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System Dynamics Modeling Based Analysis to Combat Counterfeit Drugs Supply Chain in India

Dr. Sanjay Bhushan
Assistant Professor
Department of Management, Faculty of Social Sciences
Dayalbagh Educational Institute, Dayalbagh, Agra (U.P.)
bhushan.sanjay@dei.ac.in, *bhushan.sanjay@rediffmail.com*

Prof. Devanath Tirupati
Chairperson
Supply Chain Management Centre
Indian Institute of Management, Bangalore (Karnataka)
devanath@iimb.ernet.in

Dr. D. N. Suresh
C.O.O., Supply Chain Management Centre
Indian Institute of Management, Bangalore
sureshdn@iimb.ernet.in

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Abstract

The Counterfeit Drugs Supply Chain dynamics seem to follow a counterintuitive pattern. Despite it being targeted by law enforcement policies globally, it has been going on increasing rampantly. This paper proposes and investigates a dynamic hypothesis based on Systems approach questioning the very way in which the supplies of counterfeit drugs have been regulated. Using the modeling and simulation framework of System Dynamics, a holistic influence model has been propounded which highlights the mutual interplay of influencing factors in major sub-sectors having circular causality under the Counterfeit Drugs supply chain ecosystem. With the support of empirical facts and data, long-term impacts of various decision scenarios have been simulated to assess alternative policy for giving a holistic response to dismantle Counterfeit Drugs (CFD) markets in India. The goal of this research is to identify the key policy intervention points that are critical for this purpose. It was also intended to assess the cascading effect that these interventionist decisions create over the entire chain. System dynamics modeling is considered as suitable approach to investigate these key parameters impact. The motivation behind looking at counterfeiting in Indian pharmaceutical industry from a system dynamics point of view is that all the sub-sectors or stakeholders along with their impact over the central incidence of counterfeiting are included in the ecosystem modeling.

Key Words: Counterfeit Drugs Supply chain, System Dynamics Modeling and Simulation, Scenario analysis.

Section-I

Introduction:

The World Health Organization (WHO) estimates the counterfeit drugs market to account for more than 10 percent of the global medicines market. In developing countries, this estimate is as high as 25 percent of the total amount of medicines consumed.

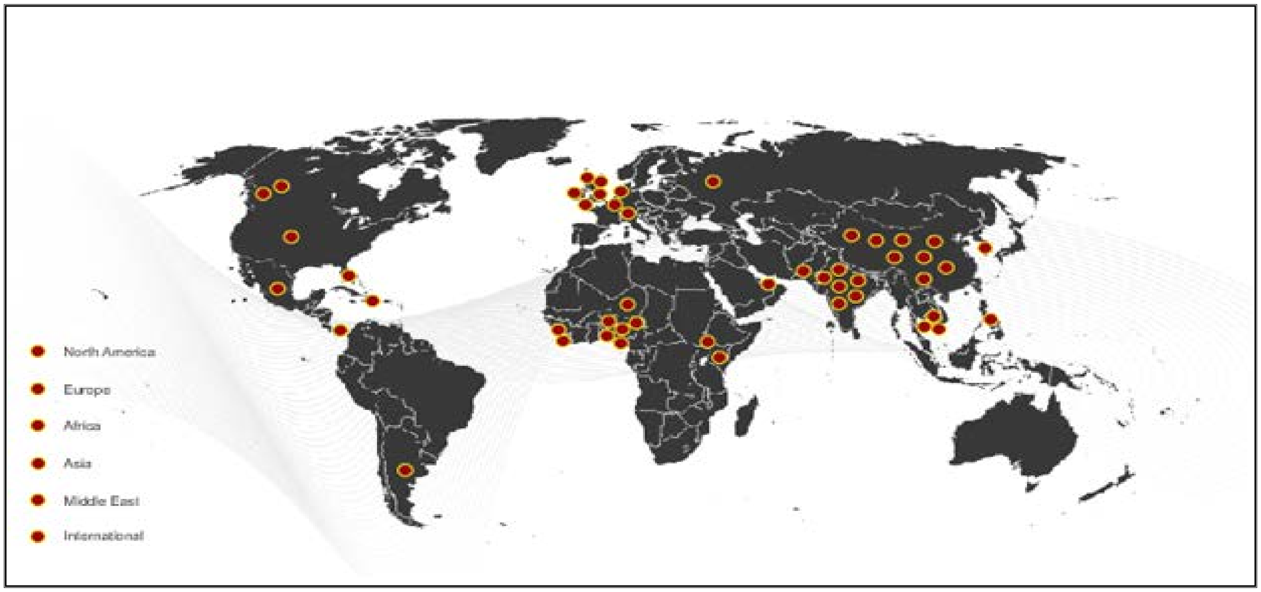


Fig 1: Global Distribution of Counterfeit Drugs Markets

This counterfeit drugs supply chain is a part of the overall industry of counterfeit and pirated goods which a OECD 2008 study concluded to account for up to USD 250 billion in 2007 (see figure 2) and estimated to have increased from 1.85% in 2000 to 1.95% in 2007.

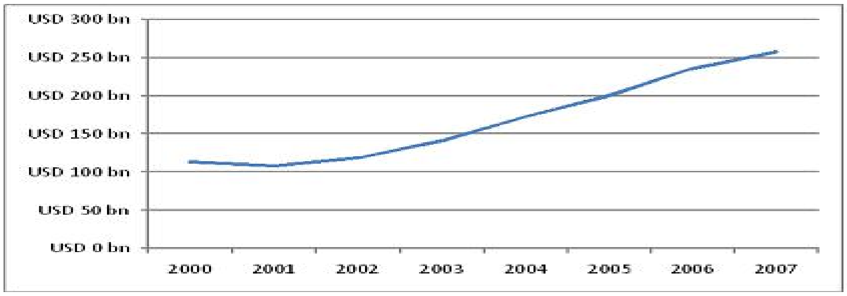


Figure 2: Evolution of trade in counterfeit and pirated products (upper limit)

Counterfeit drugs can include lifestyle drugs, life-saving drugs, patents/generic drugs and even medical devices. Some generally marketed counterfeit pharmaceuticals include medicines used for treating cancer, HIV, malaria, osteoporosis, diabetes, hypertension, cholesterol, cardiovascular disease, obesity, infectious diseases, Alzheimer's disease, prostate disease, erectile dysfunction, asthma and fungal infections; antibiotics, anti-psychotic products, steroids, anti-inflammatory tablets, pain killers, cough medicines, hormones, and vitamins; treatments for hair and weight loss. Counterfeit drugs are fraudulently manufactured, and also include cases where drug identity or its source is misrepresented, to wrongly influence the judgment of patients and healthcare professionals. Counterfeit drugs can be introduced at any of the following stages of the Healthcare Supply chain:

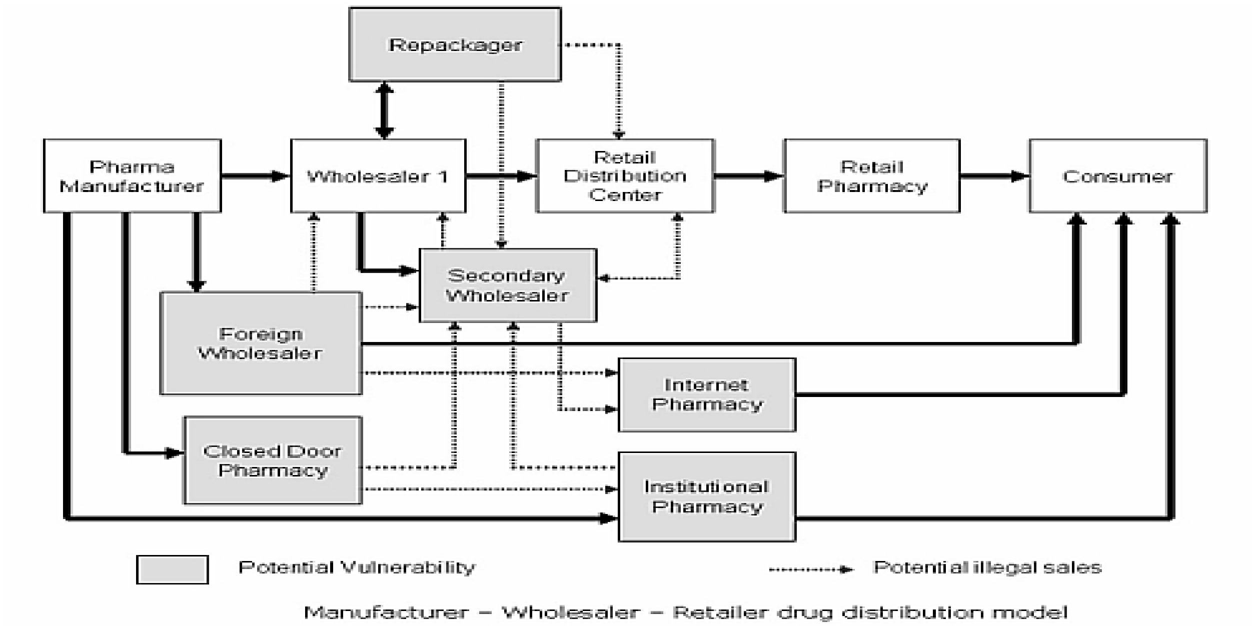


Figure 3: Network Flow Diagram of Pharmaceutical Supply Chain

Any attempt to contain counterfeit supplies must commit to minimizing opportunities for counterfeiters and diverters to infiltrate the above projected soft-entry points of a nation's drug supply chain. In addition to the soft entry points highlighted above, there is the issue of diverted drugs, where drugs meant for a specific purpose or a market are diverted to other market(s) for monetary benefits.

As a result of new age of outsourcing and globalization, the supply chain—from raw material to finished product—has become more complex involving re-packager and distributors in a variety of locations. Like any chain, the drug supply chain is only as strong as its weakest link, and the proliferation of additional handlers, suppliers, and middlemen creates new entry points through which such drugs can infiltrate the market and social supply. According to a study conducted by IBM (Global Chief Supply Chain Officer Study 2012), the responses of the supply chain executives from the Life Sciences industry (see sidebar, Survey sample) are nearer to the global response indicating five primary challenges of Pharmaceutical supply chain: visibility, risk, cost containment, customer demands and globalization.

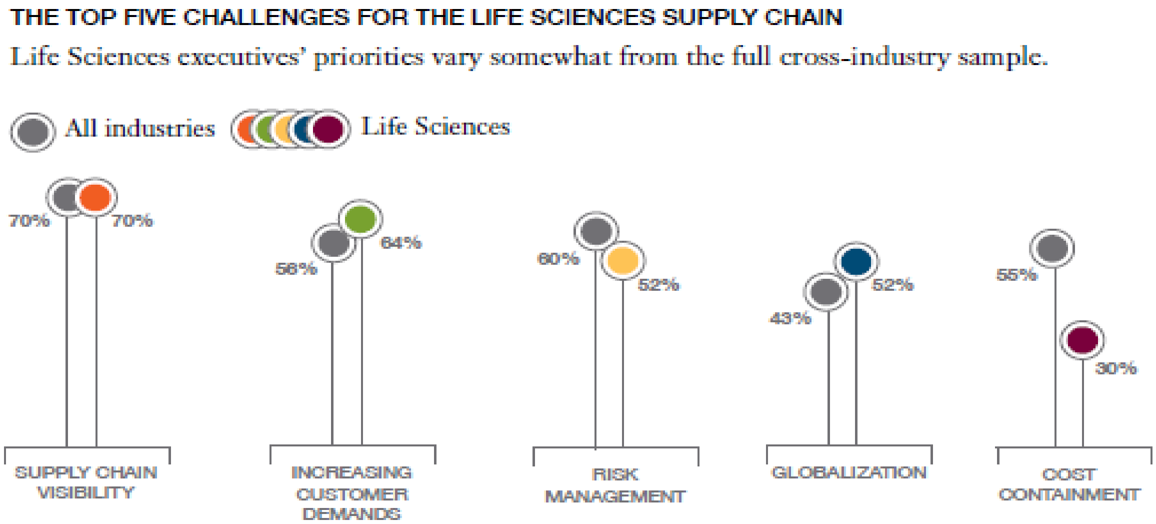
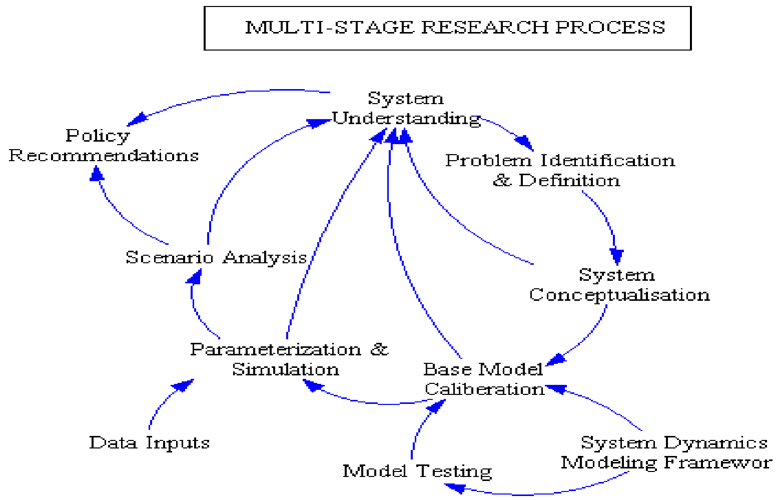


Figure 4: Global Challenges of Life Sciences Supply Chain

Reducing the risk of counterfeit drugs and contaminated medications amidst the complexity of global manufacturing, outsourcing and distribution are among the top concerns of the pharmaceutical and life sciences industries today. Though attempts have been made at anti-counterfeiting measures, complexity of this problem demands an integrated holistic approach to understand the functioning of counterfeiting ecosystem. The battle against counterfeit drugs has been complex problem given the multi-dimensional characteristics that this involves. These emerge as a consequence of the complexities involved, given the non-linear interactions between the main issues of concern.

Problem Investigation and Model Development:

In the above context, the problem persisting in the pharmaceutical sector called for a multi-layer approach of system understanding, dynamic model development and policy analysis. Hence, in the present research, a systemic research process has been followed which can be depicted below:



At the initial stage, a holistic influence model has been constructed by invoking the Causal Loop Modeling functionality of System Dynamics (Sterman 2000) based on extensive literature survey and expert interactions. It has been able to generate adequate system insight and clarity in problem definition. This model (Figure 5) signifies the need to better understand the interconnections of complex dynamic systems, particularly in today's highly integrated and chaotic global environment. Contrary to the application of reductionism in problem solving, it stresses the prudence to see the "the big picture" emerging across the Counterfeit Supply chain. On this principle structure driven behavior, the underlying causal loop systems or archetypes were studies at greater depth I this research.

The gain of system dynamics approach used here is that considering aggregated variables encourages both a systemic view of the interactions of resources, influence and information flows, and a more strategic perspective of the management of the system. The model proposed below is a qualitative model based on extensive literature survey which primarily intends to investigate causal feedbacks loops inside a national supply chain network structure. Dynamic problem conceptualization with Causal Loop Diagrams (CLDs) is an optimal way to lead concentration on decision points and performance measures (Lane, 2008). Rather than writing equations, CLD could be used to shape a qualitative discussion about feedbacks effects, in preparation for quantitative formulation. However, the model proposed is, at this point, an exploratory one and very difficult to simulate in its entirety in want of scarcity of data, yet, certain crucial inherent dynamics can always be captured and used for alternative policy formulations.

In the holistic model structure of supply chain ecosystem, the suppression of micro level details was necessary to provide a strategic overview of the problem rather than wade through other details. This diagram aims to communicate strategic links and feedback loops- both positive and negative, to be considered during planning and design, in order to achieve the final challenge of intervening counterfeit drug supplies on sustainable basis. It was also meant to draw healthcare stakeholders into thinking about all feedback loops present in the problem under study and all consequences to their choices. There are whole ranges of dependent and independent variables and feedback loops that capture their mutual influences (Table 1) and can be depicted as:

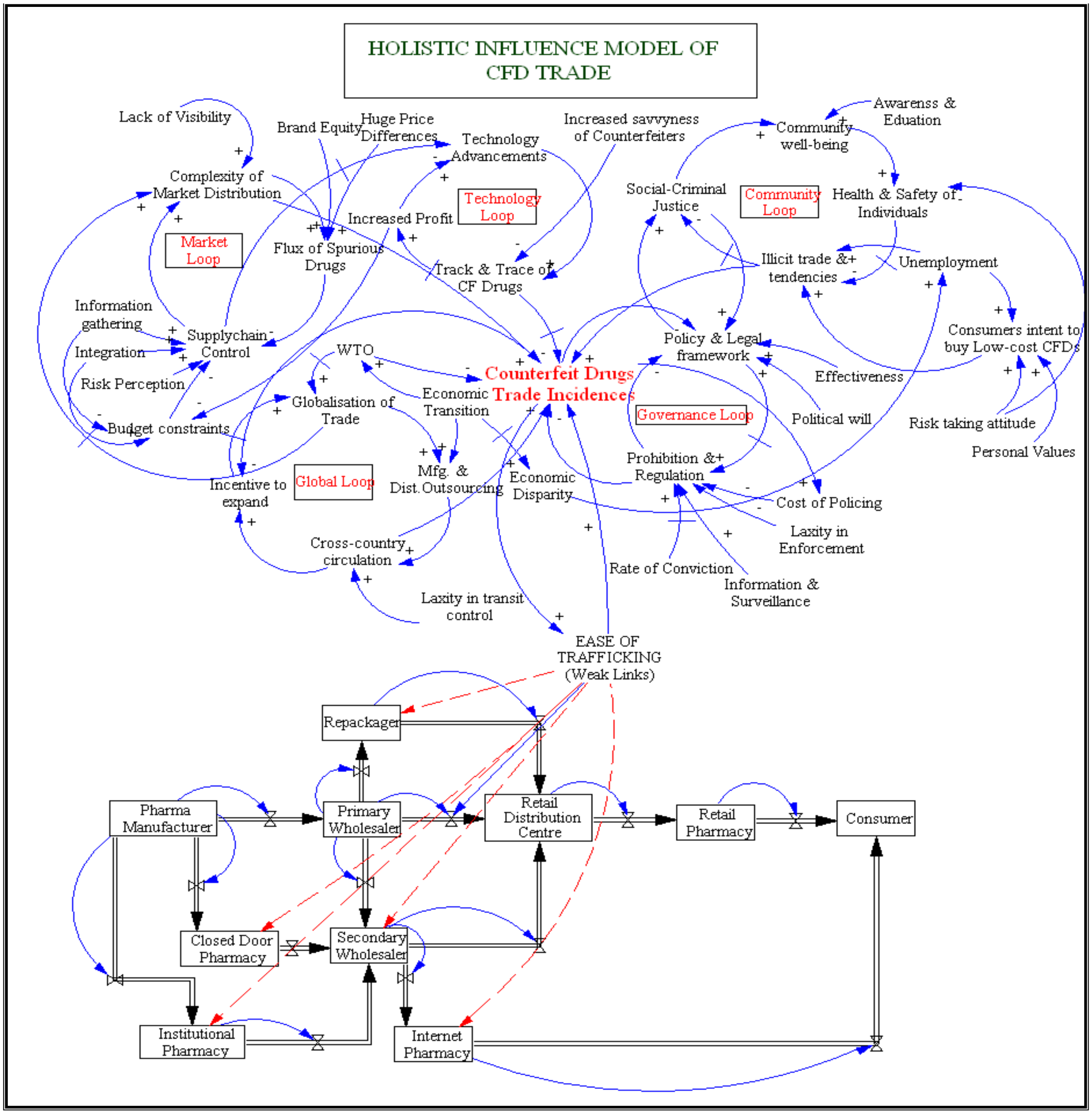
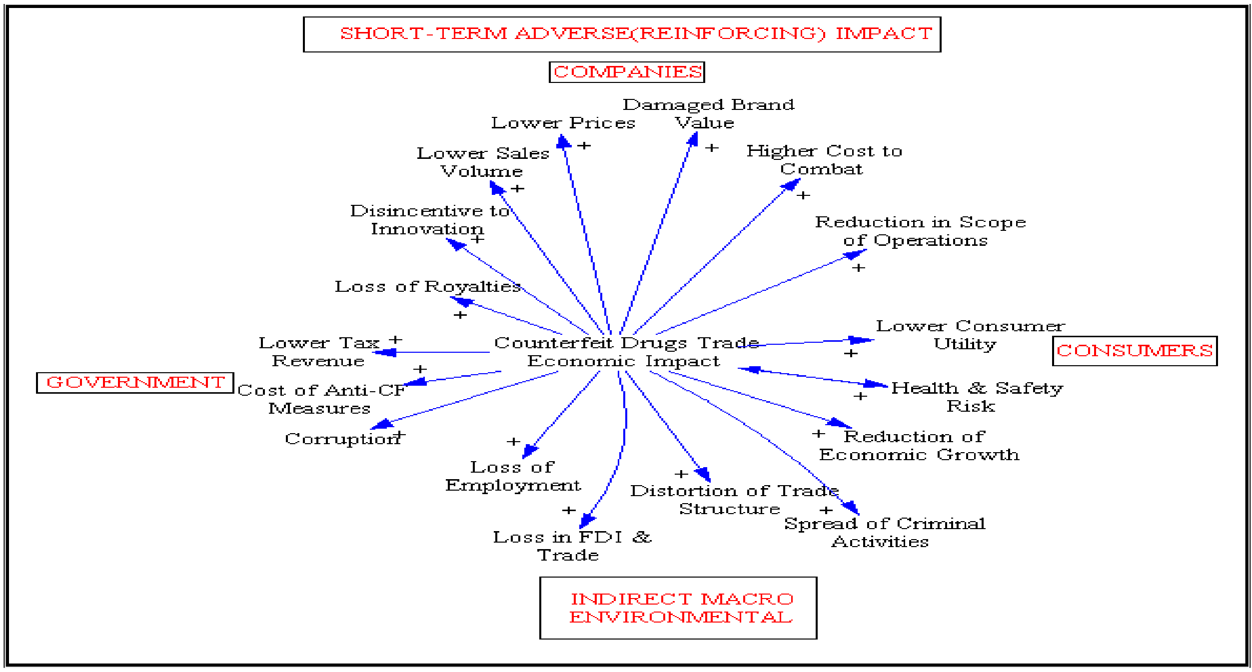


Figure 5: Holistic Base Spheres (Loops) of Interactions and Influences in Counterfeit Drugs Supply Ecosystem

Central to the above portrayed system is the Counterfeit Drugs Incidence as it constitutes the primary focus for the investigation. There are five peripheral spheres that interact with one another as well as with the central CFD Loop. We used these spheres of interaction analysis in order to identify certain variables that were of particular importance to the study in question. From there, we developed their impact scenario into a basic causal structure.

COMMUNITY LOOP			TECHNOLOGY LOOP		
	INFLUENCE			INFLUENCE	
Community Well-being	(+)	Health & Safety of Individuals	Technology Advancement	(+)	Track & Trace of CFDs
Social-Criminal Justice	(+)	Community Well-being	Track & Trace of CFDs	(+)	Increased Profit
Awareness & Education	(+)	Community Well-being	Increased Profit	(+)	Technology Advancement
Unemployment	(+)	Illicit Trade & Tendency	Increased Savvyness	(-)	Track & Trace of CFDs
Consumer Intent to Buy	(+)	Illicit Trade & Tendency	**Supplychain Control**	**(-)**	**Technology Advancement**
Risk Taking attitude	(+)	Consumer Intent to Buy	**Increased Profits**	**(-)**	**Budget Constraints**
Personal Value	(+)	Consumer Intent to Buy	**Track & Trace of CFDs**	**(-)**	**Counterfeit Trade Incidence**
Social-Criminal Justice	**(+)**	**Policy & Legal framework**			
Policy & Legal Framework	**(+)**	**Social-Criminal Justice**			
Illicit trade & tendency	**(+)**	**Counterfeit Trade Incidence**			
Risk taking Attitide	(-)	Health & Safety of Individuals			
Health & Safety	(-)	Illicit trade & Tendency			
Illicit trade & tendency	(-)	Socio-Criminal Justice			
MARKET LOOP			**GLOBAL LOOP**		
			Economic Transition	(+)	WTO
Complexity of Distributior	(+)	Flux of Spurious Drugs	Economic Transition	(+)	Economic Disparity
Lack of Visibility	(+)	Complexity of Distribution	WTO	(+)	Globalisatio of Trade
Information Gathering	(+)	Supplychain Control	Globalisation of trade	(+)	Mfg. & Dist.Outsourcing
Risk-Perception	(+)	Supplychain Control	Mgf. & Dist. Outsourcing	(+)	Cross-country Circulation
Globalisation of Trade	**(+)**	**Complexity of Distribution**	Cross-country Circulation	(+)	Incentive to expand
Complexity of Distributior	**(+)**	**CFD Incidences**	Incentive to expand	(+)	Globalisatio of Trade
Information Gathering	(-)	Budget Constraints	Laxity of Transit Control	(+)	Cross-country Circulation
Integration	(-)	Budget Constraints	**Cross-country Circulation**	**(+)**	**CFD Incidences**
Increases Profits	(-)	Budget Constraints	**Economic Disparity**	**(+)**	**Unemployment**
Flux of Spurious Drugs	(-)	Supplychain Control	**CFD Incidences**	**(-)**	**Incentive to expand**
Supplychain Control	(-)	Complexity of Distribution	**WTO**	**(-)**	**CFD Incidences**
GOVERNANCE LOOP					
Political & Legal FW	(+)	Prohibition & Regulation			
Political Will	(+)	Political & Legal FW			
Effectiveness	(+)	Political & Legal FW			
Informatio & Surveillance	(+)	Prohibition & Regulation			
Laxity in Enforcement	(+)	Prohibition & Regulation			
Rate of Conviction	(+)	Prohibition & Regulation			
CFD Trade Incidences	**(+)**	**Cost of Policing**			
CFD Trade Incidences	**(-)**	**Political & Legal FW**			
Cost of Policing	(-)	Prohibition & Regulation			
Prohibition & Regulation	(-)	Political & Legal FW			

Table 1: Feedback integrated Causal Loop Variables indicating their Influences



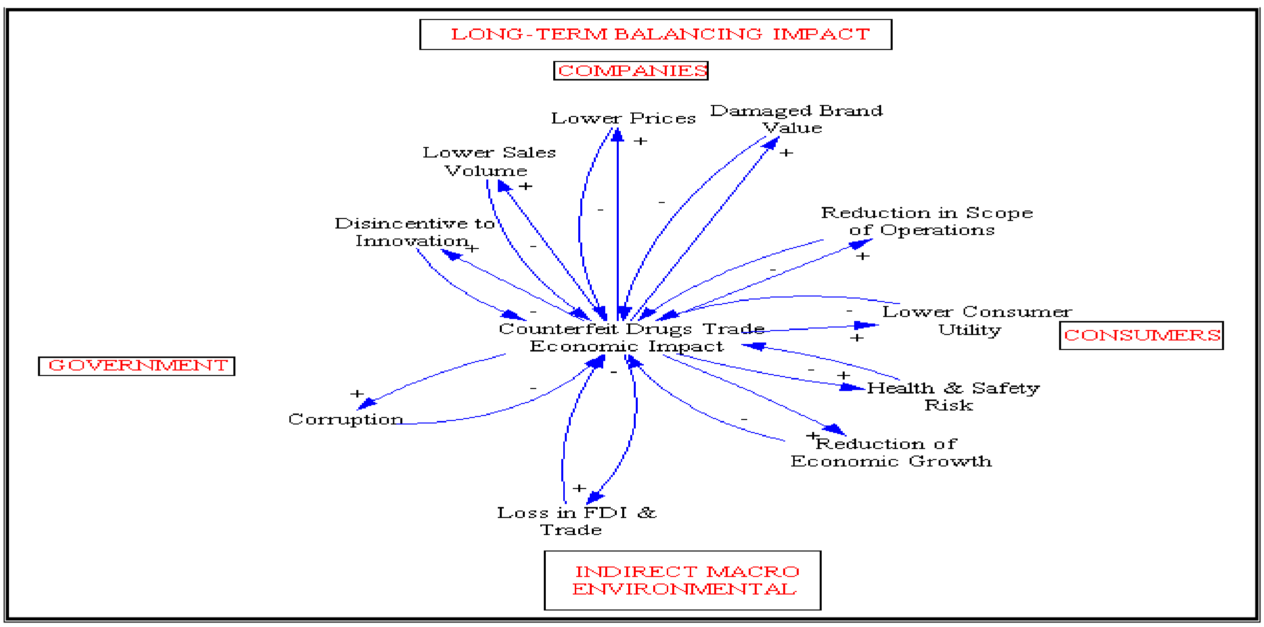


Figure 5: Short-term (Reinforcing) and Long-term (Balancing) Economic Impacts of CFD Trade

In addition of the holistic influence modeling, some useful insights can also be generated about the various kinds of economic impact that the Counterfeit Supply chain creates over a short and a long run. It is interesting to understand that various adverse economic impacts for e.g. Damaged brand value, reduction of operations scope, lower consumer utility, health and safety risk, reduction of economic growth, corruption etc. can endogenously counter balance CFD trade in long run and thus, preventing it to explode beyond recovery. This very significant insight explaining the inherent counterintuitive dynamics of CFD trade can not be generated through currently followed reductionist short-term approach of problem diagnosis.

Section-II: Modeling Framework of Base-Case Scenario

Precursor to the any system dynamics modeling process is the development of causal loop diagram describing the fundamental causal logic used in model. It explains the flow of feedback influence and the nature of inter linkages existing among the system variables. Following this, in this section, a stock-flow framework has been modeled extracted from the basic Causal Loop Diagram (Appendix-I) to simulate the prevalent scenario and the effect of combating policies on the Counterfeit Drugs Supply in India. As mentioned earlier too, it was not found feasible to simulate the entire causal loop model developed in the previous section for the want of adequate and reliable data related to Counterfeiting in the Indian pharmaceutical industry. Hence, Stock-Flow framework developed in this section is a limited representation of the entire causality and complexity prevalent in the Indian scenario, yet, it is adequately capable of capturing some critical decision making scenarios for alternative policy analysis. .

In our study, we created the system model involving four sub-sectors, namely, Technology-Market Adoption Sector, Community Sector, Governance Sector and Counterfeit Drugs Supply control sector. Primarily, within these sub-sectors; the effect of anti-Counterfeiting technology adoption, Community sensitization, Government regulation on drugs licensing and incidence of counterfeit drugs supply have been simulated. These scenarios are used for analyzing the effect of different policies applied to regulate the counterfeit drugs market in India. The simulation results show that fastening technology adoption and promoting community education together with stringent licensing and reviewing control by the government can significantly reduce the incidences of counterfeit drugs supplies in the Indian market. From these findings, a national government should implement suitable, holistic and responsive policies that aim to control the counterfeit drugs market and thus lower the chance that Indian society is perpetually forced to suffer and compromise on its health safety.

Simulation Base-Case Scenario:

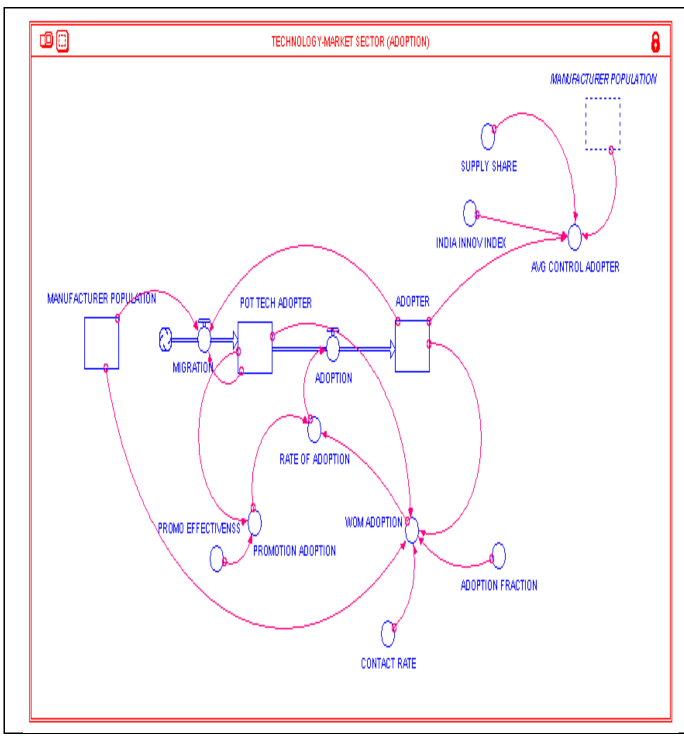
The simulation of the base-case scenario shows the evolution of four sub-sectors discussed above with their initial configuration. In this base case, the interrelationships among various constituting variables of chosen sectors are simulated over a period ranging 0-48 years. The input data for the base case exist of the values taken from different secondary sources as explained in Table 1. The average of three runs of each scenario is used to determine the output, to deal with randomness in lead time and repair yield which might have affected the results slightly.

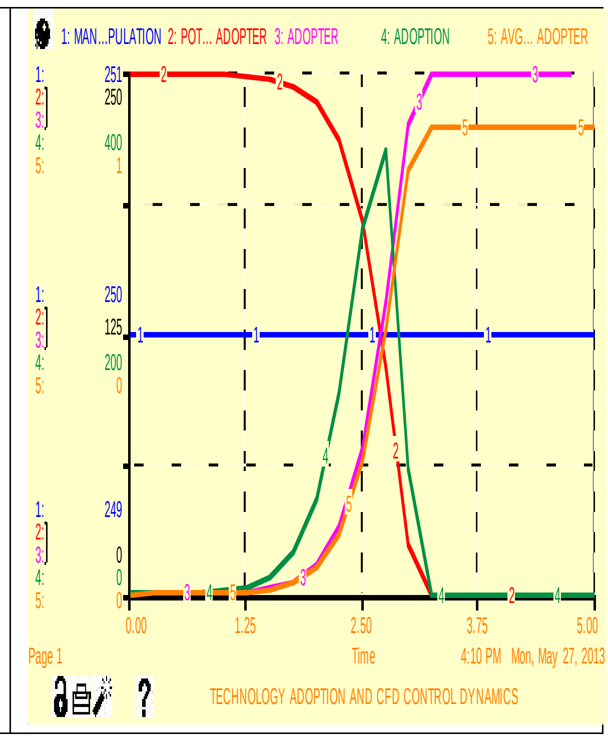
Base-Model: INITIAL CONDITION (YR 2012)	
INPUT KEY PARAMETERS	**VALUES**
Technology-Market Adoption Sector	
Mfr. Population	250 Units (Large Manufacturers)
Supply Share	0.7 (70%)- Effective Supply Chain Control
Promotion effectiveness	0.0003 (Bass-Developing Country Estimate)
Adoption Fraction	0.554(WOM Coefficient for Developing country)
India Innovation Index	0.9 (Innovation Efficiency Index)
Community Sector	
Susceptible Population	850 Million (Above 14 Years of Age)
Social Contact Rate	100-120 (India Social Group Index)
Self- Awareness Fraction	0.02
Innovation Coefficient	0.016 (Innovator and Early Adopters Fraction)

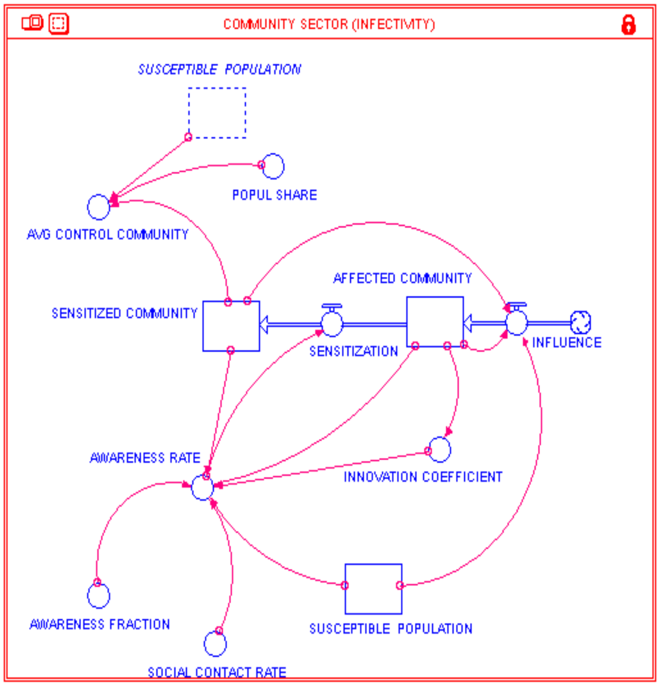
Governance Sector	
Drug Manufacturers Population	10526
Drug Inspectors	1200
Projected New Hiring / Year	200
Mfr-DI Ratio	8.77
New Unit Launch rate	0.10 (Assumed Value)
Industry churn rate	0.05 (Assumed Value)
Unfair Trade Practices (Crime Rate)	0.25
Approved Drug Licences (Own+Loan)	90000
Average review Time	5 Years
Rejection-Revocation-Expiry Fraction	0.35
CFD Supply Chain Control Sector	
CFD Incidences Value	475 Million Rs. (0.25 of 19 Billion Rupees)
Pharma Crime Growth rate	0.32
Source: CDCSO, WHO, OECD	

Simulation-Flow:

Starting from the base year 2012, we can see the gradual flow of simulation across all the four sub-sectors moving from growth to saturation and in some cases decline respective to their characteristics in the entire Counterfeit macro sector. Table (2) highlights primarily the starting initial condition and the final condition over the simulated time-frame of maximum 48 Years (Simulation Graph Scale 1 Time-interval = 4 years)






COMMUNITY SECTOR (INFECTIVITY)
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POPUL SHARE
AVG CONTROL COMMUNITY
AFFECTED COMMUNITY
SENSITIZED COMMUNITY
SENSITIZATION
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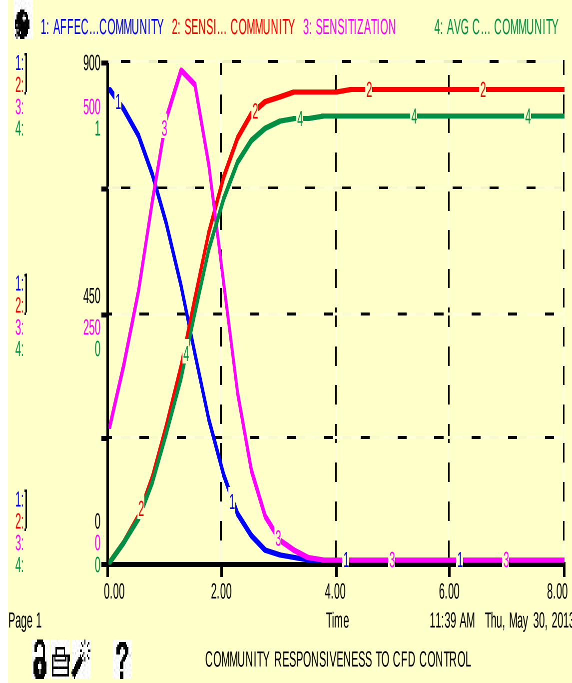
AWARENESS RATE
INNOVATION COEFFICIENT
AWARENESS FRACTION
SUSCEPTIBLE POPULATION
SOCIAL CONTACT RATE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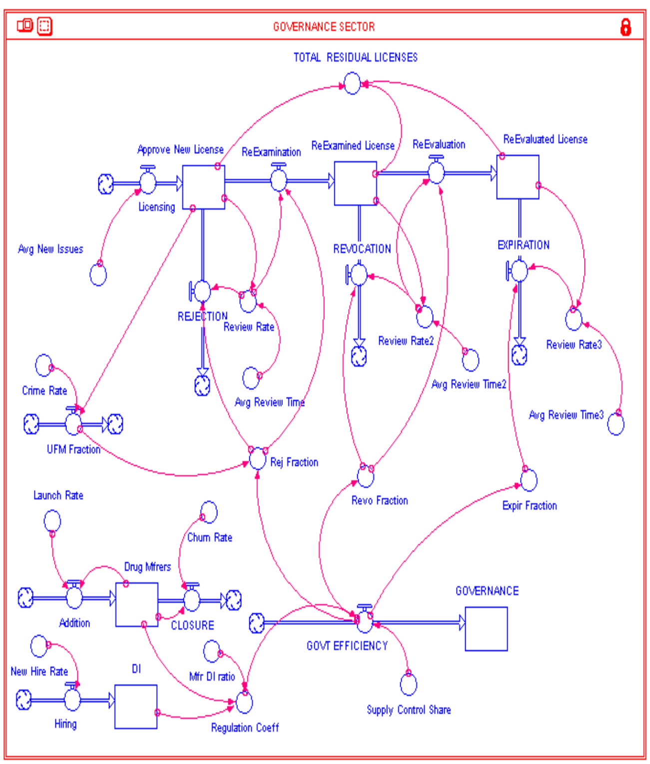
COMMUNITY RESPONSIVENESS TO CFD CONTROL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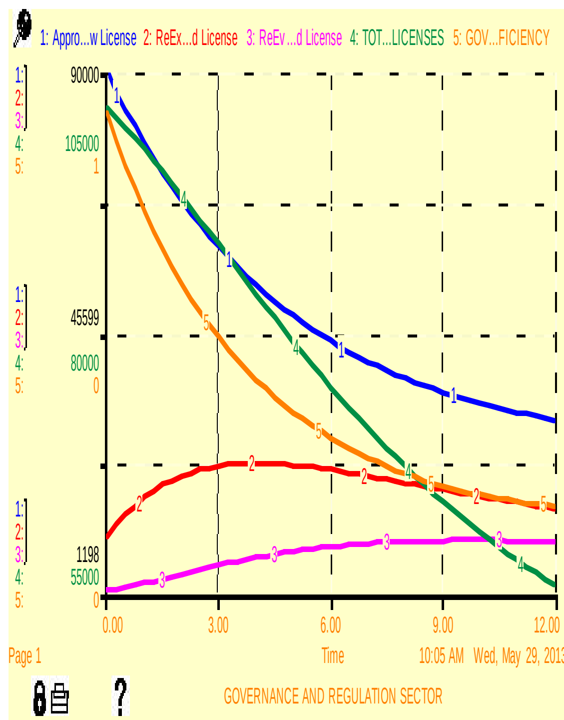
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GOVERNANCE AND REGULATION SECTOR

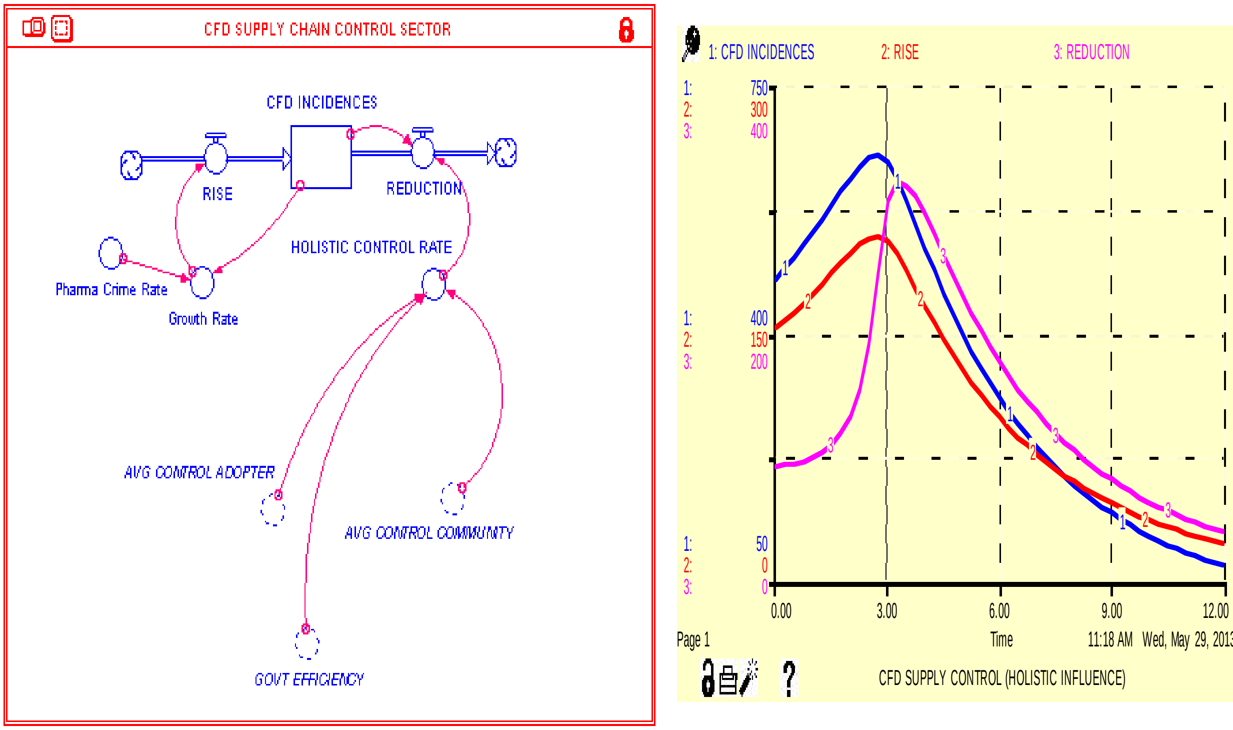


Figure 6: Base Model: Sub-Sector (1) Technology-Market Adoption (2) Community Sensitization (3) Governance & Regulation (4) CFD Supply chain Control

	TECHNOLOGY-MARKET ADOPTION CONTROL			
TIME	**POT ADOP**	**ADOPTER**	**ADOPTION**	**AVG CONTROL**
YR. 2012	250	0	0.07	0
YR. 2035	**0**	250	0	**0.63**
	COMMUNITY SENSITIZATION AND CONTROL			
	AFFECT POP	**SENSI POP**	**SENSITIZATION**	**AVG CONTROL**
YR. 2012	850	0	136	0
YR. 2034	0	850	0.01	**0.7**
	GOVERNANCE	CONTROL		
	APPROV LICEN	**RE-EXAMINED**	**RE-EVALUATE**	**EFFICIENCY**
YR. 2012	90,000.00	10,385.21	1,198.36	0.58
YR. 2060	30,541.74	15,347.34	9,654.70	**0.35**
	CFD SUPPLY	CONTROL		
	CFD VALUE	**RISE**	**REDUCTION**	**HOLISTIC CONTROL**
YR. 2012	475	152	91.35	0.19
YR. 2060	67.24	27.57	48.29	**0.56**

Table 2: Initial Condition - Final Condition Simulation Flow

Description of Sub-Sector Modeling and Simulation Results:

There are factors that contribute to counterfeiting in pharmaceutical industry and also those that play a role in curbing it. This interplay of factors results in causal links being established between the various participants in the entire ecosystem. These inter-links, if systemically optimized, may collectively enhance or work together to reduce incidence of counterfeiting. The motivation behind looking at counterfeiting in Indian pharmaceutical industry from a system dynamics point of view is that all the sub-sectors or stakeholders along with their effect on the incidence of counterfeiting are included in the ecosystem to determine its extent in the long-term.

Starting with the Technology-Market sub-sector, the gradual adoption of anti-counterfeiting technology has been simulated using the famous Bass Model (Bass, 1969) of technology diffusion with the adjusted coefficient values of promotion and word-of-mouth suggested for developing country like India. In addition to it, the impact of innovation efficiency climate of India and the effective share of supply chain control commanded by major drug manufacturers have also been appropriated in the model to finally arrive at the average control on CFD value. Next, in the community sub-sector model, the basic framework used to depict gradual sensitization of Indian community about counterfeit drugs hazards is another very effective model of 'infectivity' (used to explain the phenomenon of gradual transmission of some contagious disease over a large population) and Roger's diffusion estimate about learning and adoption of new knowledge in any population at gradual stages (Innovator-Early adopter-Early majority-Late majority-Laggards). However, here also these generic models have been suitably customized in typical Indian context with the application of additional converter variables like Average size of Indian Social networking group, Contact rate, and size of affected population group above 14 years of age.

Coming to the Governance sub-sector modeling, a typical license approval and re-evaluation process of Indian regulatory system has been modeled together with the consideration of variables like effective Drug Inspectors-Manufacturers Control ratio, Pharmaceutical Unfair trade fraction and crime rate and Growth rates wit respect to pharmaceutical manufacturing and hiring of enforcement officials. Finally, in the Counterfeit Drug Supply-chain sub-sector, the overall impact of the collective control rates of Technology adopter sector, Community sector and Governance sector over the incidences of CFDs in value term has been investigated. It would be prudent to mention here that, many countries are now working on measures to track and trace CFD medicines to enable pharmaceutical manufacturers, working together with enforcement agencies and community, to follow the path of counterfeit medicines back to the source and to fix all the point in the supply chain where the diversion or infiltration may take place. The proposed modeling is one such humble effort to assist all the stakeholders of Indian health care fraternity in curing and controlling this social evil.

Model Testing: As proposed by Forrester (1958, 1961) and Senge (1979), a system dynamics model can be validated by Extreme Conditions test. Extreme condition test asks whether the model behave appropriately when the inputs take on extreme values such as zero or infinity (Lee, 2006). In this research, we assume two situations to test: (1) the adoption fraction for Anti-Counterfeit technology diffusion in the Technology-Market Sector is set to 100% (1.0) which is the maximum possible in pharmaceutical industry, and, (2) the value of Innovation Population Coefficient (based on Roger's Distribution Curve) in the Community Sector is set equal to zero.

In the proposed model, the adoption of Anti-CFD technology greatly depends on mutual exchange of information, i.e. word-of-mouth, particularly in the case of developing countries *(Talukdar, Sudhir, & Ainslie 2002)*. Once the coefficient value of this from the present 0.554 is set to maximum possible 1.0 i.e. 100%, there are faster adoptions or diffusion of technology in the pharmaceutical industry (see figure 3 below). In an another case of testing extreme condition, when we set the innovation coefficient value from current 0.016 to Zero, i.e. minimum possible, we see a complete non-sensitization of community population about the hazards of counterfeit drugs effects. As the above results of test prove, the extreme-condition test is reasonable and the model can be used with high confidence level for further policy analysis.

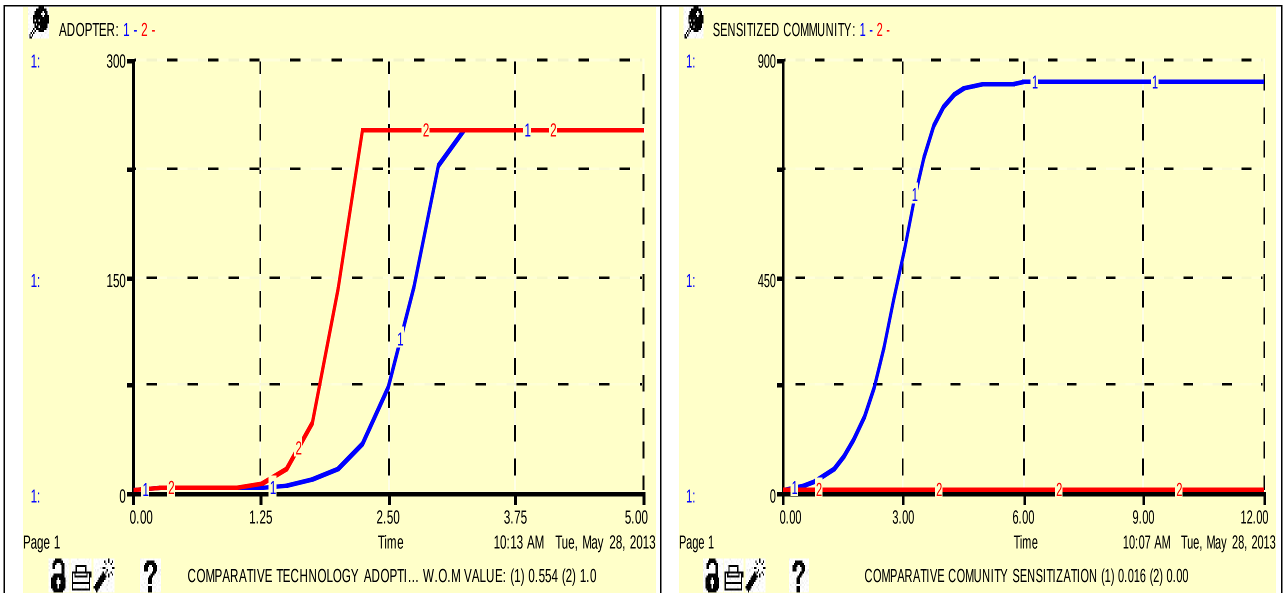


Figure 7: Extreme Condition Comparative Scenarios

Section-III: Simulation Scenario Analysis

One of main purposes of simulation analysis was also to trace key intervention decision points for suggesting suitable amendments in the present policy direction in Indian Pharmaceutical Sector. For this reason, we presume following scenarios to simulate that when some variables are incorporated or changed, how they affect the overall performance of Anti-Counterfeit Supply measures.

Policy- Intervention Scenario 1: Revenue Savings Impact on Counterfeit Drugs Supply:

As it is elaborated in the previous section that the holistic control exerted by the combined forces of Technology Adopter sector, Community sector and Governance sector results into the eventual net positive control and reduction of the stock of CFD value estimated to have come down from initial Rs. 475 million to Rs. 47 million at the end of 12 time-intervals. The same effect can simply be reversed (Figure 8) to ideate the prospect of indirect revenue savings as the prevented loss of CFD revenue is nothing but net positive revenue savings for the entire pharmaceutical sector.

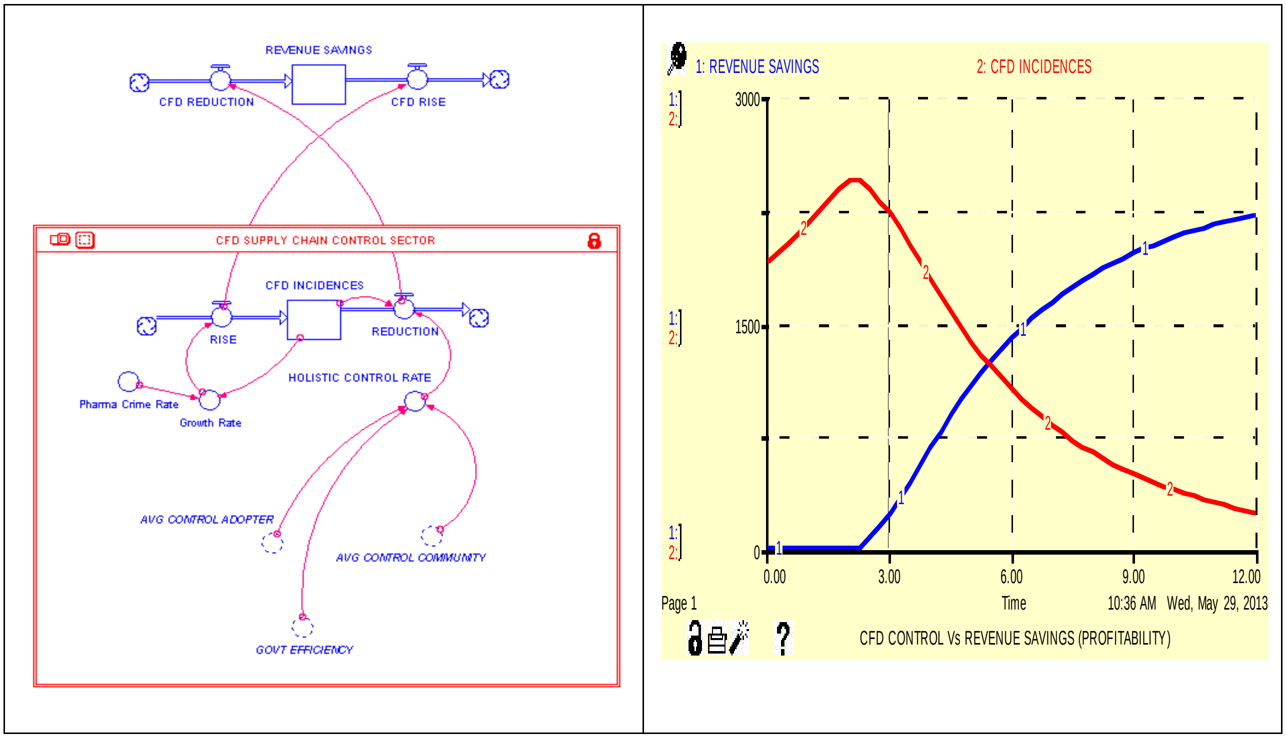


Figure 8: Revenue Savings vs. CFD Incidences Diagram

Now, once we come in position to pull off a large sum of revenue from the CFD Supply chain and inject back into the main pharmaceutical sector economy, it is able to generate a cascading effect over the entire ecosystem of healthcare sector, comprised of Industry, Community and Government. This cascading effect can be clearly demonstrated by the Causal Loop Diagram (Appendix-I) and that can further be converted into the stock-flow model frame by considering additional parameterization in our base model as presented and depicted in the following table (Table 2) and the holistic model (Figure 9) respectively:

Revenue Scenario Key Parameters	**Value**
Technology-Market Adoption Sector	
R&D Intensity Fraction (% Investment of Revenue on Innovation)	.05 (5% in India)
Community Sector	
CSR Investment Fraction (Mandatory % Investment of Profit earned)	.02 (2%)
Governance Sector	
Pharma Tax Rate (On revenue earned)	.15 (15%)
CFD Supply Chain Control Sector	
Profit Margin in Pharma (% of Sales Revenue)	.30 (30%)
Source: CDCSO	

Table 3: Revenue Scenario Parametric Values

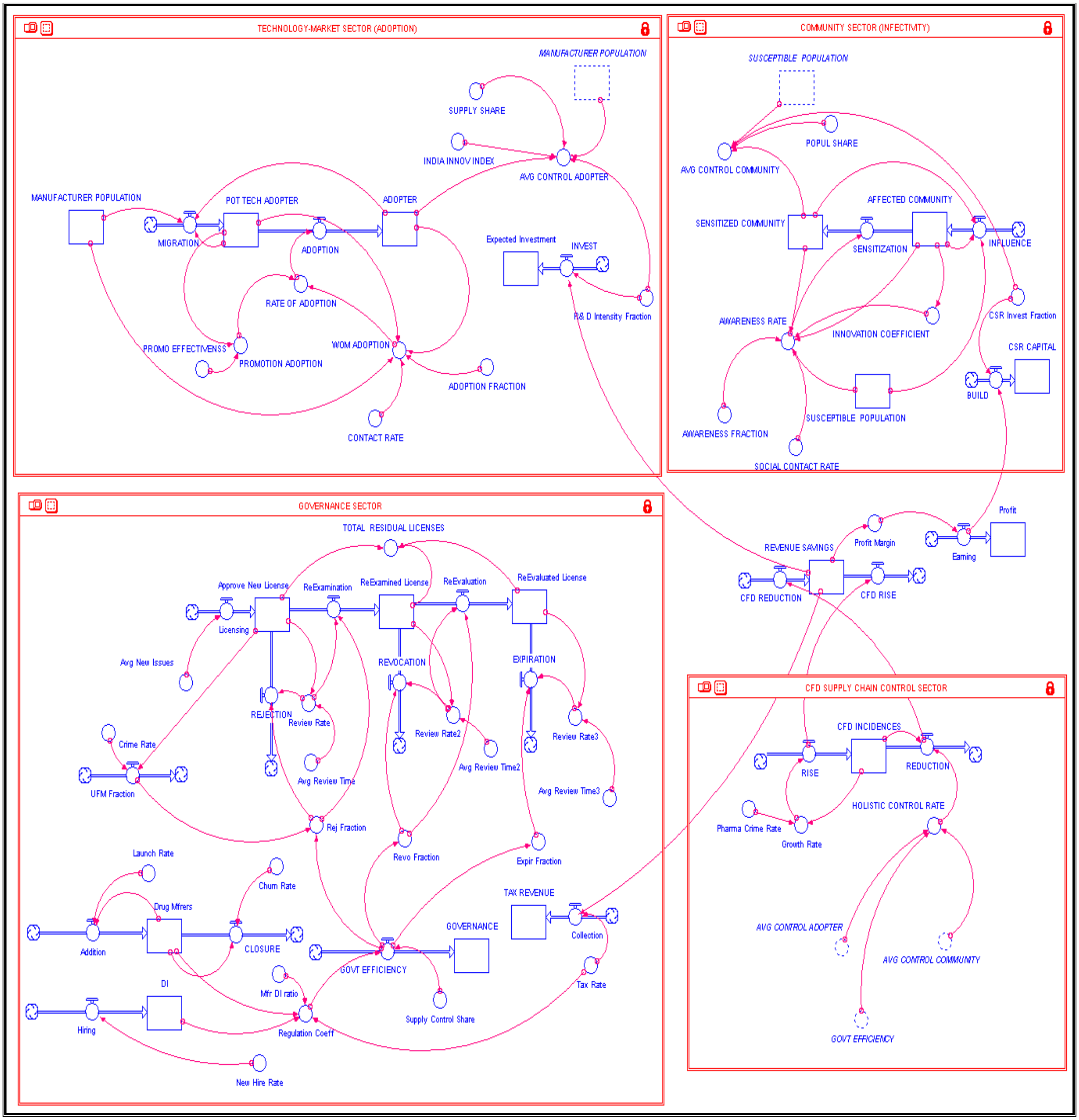
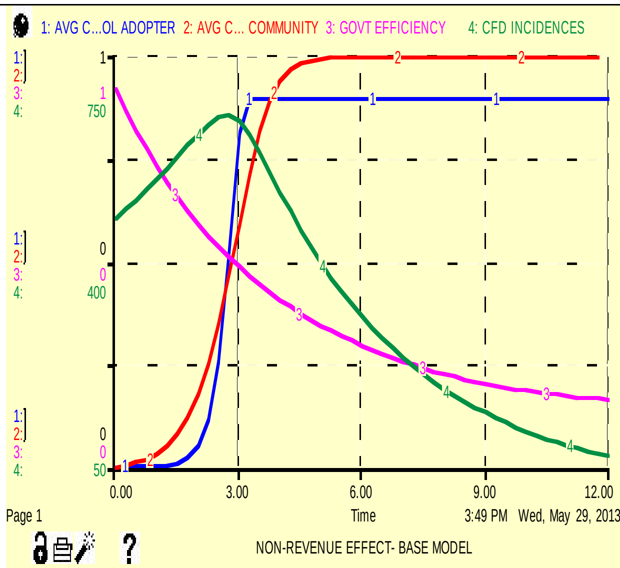
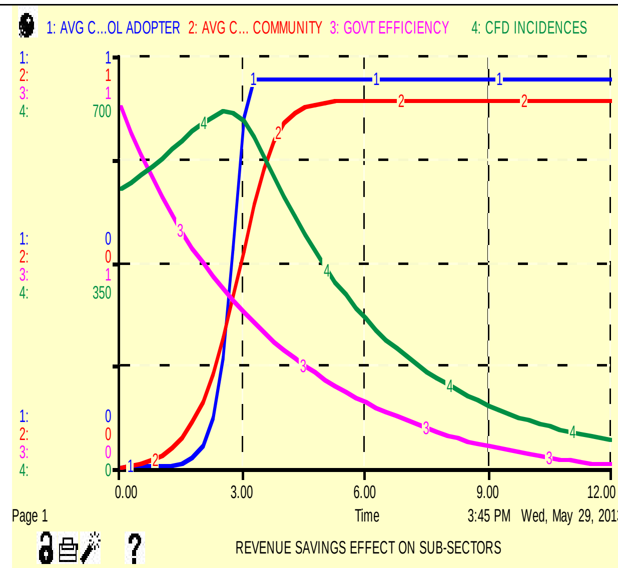


Figure 9: Revenue Savings Induced Cascading Effect over Anti-CFD Ecosystem

The resultant improvement in the overall performance of Anti-CFD Supply measures can comparatively be visualized in the following depiction of simulation graphs and the appended values of various constituting sectors-





Non-Revenue Scenario	**Revenue Effect Scenario**
Adopter Control: 0.63 **Community Control: 0.70** **Govt. Efficiency: 0.35** **CFD Value: 67 Million Rupees**	**Adopter Control: 0.66** **Community Control: 0.71** **Govt. Efficiency: 0.40** **CFD Value: 45 Million Rupees**

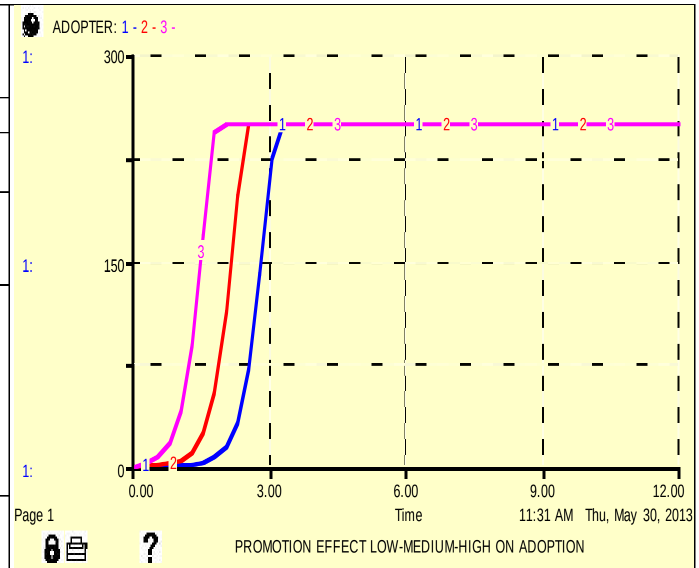
Policy Intervention Scenario 2: Technology-Market Adopter Sector

Role of technology is paramount in any endeavor to counter and control counterfeit drugs supply. A variety of anti-counterfeiting technologies are available currently but on the other side, with increasing technical competency of counterfeiters, traditional ACM's like holograms, breakable caps and even bar codes are losing their effectiveness. Hence, new advanced technology needs to be promoted aggressively for combating counterfeiting like RFID, Nano printing, biometric systems, OCR etc. (CII, August, 2009). An effective track and trace device would not just control proliferation of counterfeiting in pharmacy supply chain, but will also enhance consumer's confidence on the firms' product. Mass serialization and E-pedigree also enable the traceability of medicine supply using the global track-and-trace process and is able to track the entire lifecycle of the product in the supply chain market.

In these simulation trials, we analyze the change in behavior of the model in different scenarios with change in the values of promotion effectiveness for Anti-CFD technology, while keeping other effects like word-of-mouth constant. Table 4, adjoining the simulation graph gives the details of the values of parameters in different low-medium-high scenarios and corresponding patterns of technology adoption in the adopter pharmaceutical industry of India.

Table 4:

Simulation 2		Promotion Effectiveness parameter value (Technology-Market Sector)
Scenario No.	Period (in Years) of Complete adoption	
	α_1	Base-Year 2012
1	Low 0.0003	8 Years
2	Medium 0.003	10 Years
3	High, 0.03	13 Years

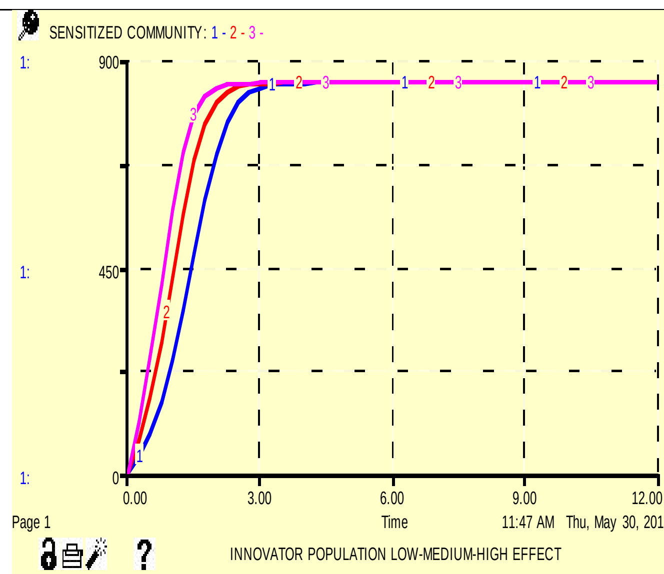


Policy Intervention Scenario 3: Community Sector

Overall sensitization of potentially affected community against buying counterfeit medicines is an important factor for securing health and safety and also ensuring success of various policies and measures to combat counterfeiting in India. The holistic influence model developed in the beginning highlights how price-sensitive consumers in India are vulnerable to either purchase substandard but affordable CFDs even rationally expecting some degree of counterfeiting of the latter. Consumer personal values and risk attitude may also have heavy impact on consumers' attitudes toward counterfeits and their willingness to knowingly purchase counterfeit goods (Phau et al, 2009). Thus, under this scenario, we have analyzed the change in community sensitization pattern with the change in the values of effectiveness of various community promotion measures. Table adjoining the simulation graph gives the details of the values of parameters in different low-medium-high scenarios and corresponding behaviors of community sensitization.

Table 5:

Simulation 3		Promoter Population Effectiveness parameter value (Community Sector)
Scenario No.	Period (in Years) of Complete Sensitization	
	α_1	Base-Year 2012
1	Low 0.16	22 Years
2	Medium 0.32	19 Years
3	High .50	16 Years

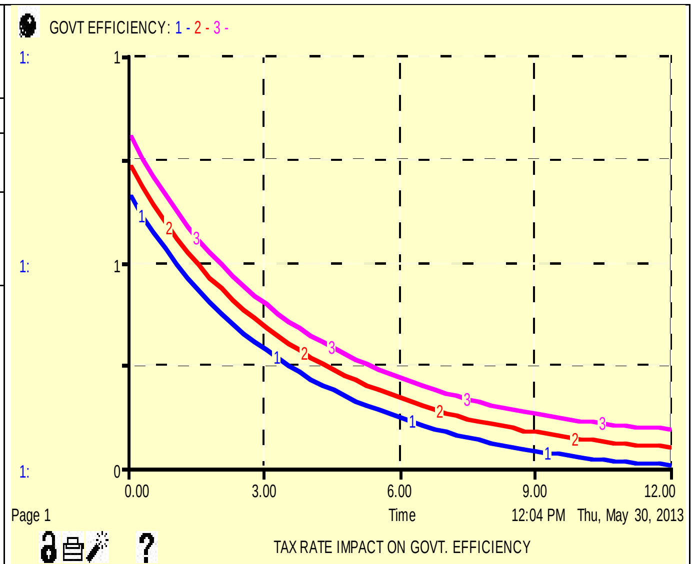


Policy Intervention Scenario 4: Governance & Regulation Sector

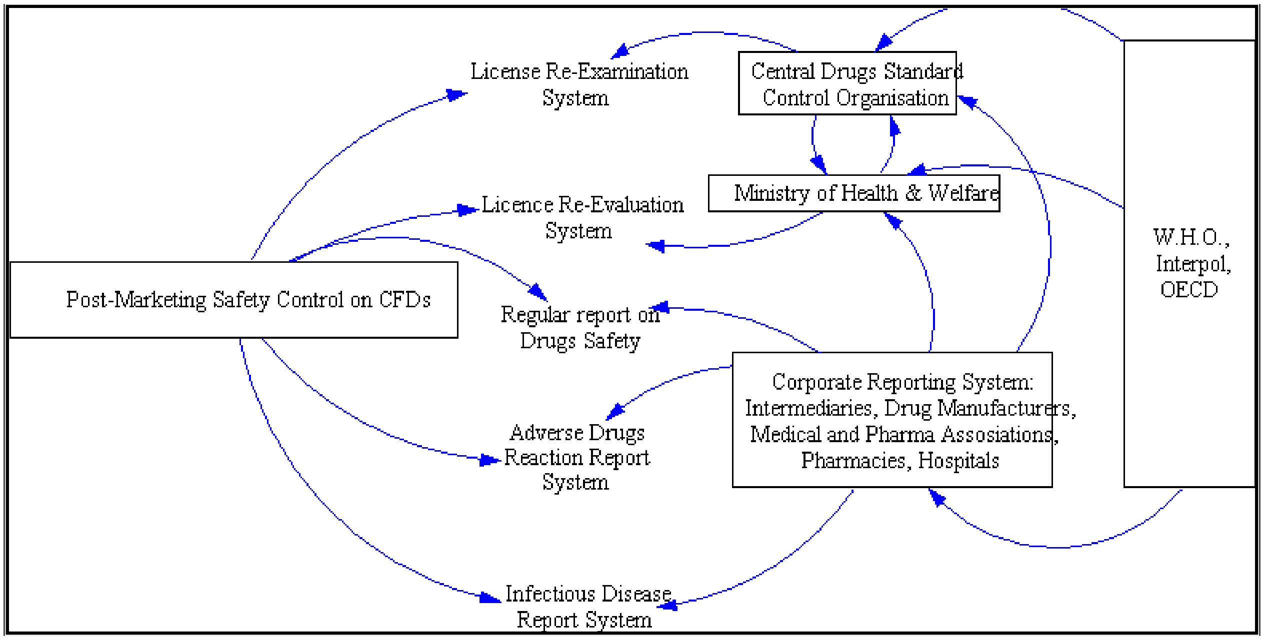
In our modeling, Governance is referred as a collective body of enacted laws for license regulation and control of infiltration of counterfeit drugs in India. For it to be effective, legislation must be complemented with effective law enforcement and resource generation. Apart from developing strategies to reduce corruption and criminal activity, it must promote inter-sector cooperation between regulatory authorities, police, industry and the judiciary. In the following simulation, the effect of enhanced tax rate on the overall efficiency of governance system is projected. The proceeds from enhanced tax-rate can be utilized for hiring of additional drug inspectors, training of enforcement staff, heightening vigilance and awareness and also to procure new technologies for tracking the movement of CFDs and Counterfeiters too.

Table 6:

Simulation 4		**Tax Rate Effectiveness parameter value (Governance Sector)**
Scenario No.	**Percentage Control on CFD**	
	α_1	**Base-Year 2012**
1	Low 0.15	.35
2	Medium 0.25	.40
3	High .30	.44



Ensuring these properties requires the creation of a competent network of national and International drug regulatory authorities particularly in the post-marketing stage with the necessary human and other resources to control the CFD supply chain. In this regard, we also propose a network model with following reporting and information transmission flows between the stakeholders groups as envisaged in the model:

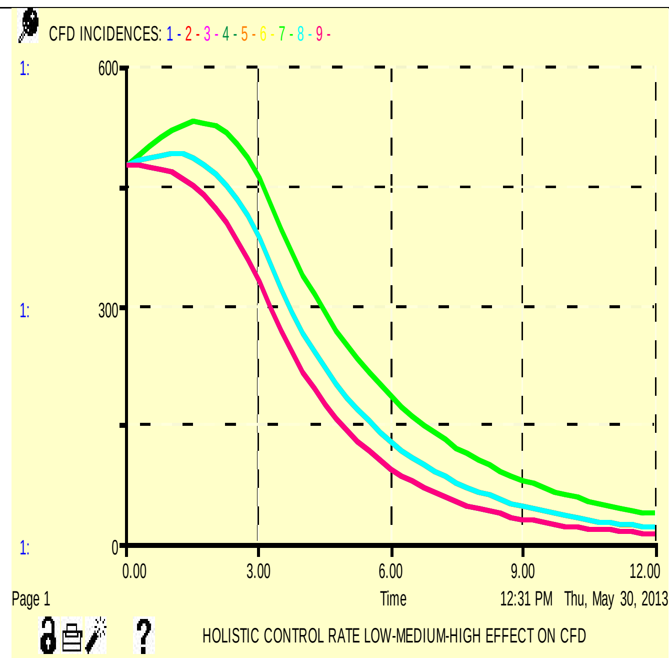


Scenario 4: CFD Supply Sector

The scenario predicted here is of varying rates of Holistic control exerted together by the three important stakeholders' groups viz. Market (Industry), Community and Government. It clearly projects the diminishing trend in the incidences of Counterfeit drugs supply over time.

Table 7:

Simulation 4	**Holistic Control Rate Parameter value (Market-Community-Governance-CFD Supply Sector)**	
Scenario No.	**Reduction on CFD Value**	
	α_1	**Base-Year 2012 Value: Rs. 475 Million**
1	Low 0.59	32.23 Million
2	Medium 0.65	14.95 Million
3	High 0.70	7.81 Million



Summary of Scenario Results:

Scenario-Sensitivity analysis of the macro model throws light at an important point that, even with the current state and extent of control that the various stakeholders' groups are presumably supposed to exercise, there can be gradual net positive control over Counterfeit drugs supply in India in a long run. However, the situation can certainly be bettered by putting extra but comprehensive efforts and resources in the system towards this objective of bringing CFD incidence to minimum. New Anti-CFD technology, R& D, Promotional programmes, Efficient and resourceful government machinery, Community sensitization and most importantly, channelization of these all cohesively towards a common direction may ultimately serve the intended purpose.

CONCLUSION

The healthcare sector of India is demanding for new models of decision support which should have the capability to capture inherent complex dynamics of the system, indicate critical intervention points, support different scenario analysis and decision making process used by different healthcare stakeholders in the short-medium-long term. It should also be able to predict and quantify future system performances, benefits and risks, and also the extent of integration between partner groups. It was surprising to find that in all the available decision models and literature studied related CFD supply chain, there was little information of 'behavior over time' nature; rest alone, the holistic decision-frame. Mostly the data presented in the various papers and government reports were of a general statistical nature and revealed little about inherent causal dynamics. However, a decision model must be holistic in a sense that it should be able to record some in depth treatment of dynamical structure of the CFD supply chain spiral, where, the dynamic feedback loops explain the behavior over time and thereby one can trigger a composite crack down on counterfeit drugs supply in India.

The system dynamics macro model presented here does not intend to be exhaustive in its present form and capture all the dynamic causal complexities, but rather aims to lead policy insights and a better understanding of the problem in the sight. We could learn during this investigation that developing viable decision support models to simulate dynamic systems is an iterative and complex problem. The CFD trafficking system in India, in particular, is highly segmented, complex and extensive. Consequently, modeling can only provide significant insights into these systems if they are updated routinely with accurate data. Our baseline models can be used in such a manner given the availability of an appropriate data support. In addition, future research should also concern with the calibration of more causal relations and variables identified, permitting a complete dynamic simulation of the holistic influence model which we have developed in the first instance. Further, it ultimately needs to be validated through real data support and case studies development.

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Acknowledgement:

The first author humbly owes his deepest sense of gratefulness to **Most Revered Prof. P.S. Satsangi**, Chairman, Advisory Committee on Education, Dayalbagh Educational Institutions for His Eternal Blessings, Grace and Guidance at every step of life. He also expresses his deep appreciation to Prof. Devanath Tirupati, Chairperson, SCMC, IIM Bangalore and Prof. Sanjeev Swami, Head & Dean, Faculty of Social Sciences, DEI for their valued inputs and advice shared in carrying out this research. The present study was done under the Memorandum of Association between Department of Management, DEI and Supply Chain Management Centre, IIM Bangalore. Hence, the author acknowledges the active support provided by the staff and officials of both the institutions for facilitating this collaboration.

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- www.**who**.int *(World Health Organisation)*
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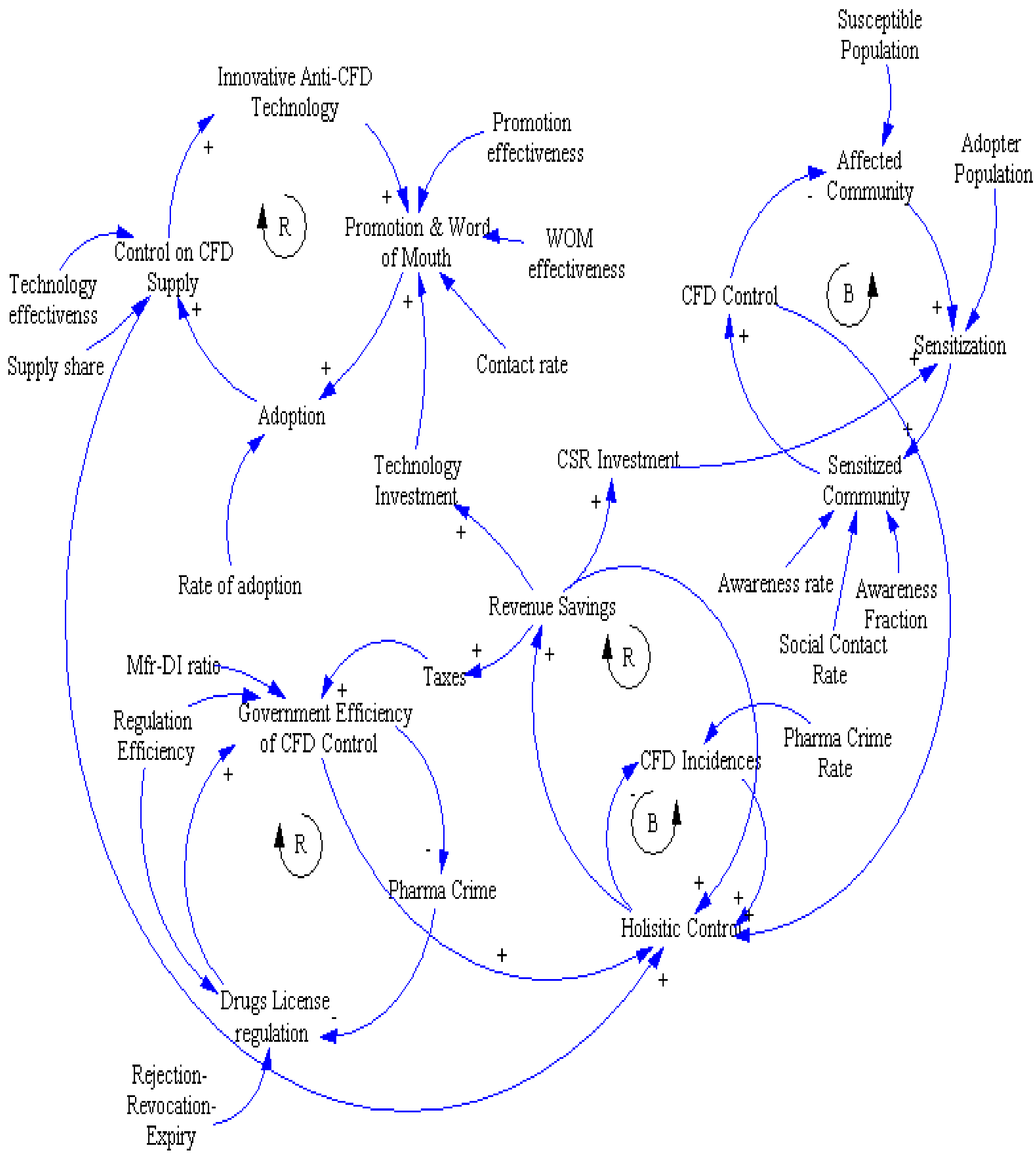
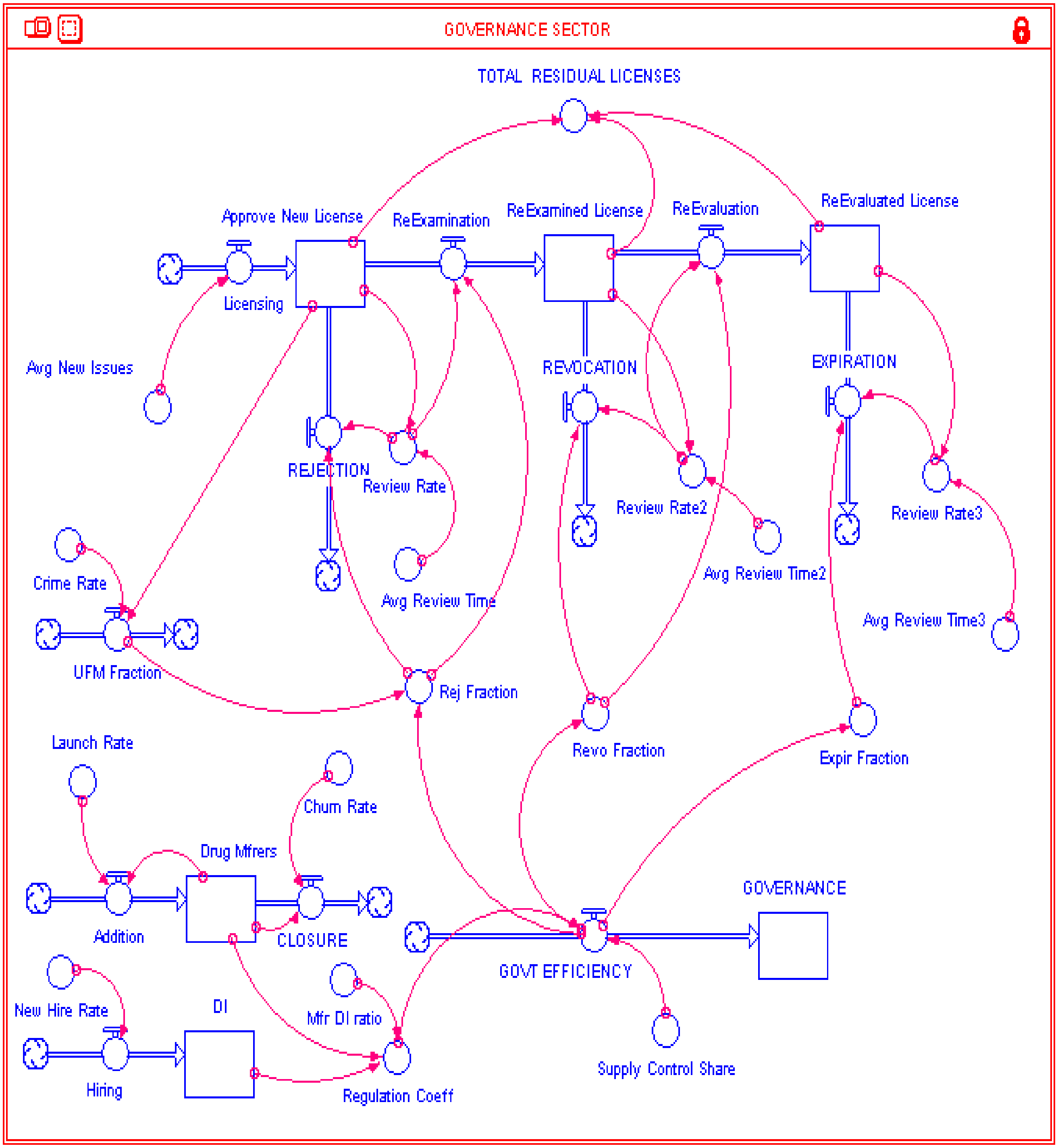
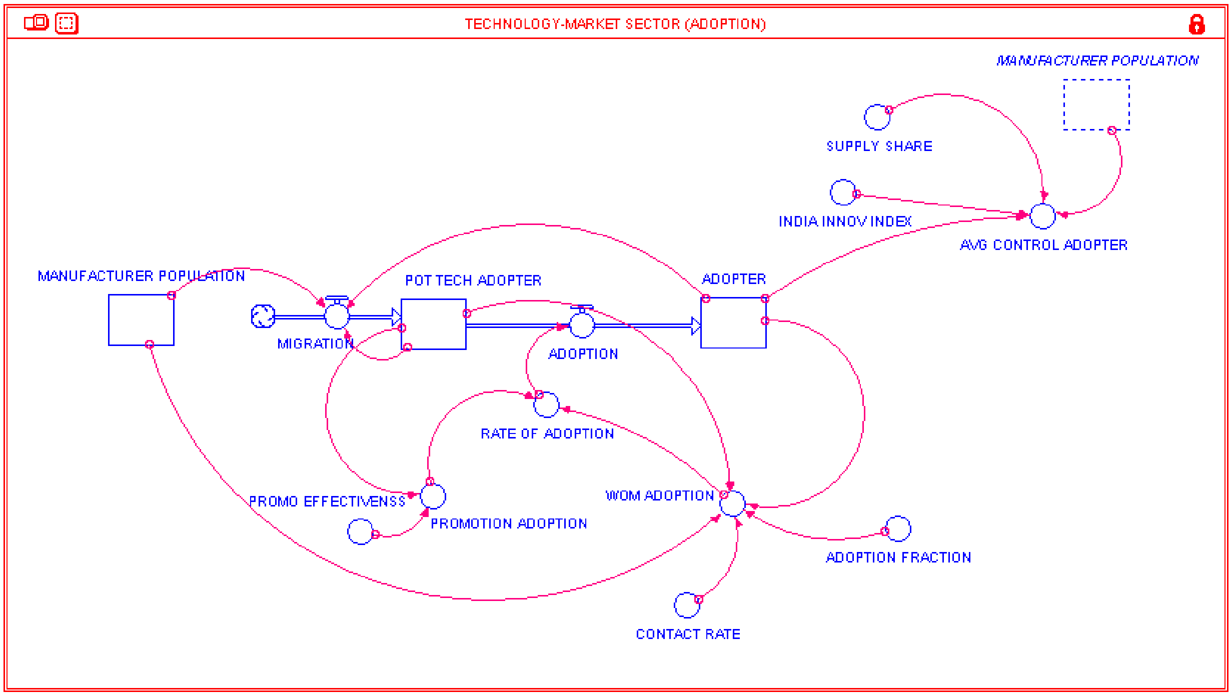
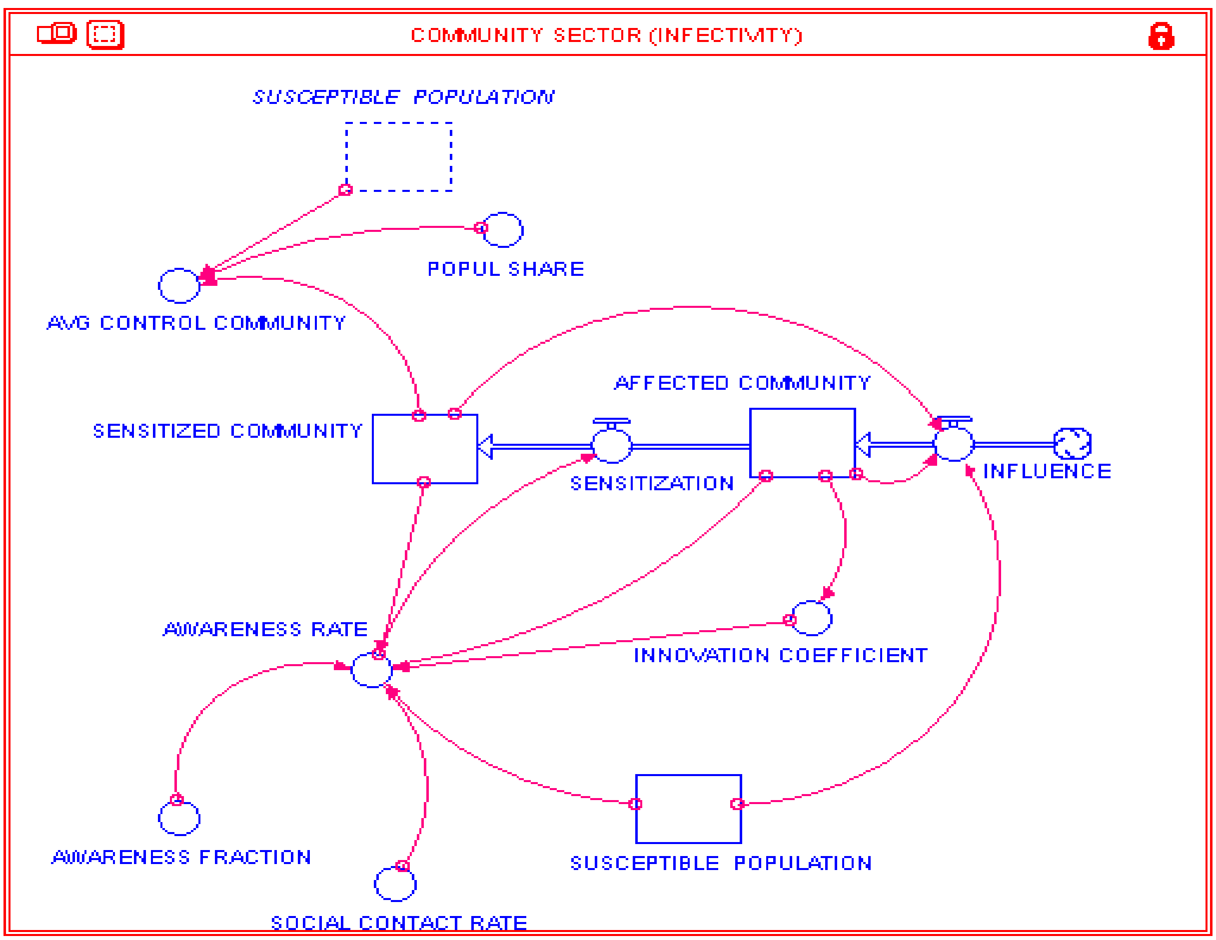
Appendix-I: Causal Loop Diagram of Base-Model & Revenue Effect

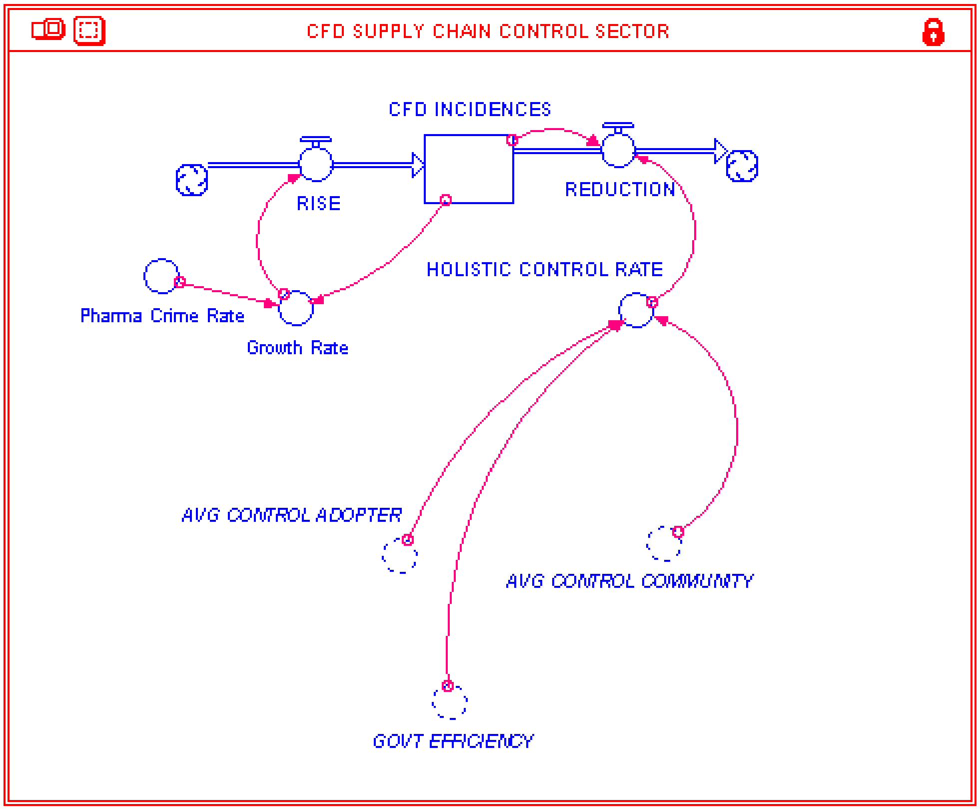


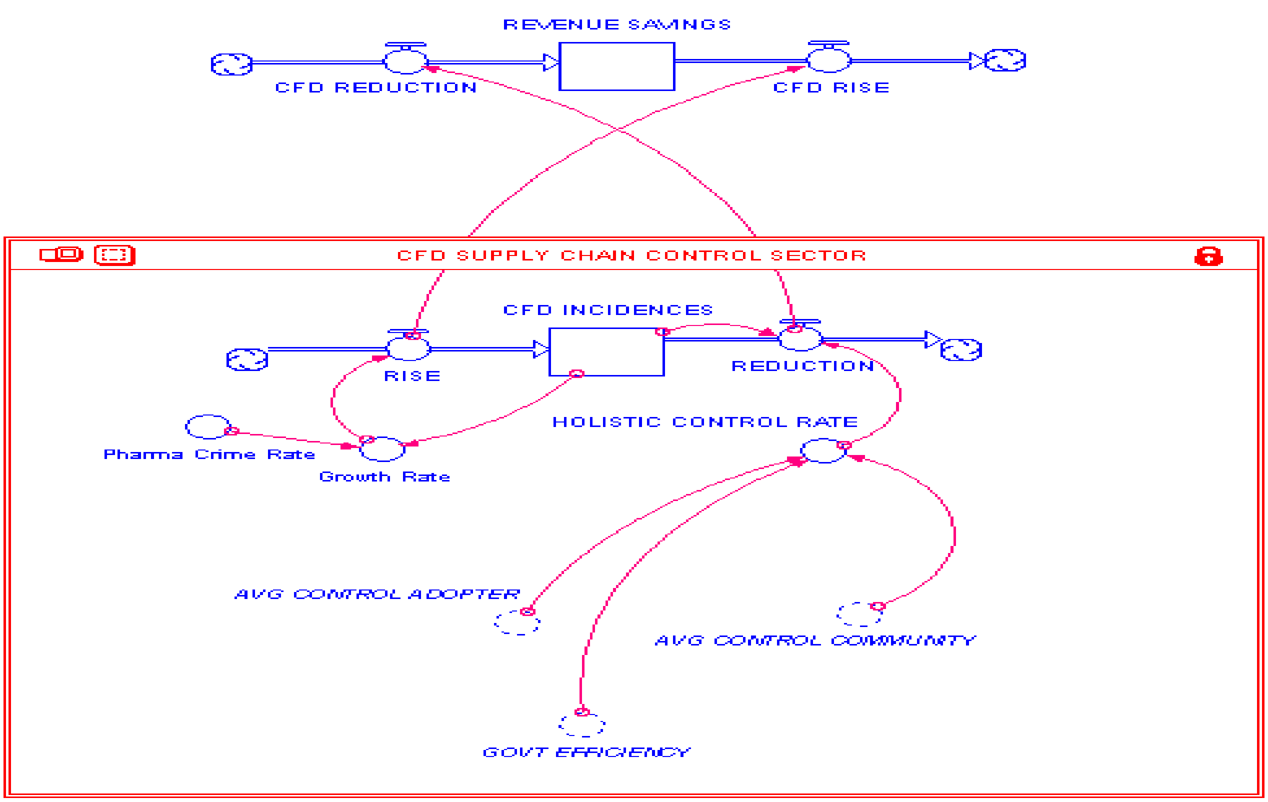
Appendix-II: SD Stock-Flow Base Models (Sector-wise):




TECHNOLOGY-MARKET SECTOR (ADOPTION)
MANUFACTURER POPULATION
SUPPLY SHARE
INDIA INNOV INDEX
AVG CONTROL ADOPTER
MANUFACTURER POPULATION
POT TECH ADOPTER
ADOPTER
MIGRATION
ADOPTION
RATE OF ADOPTION
WOM ADOPTION
PROMO EFFECTIVENSS
PROMOTION ADOPTION
ADOPTION FRACTION
CONTACT RATE


COMMUNITY SECTOR (INFECTIVITY)
SUSCEPTIBLE POPULATION
POPUL SHARE
AVG CONTROL COMMUNITY
AFFECTED COMMUNITY
SENSITIZED COMMUNITY
SENSITIZATION
INFLUENCE
AWARENESS RATE
INNOVATION COEFFICIENT
AWARENESS FRACTION
SUSCEPTIBLE POPULATION
SOCIAL CONTACT RATE


CFD SUPPLY CHAIN CONTROL SECTOR
CFD INCIDENCES
RISE
REDUCTION
HOLISTIC CONTROL RATE
Pharma Crime Rate
Growth Rate
AVG CONTROL ADOPTER
AVG CONTROL COMMUNITY
GOVT EFFICIENCY


REVENUE SAVINGS
CFD REDUCTION
CFD RISE
CFD SUPPLY CHAIN CONTROL SECTOR
CFD INCIDENCES
RISE
REDUCTION
HOLISTIC CONTROL RATE
Pharma Crime Rate
Growth Rate
AVG CONTROL ADOPTER
AVG CONTROL COMMUNITY
GOVT EFFICIENCY

Appendix-I1: System Equations (Sector-wise):

CFD SUPPLY CHAIN CONTROL SECTOR

CFD_INCIDENCES(t) = CFD_INCIDENCES(t - dt) + (RISE - REDUCTION) * dt

INIT CFD_INCIDENCES = 475

INFLOWS:

RISE = Growth_Rate

OUTFLOWS:

REDUCTION = CFD_INCIDENCES*HOLISTIC_CONTROL_RATE

Growth_Rate = CFD_INCIDENCES*Pharma_Crime_Rate

HOLISTIC_CONTROL_RATE = MEAN(AVG_CONTROL_ADOPTER,AVG_CONTROL_COMMUNITY,GOVT_EFFICIENCY)

Pharma_Crime_Rate = .32

COMMUNITY SECTOR (INFECTIVITY)

AFFECTED_COMMUNITY(t) = AFFECTED_COMMUNITY(t - dt) + (INFLUENCE - SENSITIZATION) * dt

INIT AFFECTED_COMMUNITY = SUSCEPTIBLE__POPULATION-ADOPTER

INFLOWS:

INFLUENCE = SUSCEPTIBLE__POPULATION-SENSITIZED_COMMUNITY-AFFECTED_COMMUNITY

OUTFLOWS:

SENSITIZATION = AWARENESS_RATE

CSR_CAPITAL(t) = CSR_CAPITAL(t - dt) + (BUILD) * dt

INIT CSR_CAPITAL = 0

INFLOWS:

BUILD = Earning*CSR_Invest_Fraction

SENSITIZED_COMMUNITY(t) = SENSITIZED_COMMUNITY(t - dt) + (SENSITIZATION) * dt

INIT SENSITIZED_COMMUNITY = 0

INFLOWS:

SENSITIZATION = AWARENESS_RATE

SUSCEPTIBLE__POPULATION(t) = SUSCEPTIBLE__POPULATION(t - dt)

INIT SUSCEPTIBLE__POPULATION = 850

AVG_CONTROL_COMMUNITY =
(SENSITIZED_COMMUNITY*POPUL_SHARE/SUSCEPTIBLE__POPULATION)+(SENSITIZED_COMMUNITY*POPUL_SHARE/SUSCEPTIBLE__POPULATION)*CSR_Invest_Fraction

AWARENESS_FRACTION = .020

AWARENESS_RATE =
SENSITIZED_COMMUNITY*AWARENESS_FRACTION*SOCIAL_CONTACT_RATE*AFFECTED_COMMUNITY/SUSCEPTIBLE__POPULATION+INNOVATION_COEFFICIENT

CSR_Invest_Fraction = .02

INNOVATION_COEFFICIENT = (AFFECTED_COMMUNITY*.16)

POPUL_SHARE = .7

SOCIAL_CONTACT_RATE = 100

GOVERNANCE SECTOR

Approve_New_License(t) = Approve_New_License(t - dt) + (Licensing - ReExamination - REJECTION) * dt

INIT Approve_New_License = 90000

INFLOWS:

Licensing = Avg_New_Issues

OUTFLOWS:

ReExamination = Rej_Fraction*Review_Rate

REJECTION = Review_Rate*(1-Rej_Fraction)

DI(t) = DI(t - dt) + (Hiring) * dt

INIT DI = 1200

INFLOWS:

Hiring = New_Hire_Rate

Drug_Mfrers(t) = Drug_Mfrers(t - dt) + (Addition - CLOSURE) * dt

INIT Drug_Mfrers = 10526

INFLOWS:

Addition = Drug_Mfrers*Launch_Rate

OUTFLOWS:

CLOSURE = Drug_Mfrers*Churn_Rate

ReEvaluated_License(t) = ReEvaluated_License(t - dt) + (ReEvaluation - EXPIRATION) * dt

INIT ReEvaluated_License = ReEvaluation

INFLOWS:

ReEvaluation = Revo_Fraction*Review_Rate2

OUTFLOWS:

EXPIRATION = Review_Rate3*(1-Expir_Fraction)

ReExamined_License(t) = ReExamined_License(t - dt) + (ReExamination - ReEvaluation - REVOCATION) * dt

INIT ReExamined_License = ReExamination

INFLOWS:

ReExamination = Rej_Fraction*Review_Rate

OUTFLOWS:

ReEvaluation = Revo_Fraction*Review_Rate2

REVOCATION = Review_Rate2*(1-Revo_Fraction)

TAX_REVENUE(t) = TAX_REVENUE(t - dt) + (Collection) * dt

INIT TAX_REVENUE = Collection

INFLOWS:

Collection = REVENUE_SAVINGS*Tax_Rate

UNATTACHED:

GOVT_EFFICIENCY = Regulation_Coeff*Supply_Control_Share

UNATTACHED:

UFM_Fraction = Approve_New_License*Crime_Rate

Avg_New_Issues = 5000

Avg_Review_Time = 5

Avg_Review_Time2 = 5

Avg_Review_Time3 = 5

Churn_Rate = .05

Crime_Rate = .25

Expir_Fraction = GOVT_EFFICIENCY

Launch_Rate = .10

Mfr_DI_ratio = 8.77

New_Hire_Rate = 200

Regulation_Coeff = (Drug_Mfrers/DI*Mfr_DI_ratio/100)+(Drug_Mfrers/DI*Mfr_DI_ratio/100)*Tax_Rate

Rej_Fraction = (UFM_Fraction*GOVT_EFFICIENCY)/UFM_Fraction

Review_Rate = Approve_New_License/Avg_Review_Time

Review_Rate2 = ReExamined_License/Avg_Review_Time2

Review_Rate3 = ReEvaluated_License/Avg_Review_Time3

Revo_Fraction = GOVT_EFFICIENCY

Supply_Control_Share = .75

Tax_Rate = .15

TOTAL__RESIDUAL_LICENSES = Approve_New_License+ReEvaluated_License+ReExamined_License

TECHNOLOGY-MARKET SECTOR (ADOPTION)

ADOPTER(t) = ADOPTER(t - dt) + (ADOPTION) * dt

INIT ADOPTER = 0

INFLOWS:

ADOPTION = RATE_OF_ADOPTION

Expected_Investment(t) = Expected_Investment(t - dt) + (INVEST) * dt

INIT Expected_Investment = 0

INFLOWS:

INVEST = REVENUE_SAVINGS*R&_D_Intensity_Fraction

MANUFACTURER_POPULATION(t) = MANUFACTURER_POPULATION(t - dt)

INIT MANUFACTURER_POPULATION = 250

POT_TECH_ADOPTER(t) = POT_TECH_ADOPTER(t - dt) + (MIGRATION - ADOPTION) * dt

INIT POT_TECH_ADOPTER = MANUFACTURER_POPULATION-ADOPTER

INFLOWS:

MIGRATION = MANUFACTURER_POPULATION-ADOPTER-POT_TECH_ADOPTER

OUTFLOWS:

ADOPTION = RATE_OF_ADOPTION

ADOPTION_FRACTION = .554

AVG_CONTROL_ADOPTER =
(ADOPTER*INDIA_INNOV_INDEX*SUPPLY_SHARE/MANUFACTURER_POPULATION)+(ADOPTER*INDIA_INNOV_INDEX*SUPPLY_SHARE/MANUFACTURER_POPULATION)*R&_D_Intensity_Fraction

CONTACT_RATE = 10

INDIA_INNOV_INDEX = .9

PROMO_EFFECTIVENSS = .0003

PROMOTION_ADOPTION = POT_TECH_ADOPTER*PROMO_EFFECTIVENSS

R&_D_Intensity_Fraction = .05

RATE_OF_ADOPTION = PROMOTION_ADOPTION+WOM_ADOPTION

SUPPLY_SHARE = .7

WOM_ADOPTION =
POT_TECH_ADOPTER*ADOPTION_FRACTION*CONTACT_RATE*ADOPTER/MANUFACTURER_POPULATION

Profit(t) = Profit(t - dt) + (Earning) * dt

INIT Profit = 0

INFLOWS:

Earning = Profit_Margin

REVENUE_SAVINGS(t) = REVENUE_SAVINGS(t - dt) + (CFD_REDUCTION - CFD_RISE) * dt

INIT REVENUE_SAVINGS = 0

INFLOWS:

CFD_REDUCTION = REDUCTION

OUTFLOWS:

CFD_RISE = RISE

Profit_Margin = REVENUE_SAVINGS*.30