The remedies matrix: a framework for assessing remedies

Applied Example: Federal Food Drug and Cosmetic Act (FD&C)

What are the highest-level policy goals of the regime?

Policy goals

=> To reorganize and provide regulatory authority to the nascent Food and Drug Administration (FDA) to oversee the safety of food, drugs, medical devices, and cosmetics.

Deterrence: How does the regime seek to deter bad behavior? Options may include direct punishment (fines), redress of harms (compensation), denial of benefits (disgorgement of profits or other benefits), and cost imposition (e.g., a tax or fee).

Direct punishment, such as fines paid to the government

=> Direct punishment can take the form of debarments, civil monetary penalties, injunctions, and criminal penalties. Debarment prohibit corporations or individuals from participating in certain FDA-regulated activities, civil monetary penalties are fines paid to the government, injunctions can be a prohibition of a certain action such as distributing a product or a command to take a certain action, and criminal penalties can be fines that are paid to the government or prison sentences for those found liable of violations.

Redress remedies to individuals (which may include restitution or other money damages)

=> No remedies are available to individuals nor are they able to bring litigation for violations of the FD&C Act. All remedies are sought and received by the Federal Government

Denial of benefits (such as disgorgement of profits or data deletion)

=> The FD&C Act does not explicitly grant the FDA the power to seek restitution or disgorgement of profits. Nonetheless, they have successfully been sought in criminal enforcement of the FD&C Act but the legality of this power is contested and ultimately unclear.

Cost imposition (including taxes or fees)

=> Under the FD&C Act there is no systematic and intentional cost imposition. However, over the years new laws such as the Prescription Drug User Fee Act have been passed that require manufacturers to pay a fee to gain premarket approval for drugs, medical devices, and certain additives

Does the regime include a mechanism to hold the bad actors' assets at risk?

=> The FDA can issue import alerts to automatically detain certain products from entry into the United States or recommend the U.S. Attorney to pursue a seizure for alleged violations to prevent it from reaching consumers. These both can be contested by the owner or consignee once the product has been detained.

Does the regime contemplate the problem of over-deterrence?

=> There are certain caps on maximum damages per violation for civil monetary penalties and criminal penalties depending on the prohibited act but as these are for individual violations this amount can balloon massively. Generally overdeterrence is addressed by the fact that it is extremely

rare for criminal penalties to be pursued and the FDA tends to allow violators to voluntarily regain compliance before they seek heavy penalties.

Is there a market for noncompliance?
=> Noncompliance with the FD&C Act is not uncommon whether intentional or unintentional. In FY 2020 the most common violations of the Act as reported by the FDA were failure to develop a foreign supplier verification program, inadequate hazard analysis, inadequate pest control, inadequate manufacturing controls, personnel issues, and sanitation issues

Are attorney fees available to successful plaintiffs?
=> Yes, attorney fees are recoverable in the name of the United States if criminal penalties are pursued but the FDA does not have independent litigation authority and must coordinate with the Department of Justice if they seek judicial relief.

How does the regime seek to compel good behavior (carrots or sticks)?
Preapprovals (permits, licenses)
=> Premarket approval from the FDA is required for drugs, medical devices, and certain additives

Injunctive relief
=> Before pursuing an injunction in court a consent decree can be negotiated with violators. These typically require an independent audit and FDA approval with listed regulations to list the injunction although certain products can be exempted in negotiated consent decree such as medically necessary ones.

Safe harbors
=> There are multiple safe harbors from liability for violations of the FD&C Act. The Impossibility Defense allows a violator to avoid a penalty if they prove that they showed extraordinary care and could not have prevented a violation of the Act. The “guaranty clause” provides a safe harbor from liability for those who introduce a product into commerce in "good faith" with a guaranty that it did not violate the Act. 35 U.S.C. § 271(e) also provides a safe harbor from patent violations enforced by the FDA if the drug or medical device development is related to the FDA approval process.

Role of Gatekeepers and Third Parties
Does the ecosystem for the sector/practice include gatekeepers (e.g., third party service providers) who regulate conduct?
=> Accreditation bodies can apply for FDA approval which if granted allows them to accredit third party auditors. These third parties can perform consultative or regulatory audits to determine eligibility for certification and ensure compliance with food safety standards. These reports are then submitted to the FDA.

How does the regime address third parties who are involved in the underlying unwanted behavior?
=> The FDA can revoke recognition of accreditation bodies that it has reason to believe is not adequately performing its listed duties.

Other Issues
How does the regime address the problem of guile?

=> Companies that are regulated by the FD&C Act can be investigated by the FDA at any time and third party monitors also help ensure compliance with the act. Import alerts allow articles that are suspected of violating the Act to be held until they are investigated. Consumer complaints can also reveal violations of the Act that the FDA may have missed.

How does the regime address collective wrongs (small injuries to many people)?
=> Monetary fines are handled on a per violation basis allowing a small injury to snowball in cost if done to many people.

How does the regime address power differentials among victims and wrongdoers?
=> Since private parties have no standing to enforce the FD&C Act they must submit their complaints to the FDA or other relevant body who will then undertake enforcement actions. This prevents power differentials from emerging as wrongdoers must engage with the federal government not individual consumers when they violate the act.

How does the regime respond to technological change?
=> The FDA has an “Emerging Technology Team” which works with industry groups to help ensure approval of articles regulated under the FD&C Act can be done in a timely manner. This helps the FDA have a robust understanding of new technological development and its place in regulations. The safe harbor 35 U.S.C. § 271(e) also helps meet this goal by protecting industry from patent violations when they are developing something for FDA approval helping prevent other companies from stymieing technological advancement

Regulatory Structures

Is the regime complemented by an agency and what are that agency’s powers?
=> The FDA is the primary enforcement arm of the FD&C Act through which it has investigative powers to execute search and arrest warrants and gather evidence around violations of the Act. It does not have independent litigation authority so it requires the Department of Justice to pursue judicial relief. There is also overlap with other federal agencies such as the CDC and USDA along with state governments who can all be given authority to enforce parts of the act.

Monitoring or investigation?
=> Investigation

Overall Assessment of Efficacy

Does the regime achieve desired policy outcomes?
=> Overall the FD&C Act and its regulators are generally successful in their policy goals of ensuring the safety of Food, Drugs, Cosmetics, and Medical Devices in the United States. Compliance with the FD&C Act is relatively easy and most companies work with third parties to ensure they are not violating the Act. The Act is absolutely vital for consumer protection especially compared to the period before it was passed. Further, violators of the act regularly face extremely large fines, especially when their actions lead to risks for consumers. There are concerns that the transition from a fully taxpayer funded FDA to a system where over half of its funding comes from the industry groups applying for FDA approval may lead to conflicts of interests but this does not seem to have significantly decreased consumer protections in the United States.