(from the novel and new to the more commodity) but this map will suffice for our purposes.

To make a profit on the drug then there are costs in making it and hopefully revenue from selling it. Our drug therefore needs consumers. Hence we have a bidirectional flow of capital with consumers i.e. the physical drug is exchanged for monetary $. Now, those consumers also want the drug not to kill them and hence they need standards that ensure (as much as it is possible) that the drug is safe. Those standards add to the cost of the drug i.e. certification to a standard doesn't come for free. Let us assume that if our industry could get away without standards, they probably would as such costs reduce profits which the industry needs in order to pay the return to shareholders. Fortunately for those consumers, someone else needs them. That someone is the Government and what it needs are voters. These voters just happen to be also consumers. Hence in order to gain its voters the Government has a need for regulators who in turn create and police the standards that satisfy the needs of the consumers. Naturally, standards without enforcement is worthless and hence the regulators use audits which in turn use legal enforcement against the drug itself. This gives the industry two costs. The first cost is that of implementing the standard which is usually a bidirectional capital flow of investment in standards for a certification that the drug meets the standard. The second cost is the cost of legal enforcement i.e. a failure to meet the standard which can take many forms from court cases to product recall to enforced action.