In a new White Paper released today, America’s Unaccountable Generic Drug Industry How Legal Immunity Could Be Making You Sick, the national consumer group, Center for Justice & Democracy at New York Law School, says that despite what is commonly believed, generic drugs often do not match their brand name counterparts and patients who take them can suffer health problems as a result. What’s more, says CJ&D, current federal regulations require that generic drugs maintain identical labels to their brand name counterparts even if a generic drug company knows that label to be inaccurate or out-of-date. The Food and Drug Administration, recognizing this rule to be unsafe, is currently proposing to place new responsibilities on generic companies to immediately update product labels to reflect new safety information.

Generic drugs account for over 80 percent of drugs prescribed today. Center for Justice & Democracy Associate Director and author of the report, Jocelyn Bogdan, said, “We tend to take for granted the safety of generic drugs. Yet a variety of safety problems may occur as a result of a generic drug’s design, label or manufacturing process.” For example, says Bogdan, to keep costs down, generic drugs may be more likely manufactured overseas, in countries like India and China, where the FDA rarely inspects factories or the supply chain. Says Bogdan, “History shows that generic drugs or ingredients can be manufactured in dilapidated, dirty factories, about which the FDA may have nothing because of how infrequently it inspects those factories.”

“Moreover,” says Center for Justice & Democracy Executive Director, Joanne Doroshow, “thanks to recent U.S. Supreme Court decisions, if someone is harmed or killed by a generic drug due to the drug’s inadequate labeling or defective design, the company cannot be held accountable in court; the injured patient has no recourse. However, if the patient took a more expensive brand-name version of the drug, their rights are preserved. Whether or not a patient has legal rights should not depend on whether they have been prescribed a brand-name or generic drug, since consumers typically have no choice as to which version they get. Fortunately, the FDA has now taken steps to modify its regulation, so at least the generic drug industry is fully accountable for the safety of its drug labeling.”

A copy of the full White Paper can be found here: