



1 Article

2 **Game Analysis on the Evolution of Decision-making**
3 **of Vaccine Manufacturing Enterprises under the**
4 **Government Regulation Model**5 **Na Zhang^{1,2}, Yingjie Yang³, Xiaodong Wang^{4*}, Xinfeng Wang⁵**

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12 **Abstract:** The harm caused by defective vaccines to human health and social stability is
13 immeasurable. Aiming at the government's supervision of vaccine market, an evolutionary game
14 model is constructed to analyze the quality of supervision and the key factors in the dynamic
15 interaction between government departments and vaccine manufacturers under different
16 supervision modes in vaccine manufacturing process. The results show that: (1) Severe
17 punishment by government regulatory authorities, and increased costs of rectification after
18 investigation and handling of involuntary behaviors of vaccine enterprises can effectively prevent
19 involuntary behaviors of vaccine enterprises. (2) In the early stage of the game, the success rate of
20 the government's efficient supervision will make the vaccine enterprises continuously
21 self-discipline; when the vaccine market is relatively stable, the government's supervision
22 departments tend to be more conducive to passive supervision. (3) The success rate of government
23 regulatory departments and the probability of third-party reporting play a great role in promoting
24 the self-discipline of enterprises. (4) The power of government and regulation are conducive to
25 promoting the active supervision of the government regulatory authorities but corruption of
26 government and awareness of people are the different. Once the phenomenon of vaccine
27 enterprises' non-discipline increases, the government regulation must change from passive
28 regulation to active regulation. Therefore, the government should implement different measures
29 according to the characteristics of each period in the manufacturing process to effectively prevent
30 problematic vaccines. The conclusions and policy recommendations are significant for addressing
31 the issue of insufficient self-discipline of vaccine manufacturers.

32 **Keywords:** government regulation; defective vaccines; severe punishment; evolutionary game

33

34 **1. Introduction**

35 For more than two thousand years, human being has been searching for ways to fight all kinds
36 of infectious diseases. Vaccine immunization is an economical and effective way to curb infectious
37 diseases, and many diseases have been effectively controlled by vaccine immunization [1].
38 However, in recent years, "defective vaccines" incidents have emerged one after another in Anhui
39 province, Jiangsu province, Dalian city, Hebei Province, Shanxi province, Shandong province,
40 Changchun city, Wuhan city and other places in China, causing people's panic about the safety of
41 vaccines [2-4], and resulting in an unprecedented trust crisis for vaccine enterprises. When the
42 shadow of the milk powder incident and the food safety incident has not been completely removed,
43 "defective vaccines" incident will undoubtedly add insult **to the injury**. As the most economical and
44 effectual **medicines** for the prevention and control of infectious diseases, **vaccines are of great**

45 strategic significance for individual health, social public health and social stability [5]. How to
46 supervise vaccine enterprises more effectively has become the focus for all sectors of society [6].
47 Government regulation is the primary approach to solve vaccine safety problems [7].

48 In recent years, many experts and scholars have studied vaccine regulatory events, regulatory
49 approaches and regulatory models. Vaccine safety research is an important component of public
50 health program [8-11]. Some scholars discussed the mutual restriction and interaction between the
51 government and drug enterprises in the game process in order to find the reasons for the existence
52 of unsafe drug incidents and put forward countermeasures [12]. Literature [13] and [14] discussed
53 the game relationship between the government and production enterprises, local governments and
54 social supervision, and then put forward corresponding countermeasures from the aspects of
55 strengthening supervision, clarifying the relationship between regulatory departments and local
56 governments, and promoting the application of new technologies. Literature [15-17] argued that the
57 government should not only adopt severe punishment for drug safety supervision, but also
58 improve government supervision technology, advocate diversified regulatory bodies, and pay
59 attention to enterprise self-control and industry self-discipline. Literature [18], using the analytical
60 method of regulation theory, believed that drug regulatory authorities should strengthen
61 supervision of drug production process, increase punishment for violations, reduce the cost of
62 quality regulation, and improve the accountability for malfeasance and irresponsibility. Some
63 scholars mainly studied regulatory agencies, and found that the media and the public supervision
64 were an effective complement to the government regulation. Literature [19-22] put forward that
65 strengthening media supervision and penalties can raise the level of drug safety in China by
66 analyzing the game relationship between the governments, drug regulatory department, and the
67 social public.

68 At present, scholars' research on government regulation and vaccine quality and safety
69 supervision is still insufficient. Firstly, with the development of society and the continuous
70 awakening and improvement of public safety awareness, it is imperative for third-party regulatory
71 agencies to participate in vaccine quality and safety supervision. The studies on third-party
72 regulatory agencies participating in vaccine quality and safety have not received enough attention
73 so far. Secondly, the government's supervision of vaccine manufacturers pays more attention to the
74 difference between active supervision and passive supervision instead of that between supervision
75 and non-supervision before. Thirdly, in the existing game models, the government supervision
76 department is regarded as a rational economic man who pursues the maximization of his own
77 interests. This assumption is not consistent with the actual situation. In reality, the government
78 supervision department aims at minimizing social losses. Therefore, under the assumption of
79 bounded rationality of government supervisory authorities and vaccine manufacturers, this paper
80 will analyze the equilibrium results by applying evolutionary game theory to vaccine quality and
81 safety supervision. It is supposed to make the enterprise as self-disciplined as possible through the
82 joint efforts of the government and the third party, and provides the basis for the government to
83 formulate and improve various prevention policies and measures.

84 There is a famous "broken window effect" in criminal psychology. If someone breaks the
85 window glass of a building and the window is not repaired in a timely manner, others may be
86 encouraged by some demonstration to break more windows [23-26]. Over time, these broken
87 windows create a sense of disorder, and crime flourishes in an atmosphere of public indifference.
88 "Defective vaccines" of vaccine manufacturers are like cracked windows. Once one enterprise
89 manufactures "defective vaccines" based on its own interests, if the government or the public fails
90 to supervise and find out, other enterprises will follow suit and eventually cause "defective
91 vaccines" to flourish. Vaccine regulation is a typical non-cooperative game problem. As an
92 autonomous economic entity, the choice of vaccine enterprises seems rational on the surface, but it
93 may not be reasonable from the perspective of the whole society. The addition of external
94 intervention mechanism will effectively promote the system to achieve the optimal solution.
95 Therefore, participation, coordination and guidance of the government and the public are essential
96 in solving the problem of vaccine regulation. Evolutionary game theory is a method that combines

97 game and dynamic evolution, which can study the stable structure of the game system and the
 98 process of strategy selection of behavior subjects in the evolutionary process by introducing
 99 dynamic mechanism [27-30]. The basic idea is the case that in a group of a certain size, game players
 100 are not super rational players, and it is difficult to find the optimal equilibrium point in a single
 101 game, but multiple execution of the game can identify an equilibrium through trial and correction.
 102 Thus, the best strategy for game players is to imitate and improve their previous strategies.
 103 Through long-term imitation and improvement, all game players will tend to reach a definite stable
 104 strategy [31-36].

105 Under the mode of government supervision, there are many factors affecting the behavior of
 106 drug (food) enterprises, and many scholars have given different opinions. These research results
 107 focus on the impact of external and internal factors on their decision-making. This paper searches
 108 the fields of "drug regulation" and "food regulation" from Google academic and China HowNet,
 109 and the relevant summary is shown in Table 1:

110 **Table 1.** Influencing factors of drug (food) enterprise behavior decision under government
 111 supervision mode.

Scholars (Year)	Influencing factors
Song Yan (2009) ^[37]	Income from qualified drugs and fake drugs
Cao Jiantao (2018) ^[13]	additional benefit, benefit of inaction, positive utility, cost of implementation, government punishment
Song Yan (2016) ^[15]	benefits of qualified drugs, safety costs, benefits of fake and inferior drugs, accident handling costs, government fines
Fang Yu (2010) ^[16]	regulatory probability, regulatory cost, safety accident probability, violation cost, disposal cost, discount factor, social loss, penalty amount
Yan Jianzhou (2015) ^[18]	regulatory cost, safety cost, penalty, legal liability cost, social cost, reputation loss
Liu Sukun (2011) ^[38]	regulatory costs, normal earnings, excess earnings, penalties
Liu Sukun (2012) ^[39]	supervision cost, reputation loss, degree of supervision, illegal earnings, punishment, enterprise earnings, probability of illegal operation, probability of legal operation, probability of public report and verification of earnings
Jiang Shubo (2009) ^[40]	control cost, penalty amount, compensation amount, regulatory probability, disguised cost, income from superior goods, income from inferior goods, excess income
Zhao, L(2018) ^[41]	government regulations, product output, product revenue, regulatory cost

112 According to the research results in recent years, it can be seen that the cost of government
 113 supervision, social benefits, benefits of drug (food) enterprises, penalties for non-cooperation,
 114 probability of public or third-party supervision are the core factors that affect the behavioral
 115 decisions of drug (food) enterprises. Therefore, based on the existing research costs, this paper took
 116 these factors as the main parameters to construct the evolutionary game model for behavioral
 117 decisions of vaccine manufacturers under different government regulatory modes.

118 The main problems to be solved in this paper are as follows:

119 (1) This paper analyzes the competition and cooperation relationship and game strategy of the
 120 behavior decision-making of vaccine enterprises under the supervision of the government, and

121 considers the third-party supervision as an environmental factor. Combined with the analysis of
 122 variables, it discusses the conditions that affect the evolution of the interaction between vaccine
 123 manufacturers and the government towards the direction of cooperation;

124 (2) Based on the premise of bounded rationality, the decision-making process of vaccine
 125 manufacturing enterprises is regarded as a dynamic process of gradual learning. The evolutionary
 126 game model of government and vaccine manufacturing enterprises is constructed. The key factors
 127 affecting the game strategy of both sides are found by solving the model;

128 (3) By analyzing the equilibrium point and stability of the evolutionary game between the
 129 government and vaccine manufacturers, the choice of the stable strategy of the two is studied. Then,
 130 through the changes of government punishment, third-party report and other parameters, using
 131 MATLAB simulation analysis, the evolution trend of the game of the behavior decision-making of
 132 vaccine enterprises is investigated under different government supervision modes, and reasonable
 133 countermeasures and suggestions are put forwarded to provide decision-making basis for
 134 government departments.

135 2. Methods

136 2.1. Model assumptions

137 Hypothesis 1: Under different regulatory models, the game process between vaccine
 138 manufacturers and the government is also dynamic, and the strategies of both sides of the game can
 139 be adjusted at any time before reaching the evolutionary game equilibrium.

140 Hypothesis 2: Bribery and rent-seeking behaviors between government departments and
 141 vaccine manufacturers do not exist.

142 Hypothesis 3: In order to avoid the risk of penalties and ensure the maximization of benefits,
 143 the vaccine manufacturer will adopt the self-disciplined behavior to produce qualified vaccine with
 144 a certain probability x , so the probability of non-self-disciplined behavior is $1-x$. Due to the
 145 regulatory costs of the government, the supervision of vaccine manufacturers can only take a
 146 certain probability to be carried out in active supervision strategy, and the probability of passive
 147 supervision strategy is $1-y$.

148 2.2. Model symbol description

149 In this paper, the profit and loss variables between government regulatory authorities and
 150 vaccine manufacturers are set as follows:

151
 152 The government regulatory authorities need to invest certain human, material and financial
 153 resources in the active supervision of vaccine production enterprises. This investment is affected by
 154 government power and regulations, and the resulting cost of active supervision is $\frac{C_{G1}}{\pi}$ (π is the
 155 strict coefficient of government rights and regulations). Relevant research shows that the more strict
 156 the government's rights and regulations are, the lower the regulatory cost will be. $\frac{C_{G2}}{\psi}$ is the cost
 157 of passive supervision of government departments, which is related to the government's corruption
 158 of government and awareness of people. Relevant research shows that the stronger the corruption
 159 of government and awareness of people, the lower the cost of passive supervision of the
 160 government. The difference between operational supervision and passive regulation lies in the fact
 161 that passive supervision refers to the supervision conducted after the report from the third party
 162 regulatory agency or the public is received. Therefore, the cost of government passive regulation is
 163 much higher than that of the active supervision cost, namely, $\frac{C_{G2}}{\psi} > \frac{C_{G1}}{\pi} > 0$.

164 At the same time, active supervision will reduce non-self-disciplined behaviors of vaccine
 165 enterprises, which can be restrained from the source and effectively decrease social losses. Passive

166 supervision is a type of behavior regulation after the vaccine manufacturers choose
 167 non-self-discipline strategy, which usually causes some losses to the society. In the case of active
 168 supervision by government supervision departments, the success rate of their supervision is
 169 expressed by α ($0 < \alpha \leq 1$). In the case of passive supervision by corresponding government
 170 departments, the success rate is expressed by β ($0 < \beta \leq 1$), and $0 < \alpha < \beta \leq 1$.

171 Assume that λ is the probability of being reported by the third party if the enterprise is not
 172 self-disciplined. The benefits obtained by vaccine production enterprises from the self-discipline
 173 and non-self-discipline strategy are R_{v1} and R_{v2} respectively, where $R_{v2} > R_{v1}$. If the enterprise is
 174 not self-disciplined, the enterprise will suffer the penalty and reputation loss F_{v1} . Assume the
 175 penalty coefficient $\mu = \frac{F_{v1}}{R_{v2}}$, and $\mu > 1$. If the enterprise produces unqualified products and the
 176 profit is higher than the possible penalty, then the government supervision is meaningless. Assume
 177 F_{v2} is the rectification cost to be paid by the vaccine manufacturer after the non-self-disciplined
 178 behavior is detected and the disposal cost to eliminate the adverse impact on the society, C_v is the
 179 inspection cost of the vaccine manufacturers for cooperating with government supervision, and if
 180 the non-self-discipline of the vaccine manufacturer is discovered by the regulatory authorities, the
 181 government regulatory authorities will gain the benefits R_G .

182 The game payoff matrix of the two players is given in Table 2.

Table 2. Game payoff matrix.

		Government regulatory authority	
		Active regulation (y)	Passive regulation ($1 - y$)
vaccine manufac turers	Self-discipline (x)	$R_{v1} - C_v, -\frac{C_{G1}}{\pi}$	$\lambda(R_{v1} - C_v) + (1 - \lambda)R_{v1}, \lambda(-\frac{C_{G2}}{\psi})$
	non-self-discipline ($1 - x$)	$(1 - \alpha)R_{v2} - \alpha(F_{v1} + F_{v2}) - C_v, \alpha R_G - \frac{C_{G1}}{\pi}$	$\lambda[(1 - \beta)R_{v2} - \beta(F_{v1} + F_{v2}) - C_v] + (1 - \lambda)R_{v2}, \lambda[\beta(R_G - \frac{C_{G2}}{\psi}) + (1 - \beta)(-\frac{C_{G2}}{\psi})]$

184 **3. Results**

185 3.1. Duplicate dynamic equation construction

186 According to Malthusian equation, the expected benefits of vaccine manufacturers for
 187 self-discipline strategy E_1^1 and non-self-discipline strategy E_1^2 , and the average benefits \bar{E}_1 are as
 188 follows.

189
$$E_1^1 = y(R_{v1} - C_v) + (1 - y)[\lambda(R_{v1} - C_v) + (1 - \lambda)R_{v1}] \tag{1}$$

190
$$E_1^2 = y[(1 - \alpha)R_{v2} - \alpha(F_{v1} + F_{v2}) - C_v] + (1 - y)\{\lambda[(1 - \beta)R_{v2} - \beta(F_{v1} + F_{v2}) - C_v] + (1 - \lambda)R_{v2}\} \tag{2}$$

191
$$\bar{E}_1 = xE_1^1 + (1 - x)E_1^2 \tag{3}$$

192 The replication dynamic equation selected by vaccine manufacturers is as follows.

193
$$F(x) = \frac{dx}{dt} = x(E_1^1 - \bar{E}_1) = x(1 - x)\{y[(R_{v2} + F_{v1} + F_{v2})(\alpha - \beta\lambda)] + R_{v1} - R_{v2} + \beta\lambda(R_{v2} + F_{v1} + F_{v2})\} \tag{4}$$

195 Similarly, the E_2^1, E_2^2 and \bar{E}_2 of government regulatory departments are as follows:

$$E_2^1 = x\left(-\frac{C_{G1}}{\pi}\right) + (1-x)\left(\alpha R_G - \frac{C_{G1}}{\pi}\right) \tag{5}$$

$$E_2^2 = x\lambda\left(-\frac{C_{G2}}{\psi}\right) + (1-x)\left\{\lambda\left[\beta\left(R_G - \frac{C_{G2}}{\psi}\right)\right] + (1-\beta)\left(-\frac{C_{G2}}{\psi}\right)\right\} \tag{6}$$

$$\bar{E}_2 = yE_2^1 + (1-y)E_2^2 \tag{7}$$

Therefore, the replication dynamic equation of active supervision chosen by government regulatory departments is as follows.

$$G(y) = \frac{dy}{dt} = y(E_2^1 - \bar{E}_2) = y(1-y)\left[(\alpha - \beta\lambda)R_G(1-x) + \frac{\lambda C_{G2}}{\psi} - \frac{C_{G1}}{\pi}\right] \tag{8}$$

Equation (4) and equation (8) constitute a two-dimensional dynamic system (I).

3.2. Stability analysis of equilibrium point

Proposition 1 For the two-dimensional dynamic system (I), there must be $2^2 = 4$ pure strategy equilibrium points, that is (1, 1), (1, 0), (0, 1), (0, 0) respectively. At the same time, there may be an equilibrium point of a mixed strategy (x^*, y^*) , and there is $x^* \in [0, 1], y^* \in [0, 1]$.

$$x^* = 1 - \frac{\lambda\pi C_{G2} - \psi C_{G1}}{\pi\psi(\beta\lambda - \alpha)R_G} = M, y^* = \frac{R_{V1} - R_{V2} + \beta\lambda(R_{V2} + F_{V1} + F_{V2})}{(R_{V2} + F_{V1} + F_{V2})(\beta\lambda - \alpha)} = N$$

Proof: For the above two dimensional dynamical system, when $x = 0, x = 1, y = 0$ or $y = 1$, there is $F(x) = 0, G(y) = 0$. Therefore, (1,1), (1,0), (0,1), (0,0) are the equilibrium points of the system. When $0 < x < 1, 0 < y < 1$, if $y[(R_{V2} + F_{V1} + F_{V2})(\alpha - \beta\lambda)] + R_{V1} - R_{V2} + \beta\lambda(R_{V2} + F_{V1} + F_{V2}) = 0$, and $\pi\psi(\alpha - \beta\lambda)R_G(1-x) + \lambda\pi C_{G2} - \psi C_{G1} = 0$, then there is $F(x) = 0, G(y) = 0$. The possible equilibrium point of the two-dimensional dynamic system (I) (x^*, y^*) can be gotten by solving the equations (9), which is shown as follows.

$$\begin{cases} y[(R_{V2} + F_{V1} + F_{V2})(\alpha - \beta\lambda)] + R_{V1} - R_{V2} + \beta\lambda(R_{V2} + F_{V1} + F_{V2}) = 0 \\ \pi\psi(\alpha - \beta\lambda)R_G(1-x) + \lambda\pi C_{G2} - \psi C_{G1} = 0 \end{cases} \tag{9}$$

According to Friedman (1998) [28], the equilibrium points can be evolutionary stable strategy (ESS for short) after the stability test, that is, the stability of the equilibrium can be judged by local stability of Jaconbian matrix.

The Jacobian matrix of the system is:

$$J = \begin{bmatrix} \frac{\partial G(x)}{\partial x} & \frac{\partial G(x)}{\partial y} \\ \frac{\partial F(y)}{\partial x} & \frac{\partial F(y)}{\partial y} \end{bmatrix} = \begin{bmatrix} a_{11} & a_{12} \\ a_{21} & a_{22} \end{bmatrix}$$

where

$$a_{11} = (1-2x)\{y[(R_{V2} + F_{V1} + F_{V2})(\alpha - \beta\lambda)] + R_{V1} - R_{V2} + \beta\lambda(R_{V2} + F_{V1} + F_{V2})\}$$

$$a_{12} = x(1-x)(R_{V2} + F_{V1} + F_{V2})(\alpha - \beta\lambda)$$

$$a_{21} = y(1-y)\pi\psi(\beta\lambda - \alpha)R_G$$

225 $a_{22} = (1 - 2y)[\pi\psi(\alpha - \beta\lambda)R_G(1 - x) + \lambda\pi C_{G2} - \psi C_{G1}]$

226 If both of the following conditions are satisfied, the equilibrium point of the replicated
 227 dynamic equation is the evolutionary stability strategy (ESS).

228 (1) $trJ = a_{11} + a_{22} < 0$ (trace condition);

229 (2) $\det J = \begin{vmatrix} a_{11} & a_{12} \\ a_{21} & a_{22} \end{vmatrix} = a_{11}a_{22} - a_{12}a_{21} > 0$ (Jacobian condition)

230 From the above calculated data, it can be seen that $a_{11} + a_{22} = 0$, and there are non-trace
 231 conditions at the local equilibrium point (M, N) , so the equilibrium point is definitely not the
 232 evolutionary stability strategy (ESS) of the system. The remaining four equilibrium points are
 233 discussed below. Depending on the values of the determinant and trace of the Jacobian matrix, the
 234 local stability of the equilibrium points can be determined. The results are shown in Table 3:

235 **Table 3.** Determinant values and trace of local equilibrium points.

Local equilibrium points	a_{11}	a_{12}	a_{21}	a_{22}
(0,0)	$R_{V1} - R_{V2} + \beta\lambda(R_{V2} + F_{V1} + F_{V2})$	0	0	$\pi\psi(\alpha - \beta\lambda)R_G + \lambda\pi C_{G2} - \psi C_{G1}$
(0,1)	$R_{V1} - R_{V2} + \alpha(R_{V2} + F_{V1} + F_{V2})$	0	0	$-(\alpha - \beta\lambda)R_G + \lambda\pi C_{G2} - \psi C_{G1}$
(1,0)	$-[R_{V1} - R_{V2} + \beta\lambda(R_{V2} + F_{V1} + F_{V2})]$	0	0	$\lambda\pi C_{G2} - \psi C_{G1}$
(1,1)	$-[R_{V1} - R_{V2} + \alpha(R_{V2} + F_{V1} + F_{V2})]$	0	0	$-(\lambda\pi C_{G2} - \psi C_{G1})$
(x^*, y^*)	0	M	N	0

236 **Proposition 2** Assume that $\varepsilon = \frac{R_{V2} - R_{V1}}{R_{V2} + F_{V1} + F_{V2}}$ is the ratio of profit to loss of vaccine
 237 manufacturers for their non-self-discipline strategies, where $R_{V2} - R_{V1}$ is the excess return, and
 238 $R_{V2} + F_{V1} + F_{V2}$ is the loss of vaccine manufacturers for their non-self-discipline. Therefore, from
 239 the perspective of economics, it can be regarded that ε is the ratio of profit to loss for their
 240 non-self-discipline strategies.

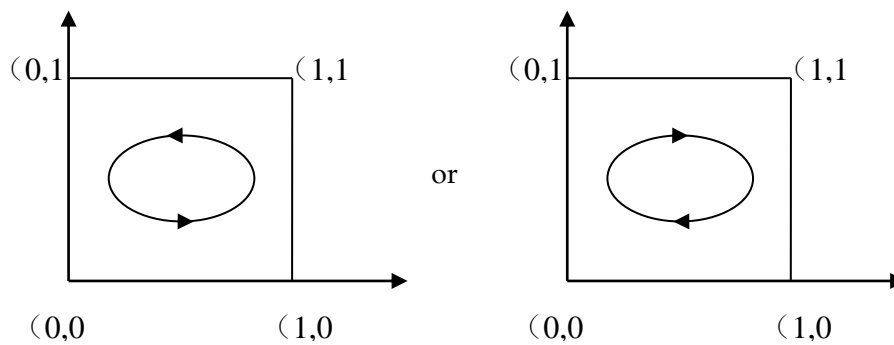
241 (1) When $\alpha > \varepsilon > \beta\lambda > 0$ or $0 < \alpha < \varepsilon < \beta\lambda$, that is, when the ratio of benefit to loss of the
 242 vaccine manufacturers for their non-self-discipline is between the probabilities of success of two
 243 different regulatory approaches, it is a transition period of the game between the two sides, the
 244 two-dimensional dynamic system (I) has no ESS, and its evolutionary path is a closed circle of
 245 infinite cycles (as shown in Figure 1a).

246 (2) If $\varepsilon > \beta\lambda > \alpha > 0$ and $0 < \lambda\pi C_{G2} < \psi C_{G1}$, that is, the profit loss ratio of
 247 non-self-discipline behavior strategy of vaccine manufacturers is greater than the probability of
 248 success of the two different regulatory approaches. Vaccine manufacturers will eventually choose

249 non-self-discipline. When conducting active supervision, government regulatory departments need
 250 to invest more human resources for supervision and more financial resources to develop and
 251 purchase high-end technologies and equipment. Therefore, the cost of passive supervision is less
 252 than that of active supervision. At this point, the behavioral strategy of two players is
 253 (non-self-discipline, passive supervision), then (0,0) is an ESS of the two-dimensional dynamic
 254 system (I), and its evolutionary path is shown in Figure 1b. Similarly, when $0 < \varepsilon < \beta\lambda < \alpha$ and
 255 $0 < \lambda\pi C_{G2} < \psi C_{G1}$, the behavioral strategy of two players is (self-discipline, passive supervision),
 256 then (1,0) is an ESS of the two-dimensional dynamic system (I), and its evolutionary path is shown
 257 in Figure 1c.

258 (3) If $\varepsilon > \alpha > \beta\lambda > 0$ and $0 < \psi C_{G1} < \lambda\pi C_{G2}$, that is, the profit loss ratio of
 259 non-self-discipline behavior strategy of vaccine manufacturers is greater than the probability of
 260 success of the two different regulatory approaches. The government supervision department
 261 chooses active supervision strategy according to the principle of interests maximization, that is, the
 262 benefits gotten by the government regulators are greater than the gains from passive regulation.
 263 The behavioral strategy of two players is (non-self-discipline, active supervision), then (0,1) is an
 264 ESS of the two-dimensional dynamic system (I), and its evolutionary path is shown in Figure 1d.
 265 Similarly, when $0 < \varepsilon < \alpha < \beta\lambda$ and $0 < \psi C_{G1} < \lambda\pi C_{G2}$, the behavioral strategy of two
 266 players is (self-discipline, active supervision), then (1,1) is an ESS of the two-dimensional dynamic
 267 system (I), and its evolutionary path is shown in Figure 1e.

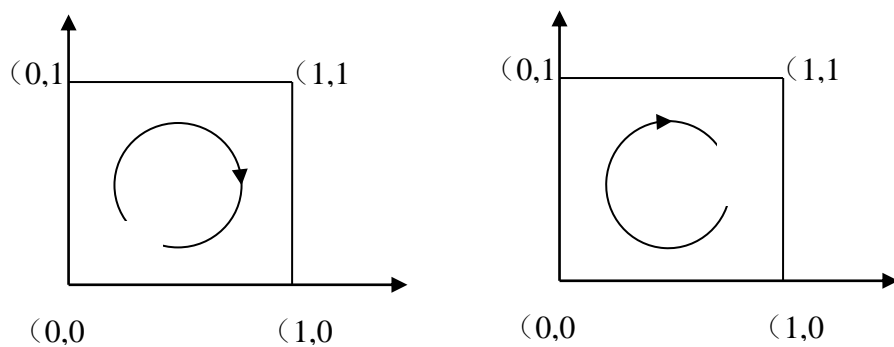
268



269

Figure 1a

270



271

Figure 1b

Figure 1c

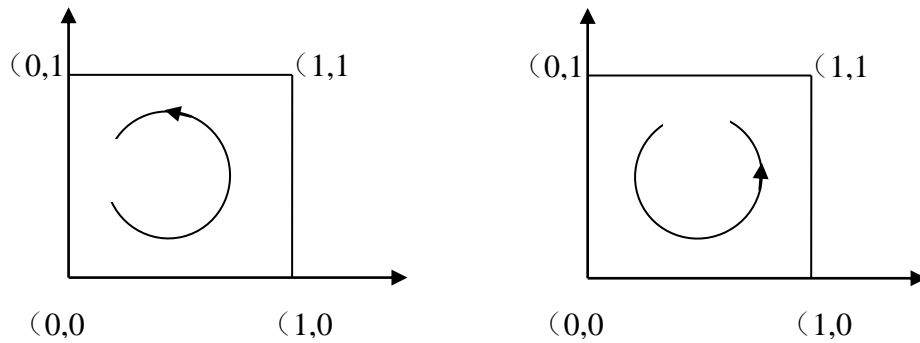


Figure 1d

Figure 1e

It is shown that the local stability can be determined by the determinant and trace values of the Jacobian matrix of the two-dimensional dynamical system (I).

Depending on the above analysis, the two-dimensional dynamic system (I) in the case (2) and (3) in proposition 2 has corresponding evolutionary stability strategy. In particular, when $\alpha > \varepsilon > \beta\lambda > 0$ or $0 < \alpha < \varepsilon < \beta\lambda$, the two-dimensional dynamical system (I) has no corresponding evolutionary stability strategy. According to the local stability analysis method of the Jacobian matrix, the stability analysis of its equilibrium point is carried out. The results are shown in Table 4.

Table 4. Stability analysis equilibrium points when $\alpha > \varepsilon > \beta\lambda > 0$ or $0 < \alpha < \varepsilon < \beta\lambda$.

Local equilibrium points	det J	tr J	Results
(0,0)	−	uncertain	Saddle point
(0,1)	−	uncertain	Saddle point
(1,0)	−	uncertain	Saddle point
(1,1)	−	uncertain	Saddle point
(x^*, y^*)	+	0	Center point

Under the above assumptions, the evolutionary game model has four saddle points and a central point, which are (1,1), (1,0), (0,1), (0,0), and

$$\left(1 - \frac{\lambda\pi C_{G2} - \psi C_{G1}}{\pi\psi(\beta\lambda - \alpha)R_G}, \frac{R_{V1} - R_{V2} + \beta\lambda(R_{V2} + F_{V1} + F_{V2})}{(R_{V2} + F_{V1} + F_{V2})(\beta\lambda - \alpha)} \right)$$

According to the solution of the model, the characteristic roots corresponding to the point (x^*, y^*) are a pair of pure virtual roots. Based on the research of Taylor [42, 43], they are stable equilibrium points of the system, but not asymptotically stable points. The evolution trajectory of the system is a closed-loop curve around the equilibrium point (x^*, y^*) . That is to say, when $\alpha > \varepsilon > \beta\lambda > 0$, or when $0 < \alpha < \varepsilon < \beta\lambda$, the behavioral strategy choice of vaccine manufacturers and government regulators is to keep changing around the equilibrium point (x^*, y^*) , the system will not automatically stabilize to the equilibrium point. Therefore, the equilibrium point (x^*, y^*) is not the evolutionary stabilization strategy of the two-dimensional dynamic system (I).

Proposition 3 When the profit-loss ratio of the non-self-disciplined behavior strategy of the vaccine manufacturer and the probability of success of the two different regulatory approaches meet the conditions $\alpha > \varepsilon > \beta\lambda > 0$ or $0 < \alpha < \varepsilon < \beta\lambda$, the convergence of the system depends

297 on the values of other parameters. According to the replication dynamic equation of the
 298 two-dimensional dynamic system (I) and the evolution phase diagram of figure 1a, it can be seen
 299 that when the value of other parameters is fixed, the lower the proportion of self-discipline of
 300 vaccine manufacturers is, the more likely government regulatory authorities are to choose the
 301 behavioral strategy of active supervision. Similarly, the higher the proportion of active supervision
 302 by government regulatory departments, the more likely vaccine manufacturers are to choose the
 303 self-discipline strategy.

304 Proof: The two-dimensional dynamical system (I) of the duplicate dynamic equation is as
 305 follows.

306
$$F(x) = \frac{dx}{dt} = x(E_1^1 - \bar{E}_1) = x(1-x)\{y[(R_{V2} + F_{V1} + F_{V2})(\alpha - \beta\lambda)] + R_{V1} - R_{V2} + \beta\lambda(R_{V2} + F_{V1} + F_{V2})\}$$

307
$$G(y) = \frac{dy}{dt} = y(E_2^1 - \bar{E}_2) = y(1-y)[(\alpha - \beta\lambda)R_G(1-x) + \frac{\lambda C_{G2}}{\psi} - \frac{C_{G1}}{\pi}]$$

308 It can be known that, when $y < \frac{R_{V1} - R_{V2} + \beta\lambda(R_{V2} + F_{V1} + F_{V2})}{(R_{V2} + F_{V1} + F_{V2})(\beta\lambda - \alpha)}$, there is $\left. \frac{dF(x)}{dx} \right|_{x=1} < 0$,

309 and $x=1$ is the evolutionary stability strategy ESS. When $x > 1 - \frac{\lambda\pi C_{G2} - \psi C_{G1}}{\pi\psi(\beta\lambda - \alpha)R_G}$, there is

310 $\left. \frac{dG(y)}{dy} \right|_{y=1} < 0$, and $y=1$ is the evolutionary stable strategy ESS. Therefore, the lower the

311 proportion of self-discipline of vaccine manufacturers is, the higher the proportion of active
 312 supervision of government regulatory departments x will be, and vice versa.

313 **4. Discussion**

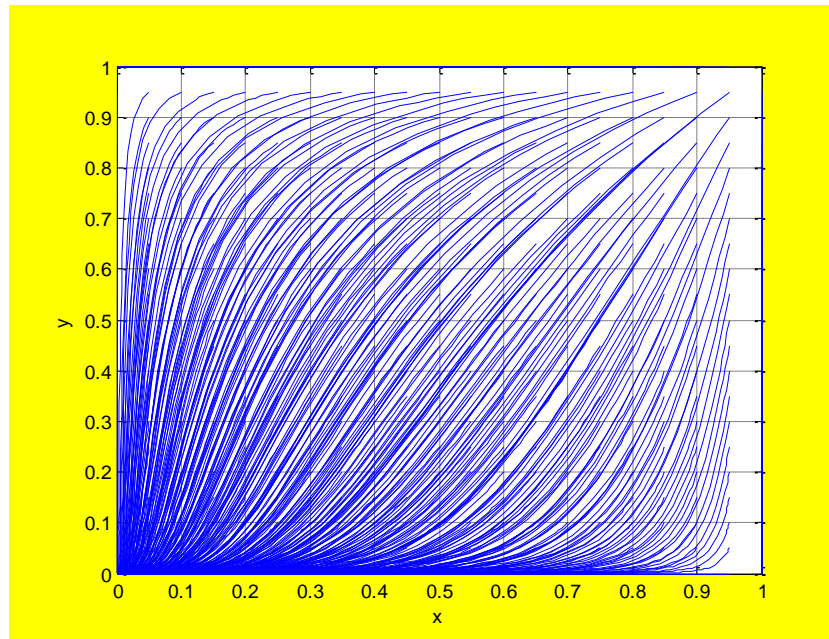
314 The optimal decision of the two sides is obtained through the establishment of the game model
 315 between the government regulatory department and the vaccine manufacturer. In view of the fact
 316 that although the government continuously strengthens the supervision of vaccine manufacturers,
 317 the non-self-discipline of vaccines occurs from time to time, it is of no practical significance to
 318 discuss the high incidence period of non-self-discipline and the period of enterprise self-discipline.
 319 In this context, based on the above analysis and the results, the influence of parameter changes on
 320 the strategic choice of both sides is discussed through analyzing the severity of undisciplined
 321 punishment, government active regulation and government passive regulation. By setting relevant
 322 parameters, MATLAB R2017b software was used for the simulation to more clearly reflect the
 323 influence of parameter changes on the evolution direction of both sides. The initial value setting is
 324 shown in Table 5:

325 **Table 5.** Parameter initial value setting.

Parameter	C_{G1}	C_{G2}	R_G	α	β	λ	R_{V1}	R_{V2}	F_{V1}	F_{V2}	C_V	π	ψ
Value	1	5	3	0.3	0.8	0.4	2	6	4	2	1	1	1

326 Matlab simulation was conducted based on the above parameter assumptions, and the results
 327 are shown in Figure 2. With the increase in the number of iterative steps in the simulation evolution,
 328 the evolutionary stable point of the game behavior between the government regulatory department
 329 and the vaccine manufacturer is (0, 0).

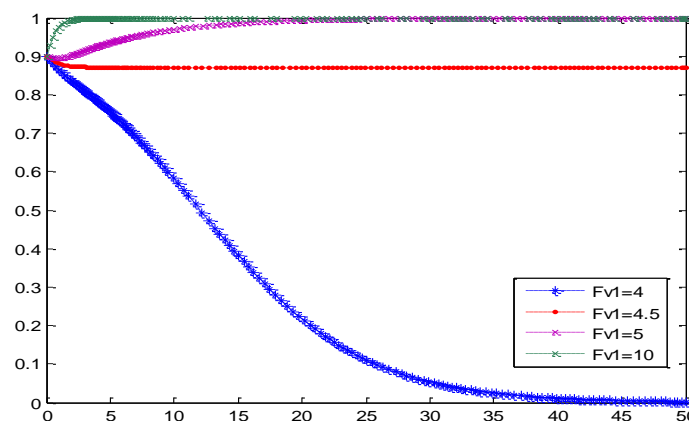
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Figure 2. Initial state of government regulatory departments and vaccine manufacturers. (1) The impact of government punishment on the evolutionary behavior of vaccine companies.

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Figure 3. Cooperative probability simulation results of vaccine enterprises under government punishment.

336

According to the definition of profit-loss ratio $\varepsilon = \frac{R_{V2} - R_{V1}}{R_{V2} + F_{V1} + F_{V2}}$, it can be seen that if

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$\frac{\partial \varepsilon}{\partial F_{V1}} < 0$, then the simulation result is inversely proportional to the simulation result ε .

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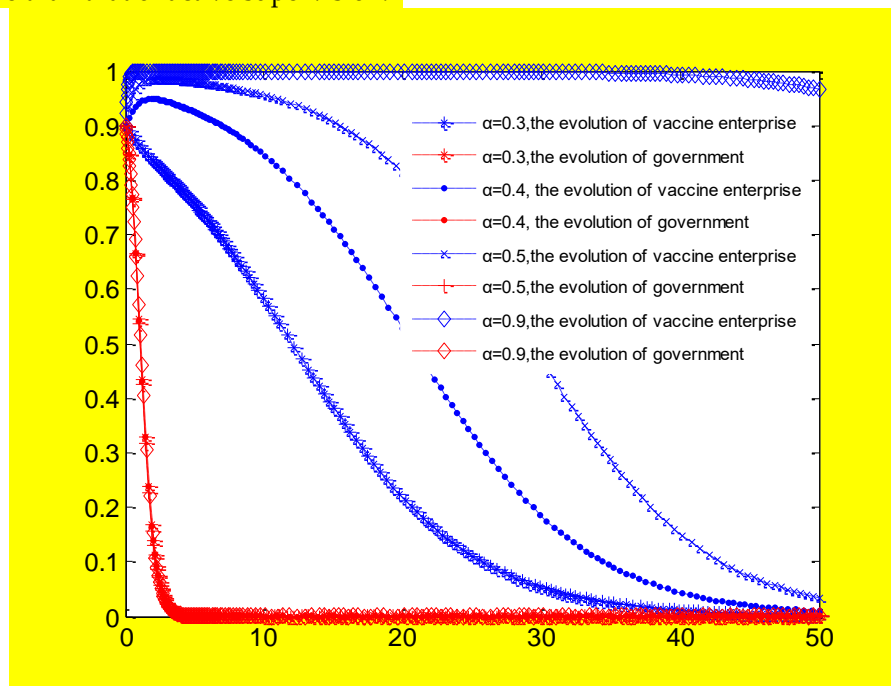
According to the evolution results in figure 3, when the punishment of non-self-discipline enterprises by government departments increases continuously, the probability of enterprises choosing self-discipline will gradually increase until the self-discipline period of vaccine manufacturers is reached. According to the figure, the government regulations can effectively prevent the vaccine production enterprise non-self-discipline behavior and the government punishes the critical point F_{V1} is 4.5. If $F_{V1} > 4.5$, the government punishment will motivate the cooperation between vaccine enterprises; once $F_{V1} < 4.5$, with the increasing extension of study time, the vaccine enterprises will eventually choose not to cooperation. That is to say, with the increase of government regulatory authorities' punishment for undisciplined enterprises, the

347 temptation of undisciplined behaviors ε is greatly reduced. When ε is smaller than both the
 348 probability of active regulation and the probability of passive regulation, vaccine manufacturers
 349 will enter a period of self-discipline based on their own comprehensive consideration. In the same
 350 way, the cost of the rectification after the investigation and punishment of the non-self-discipline of
 351 vaccine manufacturers can also lead to the same conclusion as that of the government punishment,
 352 which will not be repeated. When enterprises are found out to be non-self-discipline, the
 353 government should strictly require enterprises to rectify, raise the rectification requirements, and
 354 increase the cost of rectification, so that vaccine manufacturers avoid choosing non-self-discipline
 355 strategy.

356 (2) The impact of active regulation by government regulatory departments on the evolution of
 357 the two parties

358 Depending on the simulation Figure 4, when the government regulatory active supervision
 359 rate is increasing, the vaccine production enterprise tends to choose self-discipline, and government
 360 regulators are inclined to choose passive regulation. If the government can ensure efficient
 361 regulatory success rate, the vaccine production enterprise will go constantly in the direction of
 362 self-discipline. At the same time, as the vaccine production enterprise gradually regulate their own
 363 behavior, the probability of non-self-discipline behavior appears to be smaller and smaller, and the
 364 loss of the society suffering tends to be smaller as well. If the active regulation effect is not obvious,
 365 government regulators are likely to choose passive regulation with a relatively stable state, for the
 366 reason that at this time the government supervision cost and the effect of passive regulation are
 367 more favorable than that of active supervision.

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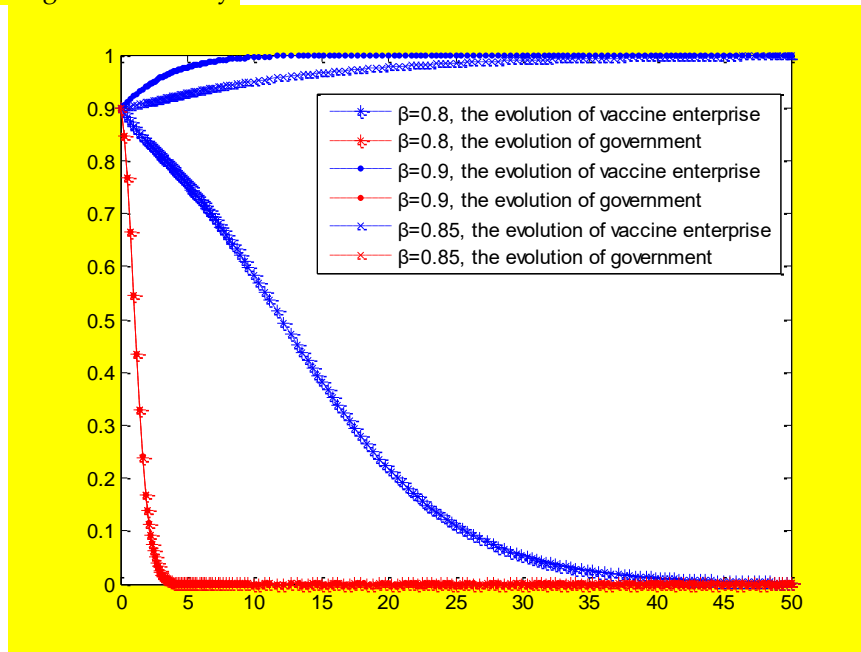
369 **Figure 4.** Simulation results of the evolutionary game between the two parties under the
 370 condition that the success rate of government's active supervision is increased

371 (3) The influence of passive government regulation and third-party reporting probability on
 372 the evolution of both parties

373 Depending on the simulation in Figure 5 and Figure 6, with the increase of the probability of
 374 passive regulation and reports from the third party, the non-self-disciplined behavior of the vaccine
 375 production enterprises is more likely to be exposed, which is a great threat to the enterprise. In the
 376 case of severe punishment by the government regulatory authorities, the possibility of investigation
 377 and punishment faced by enterprises is also increasing, which will make enterprises face high cost
 378 of punishment, and ultimately vaccine manufacturers choose self-discipline behavior. With the
 379 increase in the success rate of passive regulation and the report of the third party, governments
 380 tend to adopt passive regulation strategy. In line with the principle of the minimum loss to society,

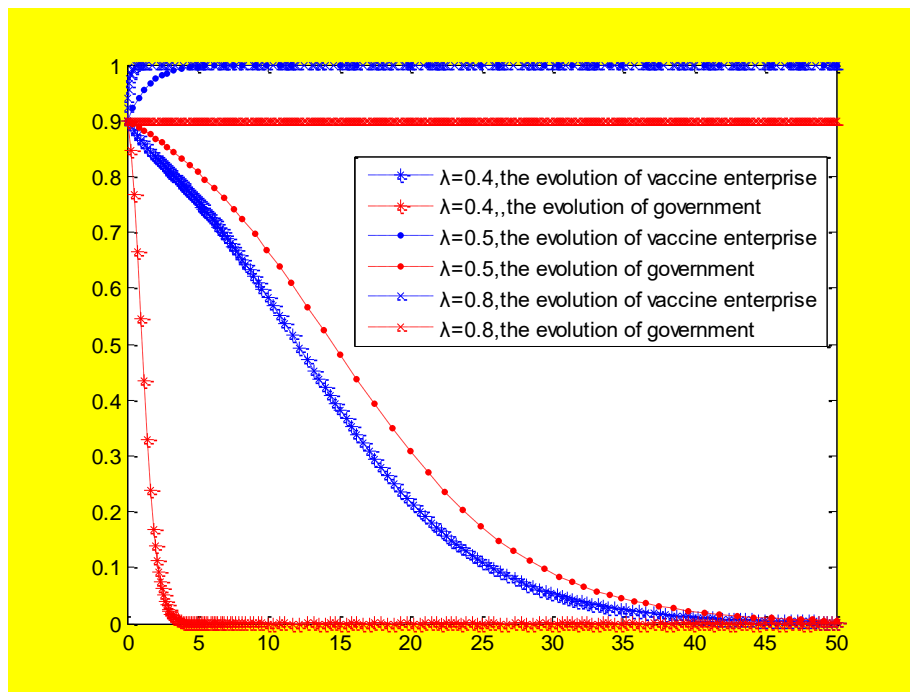
381 the government supervision department should take the initiative and increase the success rate of
 382 functional regulation to minimize non-self-discipline choices of the vaccine production enterprises
 383 and avoid damage to the society.

384



385 **Figure 5.** Simulation results of the evolutionary game between the two parties under the
 386 circumstance that the success rate of government passive supervision is increased.

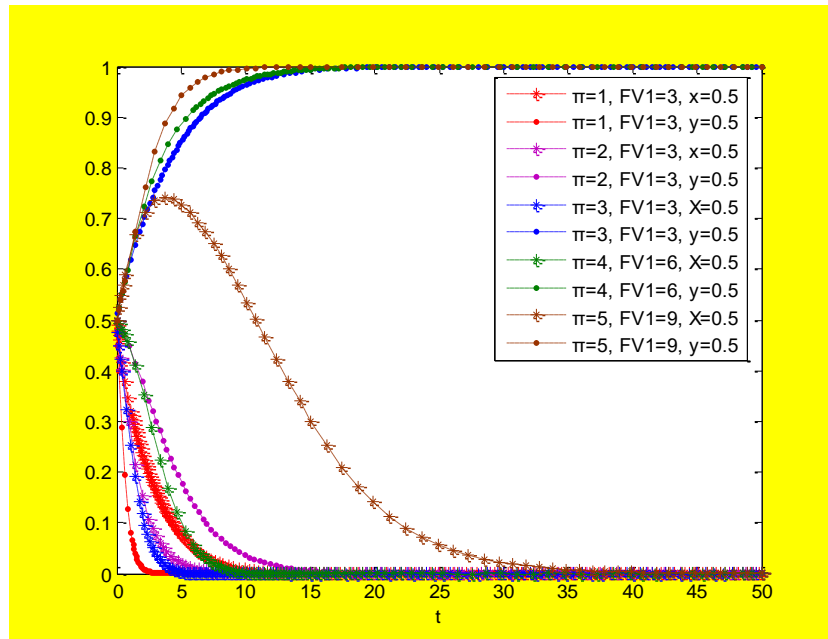
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388 **Figure 6.** Simulation results of the evolutionary game between the two parties under the condition
 389 that the probability of third-party reporting is improved.

390 (4) The influence of power of the government and regulation on the evolution of both parties

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Figure 7. Simulation results of the evolutionary game between the two parties under the condition that power of the government and regulation is improved.

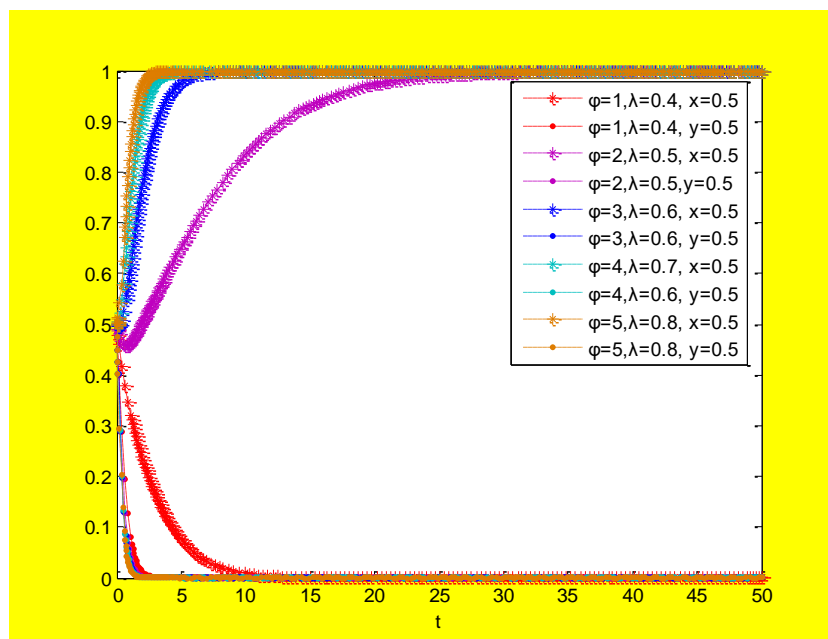
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Depending on the simulation in Figure 7 when the power of government is greater and the regulations are stricter, the regulatory cost of the government's regulatory authorities will be reduced due to the deterrence of vaccine manufacturers to the government's power and regulations. At this time, the government will choose to take the initiative due to the lower cost of active regulation. At this time, due to the strict government power and laws and regulations, vaccine enterprises will increase the penalty and reputation loss when they do not self-discipline. At this time, in order to avoid greater loss, vaccine enterprises will take the principle of maximizing their own interests, and finally turn from non self-discipline behavior strategy selection to self-discipline behavior. Therefore, greater government power and strict laws and regulations are conducive to promoting the active supervision of the government regulatory authorities and the cooperative behavior of vaccine enterprises.

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(5) The influence of corruption of government and awareness of people on the evolution of both parties

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408 **Figure 8.** Simulation results of the evolutionary game between the two parties under the condition
409 that corruption of government and awareness of people is improved.

410 Depending on the simulation in Figure 7 that the larger the coefficient of corruption of
411 government and awareness of people, the lower the cost of passive supervision of the government
412 regulatory department, and it will also tend to avoid the cost and choose passive supervision.
413 Because the opportunity cost of the government's active supervision is higher, the final choice is
414 passive supervision. However, due to the high level of corruption of government and awareness of
415 people, vaccine enterprises will increase the probability of third-party reporting, which will
416 increase the cost of non self-discipline, and finally choose self-discipline strategy. Therefore,
417 corruption of government and awareness of people are also conducive to promoting the passive
418 supervision of government regulatory departments and the cooperative behavior of vaccine
419 enterprises.

420 5. Conclusions

421 According to the above analysis, the main conclusions can be drawn: (1) Severe punishment by
422 government regulatory authorities, and increased costs of rectification after investigation and
423 handling of involuntary behaviors of vaccine enterprises can effectively prevent involuntary
424 behaviors of vaccine enterprises (2) In the early stage of the game, the success rate of the
425 government's efficient supervision will make the vaccine enterprises continuously self-discipline;
426 when the vaccine market is relatively stable, the government's supervision departments tend to be
427 more conducive to passive supervision. (3) The success rate of government regulatory departments
428 and the probability of third-party reporting play a great role in promoting the self-discipline of
429 enterprises. Once the phenomenon of vaccine enterprises' non-discipline increases, the government
430 regulation must change from passive regulation to active regulation. (4) The power of government
431 and regulation are conducive to promoting the active supervision of the government regulatory
432 authorities but corruption of government and awareness of people are the different.

433 Built on the above conclusions, the following policy suggestions are proposed for the
434 government to guide and supervise the vaccine manufacturers to take self-discipline actions.

435 (1) Raising public awareness of public safety

436 Make full use of the publicity advantages of new media platforms, strengthen the publicity
437 and education of vaccine safety knowledge, and improve public safety awareness. Specifically,
438 continuously strengthen the team construction of the vaccine regulators and use new media
439 software through various channels to improve the public's ability to identify fake and substandard
440 vaccine; strengthen public awareness and safeguard their legitimate rights and interests of
441 consumers to report complaints of their own, so as to establish the corresponding reporting
442 incentives; and actively guide the public to participate in supervision, and to encourage and
443 support in the vaccine production line staff disclosure of the vaccine quality safety problems timely.

444 (2) Severe punishment

445 Heavy penalties for non-self-discipline vaccine production enterprises should be enforced
446 according to specific situations. For a large-scale vaccine production enterprise, two hundred
447 million RMB is nothing significant, while it is too much to bear for a small-scale vaccine production
448 enterprise. Therefore, one of the principles that must be adhered to is to hit the "pain point" of the
449 non-self-discipline vaccine manufacturers. Severe punishment will be meted out to the vaccine
450 manufacturers that refuse to change.

451 (3) Improving government supervision

452 Government supervision includes active supervision and passive supervision. Active
453 supervision requires the government to continuously increase capital investment in vaccine safety
454 supervision, and urges food and drug safety supervision departments in various regions to conduct
455 regular and irregular inspections on local vaccine manufacturers with high frequency and intensity.
456 Passive supervision is mainly the third party supervision agencies and public supervision. The
457 involvement of third party regulatory agencies is a change from the traditional government

458 regulatory model. With the introduction of the third party regulatory agency, vaccine regulation is
459 linked with “Internet plus”. Through the use of various information technologies, the vaccine safety
460 supervision information platform can monitor vaccine manufacturers in real time, increase the
461 depth and breadth of supervision, and realize the traceability of vaccines in various circulation links,
462 which can effectively improve the supervision efficiency. Public supervision is an important part of
463 vaccine safety supervision. When the government is in a state of passive supervision for various
464 reasons, public supervision can effectively improve the success rate of the government’s passive
465 supervision. Although the cost of government’s passive supervision is higher than that of active
466 supervision, timely loss control is another way of self-protection. Public supervision is an effective
467 supplement to government supervision. Multiple forms of supervision coexist to achieve multiple
468 co-governance.

469 In this paper, we investigate the evolutionary game of behavior decision-making of vaccine
470 enterprises under the supervision of the government, and analyze the interaction of behavior
471 between the players. However, we have focused on the situation where there are only two
472 strategies for the players. In the future research, we will consider the evolutionary game involving
473 multi players and multi strategies, and the impact of government policies and strategies on the
474 behavior decision-making of heterogeneous vaccine enterprises.

475 **Author Contributions:** conceptualization, N.Z.; methodology, N.Z. and Y.Y.; software, N.Z.; validation, N.Z.
476 and Y.Y.; investigation, N.Z.; data curation, N.Z.; writing—original draft preparation, N.Z.; writing—review
477 and editing, N.Z. and Y.Y.; visualization, N.Z. and X.W.; supervision, Y.Y.; project administration, N.Z.; funding
478 acquisition, X.W.; resources, X.W..

479 **Acknowledgments:** We sincerely thank Xiangxiang Zhang for her technical assistance.

480 **Funding:** The relevant researches done in this paper are supported by the Natural Science Foundation of China
481 (Grant No. 41801119), the Royal Society and NSFC International Exchanges project (IEC\NSFC\170391), Social
482 Science Foundation of China(Grant No. 18FGL003), Key Project of National Language
483 Commission(ZDI135-67),China Postdoctoral Science Foundation funded project(Grant No. 2018M631220),
484 Excellent Youth Foundation of Xinjiang Scientific Committee(Grant No. 2017Q071) , Foundation of Shihezi
485 University(RCSX201754), Henan soft science project (Grant No. 202400410384).

486 **Conflicts of Interest:** The authors declare no conflict of interest. The funders had no role in the design of the
487 study; in the collection, analyses or interpretation of data; in the writing of the manuscript or in the decision to
488 publish the results.

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