# Navigating the Intersection Between Litigation and Regulatory Issues

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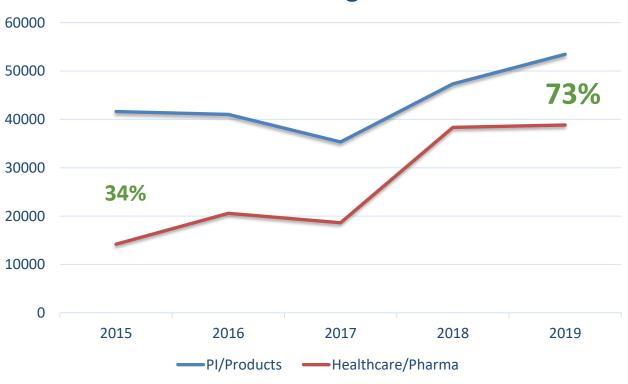
Principal, Exponent, Inc.

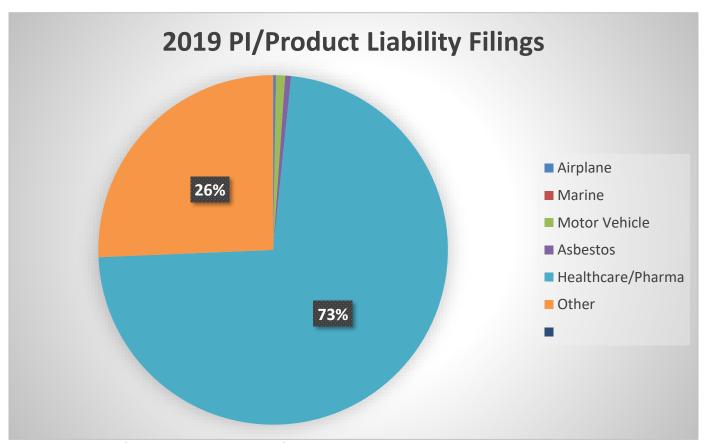
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### **Federal Court Filings 2015-2019**

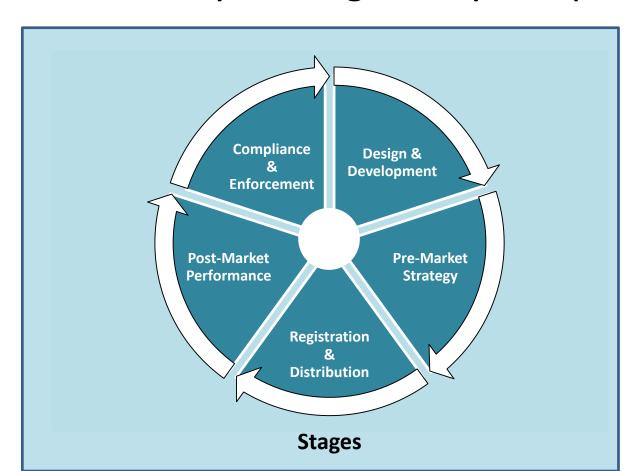




The only category with a greater number of filings than Healthcare/Pharma ...

Statutory Civil Rights (43,223)

## Total Product Lifecycle: Regulatory Perspective



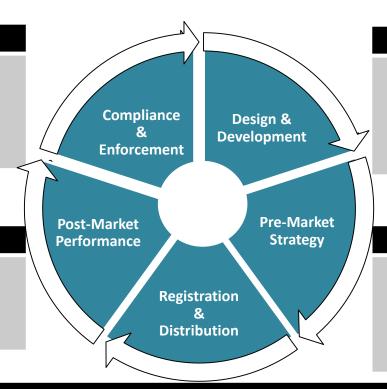
## Total Product Lifecycle: Regulatory Considerations

#### **VIGILANCE**

Complaint Capture
Adverse Event Reporting
CAPA
Audit

#### **POST-MARKET PHASE**

Product Change Control
User Training



#### PRE-MARKET PHASE

Product Testing
Design V&V
Risk Management
Labeling/IFU

#### **MANUFACTURING**

Sourcing
Production
Qualification & Validation

#### **REGISTRATION PHASE**

Regulatory Submission
Regulatory Review/Interrogation of Content

## Total Product Lifecycle: Common Potential Allegations

#### **VIGILANCE**

Failure to properly investigate complaints

Failure to report adverse events

Deficient CAPA System

Failure to Warn/Recall

#### **POST-MARKET PHASE**

Post-Market Changes lacked adequate testing Inadequate user training Unanticipated use-cases



#### PRE-MARKET PHASE

Product was not adequately tested
Improperly designed product
Unanticipated Risk
Failure to provide adequate
warnings

Failure to provide adequate IFU

#### **MANUFACTURING**

Impure components not adequately tested

Product manufactured with defects
Insufficient Process controls –
product out of spec

#### **REGISTRATION PHASE**

FDA doesn't test the product

FDA didn't inspect

## Questions?