Covered Person”;
  - ❑ Liability immunity is only in effect with respect to “Recommended Activities”; AND
  - ❑ The Recommended Activities must be in relation to governmental authorization

Covered Countermeasures

- Most Covered Countermeasures will fall within the category of "Qualified Pandemic or Epidemic Products." These are products that:
  1. Are used for COVID-19, and
  2. Must be:
     (a) approved, licensed, or cleared by FDA;
     (b) authorized under an Emergency Use Authorization (EUA);
     (c) described in Emergency Use Instructions (EUI); or
     (d) used under either an Investigational New Drug (IND) application or an Investigational Device Exemption (IDE), as defined in the Food, Drug, and Cosmetic Act
- Per a recent amendment to the PREP Act, NIOSH-approved respiratory protective devices are now independently considered "Covered Countermeasures"

Covered Persons

- Covered Persons include:
  - the United States
  - Manufacturers
  - Distributors
  - State or Local Government Countermeasure Program Planners
  - “Qualified Persons”
    - Those designated (a) by a public agency, or (b) in an EUA or EUI, to prescribe, administer, deliver, distribute, or dispense Covered Countermeasures

Recommended Activities and Authorization

- Immunity is only in effect for claims related to the development, manufacture, testing, distribution, administration, and use of a Covered Countermeasure (the "Recommended Activities")
- The "Recommended Activities" must relate to:

  (a) Present or future federal contracts, cooperative agreements, grants, other transactions, interagency agreements, memoranda of understanding, or other federal agreements; or

  (b) Activities authorized in accordance with the public health and medical response of the Authority Having Jurisdiction to prescribe, administer, deliver, distribute or dispense the Covered Countermeasures following a Declaration of an emergency.

Interpretation and Limitations

- Conditions are interpreted broadly
- PREP Act immunity, while expansive, does not extend to:
  - Acts of "willful misconduct"
  - Federal enforcement actions, whether civil, criminal, or administrative
  - Suit and liability for claims under federal law for equitable relief
- Immunity generally only runs through October 1, 2024
  - An additional 12 months beyond this date has been granted for Covered Persons to make appropriate arrangements for the disposition of Covered Countermeasures

Defense Production Act Immunity

- Defense Production Act of 1950 ("DPA") and implementing regulations (Priorities and Allocation Systems – Defense, HHS, etc.)
  - Require contractors to give preferential treatment to government contracts "necessary or appropriate to promote the national defense" ("Priority Rating")
  - Require persons to pivot the use of materials, services, and facilities to manufacture or distribute products for national defense ("Allocation")
- Immunity from contractual claims under the DPA
  - "No person shall be held liable for damages or penalties for any act or failure to act resulting directly or indirectly from compliance a rule, regulation, or order issued pursuant to [the DPA], notwithstanding that any such rule, regulation, or order shall thereafter be declared by judicial or other competent authority to be invalid ."
  - Unclear whether available for tort claims

Contracting

Thinking About Liability

Jonathan Baker and Stephanie Crawford

Purchasing IP, Parts, and Supplies

- Intellectual Property
  - Patents, licenses
  - Government authorization and consent provision may allow IP infringement
    - But patent indemnity clause may also require you to pay for that infringement
- With Suppliers and IP Owners
  - Allocate regulatory responsibilities
  - Include specific references to PREP Act applicability to the arrangement and product
  - If applicable, flow down DPA rating and other language required by DPA regulations

Government Sales

- State v. Federal
  - Some states have additional liability/immunity protections similar to PREP
- Include PREP references
  - DPA, if applicable
- Between prime and subcontractor
  - Liability
  - Indemnification
  - Disposition of the product
- Force majeure/Excusable delay in a pandemic situation
- P.L. 85-804 Indemnification
  - Permits the government to contractually indemnify prime and subcontractors against a broad array of claims, to the extent such claims relate to risks defined in the contract as "unusually hazardous or nuclear" and are not compensated by insurance or otherwise

Private Sales

- Include PREP references
- Between prime and subcontractor
  - Liability
  - Indemnification
  - Disposition of the product
- Force majeure/Excusable delay in a pandemic situation

Donation Contracts

- Federal Government/State Governments
  - May need to include language identifying the agreement as a no-cost contract
    - Specifically disclaiming any right to seek payment now or in the future
- Include PREP references
- Liability waiver and indemnification if possible
- No fixed obligations
- At-will termination

Looking Towards the Future

Scott Winkelman

Peering Around the Corner

- Pivots breed more pivoting
- Pivots end
- Things go somewhat wrong
- Law and regulation lag – then evolve to become aligned
- Best practices emerge

Questions?

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