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PILLS

Big Pharma, the FDA, and Problem Medicine

Summary Fact Sheet

People expect their pills and medicines to be safe. CJ&D's new study, *PILLS; Big Pharma, the FDA, and Problem Medicine,* shows two ways they may not be: 1) manufacturing problems, and 2) the generic drug industry's inability to ensure drug safety.

While everyday Americans have been very good to Big Pharma, helping lift Big Pharma's global value to more than $1 trillion, Big Pharma has not been good to them. Despite its excessive wealth, the drug industry has maintained a cost-cutting business model that has created situations where many drugs are of uncertain quality and potentially hazardous.

Manufacturing

- Manufacturing of pills and medicines often takes place in foreign nations where companies have moved production to make drugs "on the cheap." Those factories, as well as some U.S. plants, can be plagued with quality control problems. These include cross-contamination in the manufacturing process, serious supply chain safety issues, and the inability of the FDA to perform adequate inspections both here and abroad.

- It is the FDA's job to inspect both domestic and foreign facilities but the agency has not performed particularly well, especially overseas where the agency sometimes gives weeks of advance notice before showing up. This allows foreign manufacturers to hide bad conditions, fabricate or shred data, and use other means to conceal safety problems before inspectors arrive.

- During COVID, the number of FDA inspections dropped precipitously and there is now a serious backlog, particularly abroad.

- Among the recent medicine manufacturing safety problems the FDA has been able to catch: quality issues with Eli Lilly's COVID-19 antibody therapy bamlanivimab; drug cross-contamination at Mylan facilities both here and overseas; and dirt, mold, and bacteria at a Teva plant, which forced destruction of millions of vials of medicines, including cancer drugs.

- Legal recourse for injured patients is complicated. State tort restrictions can limit patients' rights as well as the accountability of negligent U.S. drug manufacturers. But

foreign manufacturers, which operate beyond the reach of U.S. tort law altogether, may be entirely off the hook for wrongdoing.

Generic Drugs

- When it comes to generic drugs, which represent 90 percent of all pills we ingest, safety concerns are particularly worrisome. Though they cost much less than brand-name drugs, no one saves money if a generic drug is dangerous and they are medically harmed as a result.

- Generic drugs are cheaper because generic drug companies spend a fraction of what it costs to put brand-name drugs on the market. In addition to manufacturing issues, the design and label of these drugs raise important safety concerns.

- Generic companies do not go through the expensive clinical trial process that brand-name drug companies must undergo. All a generic drugmaker must show is that a generic drug is "bioequivalent" to an approved drug. But that is not so simple.

- When the drug's patent on the brand-name drug expires, the generic drug manufacturer gets access to the ingredients but the patent does not explain how the drug is made or put together. The companies must figure this out in a "reverse engineering" process. The FDA does not independently test such drugs before allowing them on the market, relying primarily on the company's word before approving them for sale.

- "Bioequivalent" does not mean identical. Generic drugs may contain lower quality "inactive" ingredients, which can affect how drugs are absorbed, and even different concentrations of "active" ingredients. Companies don't have to prove that patients respond to the generic drug in the same way they respond to the brand name — and many patients have been horribly hurt.

- Generic drug companies are only responsible for ensuring that their warning labels are identical to the brand-name labels and may not independently modify their warning labels on medicines, even if the manufacturer knows that label to be inaccurate and out-of-date.

- Because generic drug companies cannot change a drug's label, the U.S. Supreme Court has decided they are immune from liability for harm caused by an unsafe label. Because the same immunity does not extend to brand-name drug companies, the result has been a two-tiered system of justice in America, as described by Justice Sonia Sotomayor: "A drug consumer's right to compensation for inadequate warnings now turns on the happenstance of whether her pharmacist filled her prescription with a brand-name drug or a generic."

- Until Congress or FDA regulations change what the U.S. Supreme Court has done, the vast majority of those prescribed drugs in this country have no access to the courts if they are harmed.