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Moving towards a better path? An examination of China's reforms to remedy medical corruption from pharmaceutical firms

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6 **2 reforms to remedy medical corruption from pharmaceutical**
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8 **3 firms**

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4 31 **Moving towards a better path? An examination of China's**
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12 34 **ABSTRACT**
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15 35 **Objectives:** Few studies have systematically examined the effects of the existing regulations for
16
17 36 corruption and whether the corruption has been alleviated. This study aimed at assess whether
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19 37 China's reforms to curb medical corruption were effective.
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24 38 **Methods:** Using semi structured key informant interviews, we examined the effect of the existing
25
26 39 measures on opposing medical corruption based on the Donabedian model. We analyzed
27
28 40 quantitative data from "China Judgements Online" to support the evaluation.
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32 41 **Results:** There are three main categories of countermeasures to oppose medical corruption in
33
34 42 China. First, the level of fines and criminal penalties for medical corruption behaviors were
35
36 43 insufficient. Second, regarding the health policy regulations, although NRDL (National
37
38 44 Reimbursement Drug List) and EDL (Essential Drug List) were implemented well, they were
39
40 45 incomplete and the adjustment of lists created new corruption space. Additionally, the new
41
42 46 program that centralized the purchase of pharmaceuticals was found that most purchasing
43
44 47 committees were not independent, and the selection criteria for bidding was short of scientific
45
46 48 evidence. Third, reporting scheme for Commercial Bribery Records by the health bureau is
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48 49 currently being executed poorly. Lastly, quantitative data from "China Judgements Online"
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50 50 showed no obvious decrease of institutional medical corruption in recent years, and most criminals
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4 51 committed crimes for a long time before getting caught.
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7 52 **Conclusions:** The existing countermeasures are far from ideal and cannot fundamentally reduce
8
9 53 the medical corruption in China. To change the situation, the combined efforts of legislation and
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11
12 54 administrative mechanisms should be improved.
13

14
15 55 **Keywords:** Medical corruption; Evaluation; Effectiveness; China
16

17 18 19 56 **Strength and limitations**

- 20
21 57 ● Few studies have systematically examined the effects of the existing regulations
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23 58 for corruption and whether the corruption has been alleviated.
24
25 59 ● This study aimed at assess whether China's reforms to curb medical corruption
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27 60 were effective.
28
29 61 ● This study can help improve and foster better therapeutic and practical
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31 62 innovations to combat medical corruption in the Chinese health sector, and is a
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33 63 good source of evidence for similar developing regions as China to curb medical
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35 64 corruption.
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42 65 **INTRODUCTION**

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45 66 Medical corruption is pervasive across cultures and endemic in countries regardless if they are
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47 67 small or large, poor or rich, and capitalist or socialist[1-3]. Though medical corruption is costly for
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49 68 all countries, it seems to be an especially important problem in developing and transitional
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51 69 economies where public resources are scarce[4]. Undoubtedly, there is no exception with China.
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54 70 Since the China's reform and opening up policy in 1979, public hospitals in urban and rural areas
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4 71 have remained under central government ownership. However, they were required to undertake a
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6 72 certain degree of responsibility for financing money and administering institutions by themselves.
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8 73 This privatization of healthcare financing required hospitals to rely more on the sale of services,
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11 74 drug prescriptions, and medical examinations to earn revenues[5]. The National Development and
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13 75 Reform Commission's price guidelines for basic health services (routine examinations, surgeries,
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15 76 standard diagnostic tests, and pharmaceuticals in health institutions) were supposed to be low
16
17 77 enough to ensure that the services would be affordable for patients. Moreover, hospitals were
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19 78 prohibited from earning more than 15% markup from regulated tests and drugs[6]. However, the
20
21 79 privatization of healthcare financing combined with price regulation put most public hospitals in
22
23 80 China at serious financial risk[5-6]. To compensate for the retrenchment of government health
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25 81 outlays, many public hospitals in China began to earn revenue illegally by making alliances with
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27 82 the pharmaceutical firms to procure pharmaceuticals and medical equipment. Gradually, medical
28
29 83 bribery permeated the health sectors in China[7-8].

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36 84 Specifically, there are three major forms of medical corruption: (1) patient payments to secure
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38 85 medical treatments or improve their quality, (2) physicians' use of free public facilities for private
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40 86 patients, and (3) illegal payments usually from industry (mostly pharmaceutical and medical
41
42 87 equipment producers) to health professionals or officials, that is called institutional corruption [9].
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44 88 Among these forms of medical corruption, the institutional one seems to be more common and
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46 89 usually involves the largest amount of payments[10]. Usually, pharmaceutical firms' certain
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48 90 practices corrupt medical research, the production of medical knowledge, the practice of medicine,
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50 91 drug safety, and the administration's oversight of pharmaceutical marketing, etc.[11]. It was
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52 92 estimated that in the United States, the pharmaceutical industry spent up to \$42 billion in
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4 93 promotion every year, or on average, \$61,000 per physician, to influence their prescribing habits
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6 94 and generate profits[12]. In China in 2000s, numerous incidents regarding medical
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8 95 corruption emerged and exposed again the severity of corruption in China's healthcare industry[7].
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11 96 For instance, in 2013, all public hospitals in Zhangzhou, Fujian Province were reported to be
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13 97 involved in medical corruption. A total of 1088 doctors and 133 administrators from 73 hospitals
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15 98 in Zhangzhou were found to be taking bribes and kickbacks from pharmaceutical firms, that
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17 99 amounted to \$3.34 million and was a great shock to the public[13]. In this study, we focused on
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19
20 100 the type of medical corruption that caused by pharmaceutical firms. Usually, the interactions
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22 101 between pharmaceutical companies and hospitals or physicians are guided by their financial
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24 102 interests, and can be in the form of drug or device promotion, kickbacks, and financial incentives
25
26 103 to influence physician prescribing behaviors[14-15]. Studies showed that medical corruption can
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28 104 undermine the quality of healthcare, lead to inappropriate treatments, raise the cost of care, and
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30 105 damage physician-patient relationships, negatively impacting the whole health care system[8,
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39 107 Confronted with severe medical corruption, many countries have implemented various
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41 108 anti-corruption strategies, such as creating fines and criminal penalties[19], tax policy for
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43 109 pharmaceutical companies[20], health regulations by insurance institutions(i.e. new forms of
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45 110 prescription drug pricing)[9,21-22], and improved accreditation, certification, and rating systems
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47 111 [23-24]. However, due to the varying attributes of health systems and severity of medical
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49 112 corruption in different countries, the solutions designed or taken usually differ by country. In
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51 113 China, the government began implementing a wave of activities to combat medical corruption as
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54 114 part of its 2005 health care reforms. In detail, there are three categories of solutions: (1) the fines
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4 115 and criminal penalties created by legal and regulatory bodies, such as the "Penal Law" (Amended,
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6 116 2006), "Anti-unfair Competition Law" (1993) and "Interim Provisions on Anti-commercial
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8 117 bribery"(1996)[25], (2)There are health policies that aim to reduce possible corruption in the
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11 118 process of drug selection and procurement. The first method is the establishment of the National
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13 119 Reimbursement Drug List (NRDL, 2000) and the Essential Drug List (EDL, 2009). The NRDL is
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16 120 established by a national medicine selection system. Drugs on the NRDL have a subsidized price,
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18 121 but this also means that these get higher scrutiny of their prices. As a part of the national
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21 122 reimbursed drug list, the essential drugs are selected to ensure the accessibility and quality of
22
23 123 basic drugs available in health institutions[26]. The second regulation by the health department is
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25
26 124 the new program that centralizes purchase of pharmaceuticals and controls costs by public tenders,
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28 125 bidding, and auction processes as required by the China Food and Drug Administration since
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30
31 126 2009[27]. (3) Finally, the National Health Bureau created a reporting scheme for commercial
32
33 127 Bribery Records. As required by the National Health Bureau, regional health bureaus must
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36 128 blacklist "manufacturers, operators or distributors" involved in commercial bribery, and instruct
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38 129 health administrations to discipline responsible persons, including both people in the health
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41 130 institutions and companies[28].

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43
44 131 In our literature review, we found that though much information has been accumulated on how
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46 132 to develop regulations and countermeasures that restrain medical corruption in various countries,
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49 133 there is little existing research that systematically examines the effects of these regulations on the
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51 134 elimination or alleviation of medical corruption from pharmaceutical firms. Thereby, with the
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54 135 understanding that Chinese leadership is combating the rampant corruption within its society, this
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56 136 study sought to assess whether China's reforms to curb medical corruption were effective. This

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3 137 study can help improve and foster better therapeutic and practical innovations to combat medical
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6 138 corruption in the Chinese health sector. Additionally, we think this study may provide good
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9 139 suggestions to other developing countries that may be suffering from similar problems during their
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11 140 economic and social transition periods.

141 **METHODS**

142 **Analytic framework**

143 To examine the effects of existing countermeasures for curbing medical corruption, we formulated
144 an interview instrument based on the Donabedian model[29]. According to the Donabedian model,
145 information about the countermeasure programs can be drawn from three categories: structure,
146 process, and outcomes. Questions designed for experts were related to the design of the
147 regulations, their implementation, and their effectiveness. Main discussion questions were as
148 follows:

- 149 • What do you think are the regulations for medical corruption in China?
- 150 • How would you describe each kind of regulation for curbing medical corruption, including its
151 design, execution/implementation, and effectiveness in China?
- 152 • Can you identify any countermeasures in other countries that can help stop the medical
153 corruption in China?

154 In addition, to support the evaluation, particularly the "outcome" section of the framework, we
155 analyzed quantitative data of the current medical corruption in China.

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4 156 **Data source**

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7 157 *Qualitative data*

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10 158 To evaluate the current countermeasures for medical corruption in China, we interviewed eight
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12 159 experts in health policy from universities in the city of Shanghai in the health policy area, and four
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14 160 officers in drug procurement agencies in Shanghai and Beijing, for a total of 12 voluntary
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16 161 participants. Interviews were conducted from March 1, 2017 to April 9, 2017.

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19 162 *Quantitative data*

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21 163 There is no specific and sound reporting system for medical corruption in China today. Therefore,
22
23 164 in order to reflect the current state of institutional medical corruption in China, we referred to
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25 165 "China Judgements Online," an online database of case verdicts in the whole China. The database
26
27 166 was established in 2010 by the Supreme People's Court contains case verdicts from every field. In
28
29 167 the initial period when the system was established, only the serious verdicts released by the
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31 168 Supreme People's Court must be released. From 2013, the local and intermediate courts in
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33 169 different provinces were also encouraged to send verdicts to this system[30]. We retrieved case
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35 170 verdicts related to medical corruption that occurred from January 1, 2010 to December 31, 2016,
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37 171 using the keywords "medical," "corruption," and "health institution". We chose to collect data
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39 172 starting from 2010, the year in which the online system was launched. We found that there were
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41 173 fewer released verdicts before the year 2013 than after, likely because the government did not
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43 174 make it compulsive to upload verdicts until 2013. Therefore, we discarded data before 2013 and
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45 175 used data from 2013 to 2016. We found a total of 856 related verdicts. Though the sample size was
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176 relatively small, the data uploaded provide a representative sample from each province.

177 **Data analysis**

178 Two trained researchers analyzed the qualitative data using NVivo10 to sort the interview answers
179 and the Donabedian model as an a priori organizational framework. Using a hierarchical coding
180 structure, the researchers deductively identified all themes, then coded and analyzed those that
181 were relevant. In addition, we conducted a literature review of medical corruption governance in
182 both developing and developed countries so that to search for ideas to curb medical corruption in
183 China.

184 When screening the verdicts from "China Judgements Online", we first eliminated duplicate
185 cases. Second, we asked two of the authors who were health policy experts to carefully conduct a
186 review of the verdicts. The criterion was that the included verdicts needed to depict institutional
187 medical corruption, specifically relating to the procurement of drugs and devices. After conducting
188 two rounds of review, we kept a total of 336 verdicts for descriptive analysis of the current status
189 of medical corruption in China. In our analysis, we reviewed the year the verdict was released, the
190 level of the court that decided the verdict, the amount of illegal money involved, the institutions of
191 those bribed, and the period during which the corruption took place.

192 **Ethics statement**

193 All research activities were conducted with integrity and in line with generally accepted
194 ethical principles. Verbal consent forms for participation and publication were obtained from all
195 interviewees.

196 RESULTS

197 Qualitative evaluation on regulations for institutional medical corruption in China

198 *Evaluation of fines and criminal penalties*

199 Since its 2005 health reforms to restructure the health care system, China has strived to establish
200 more effective laws to curb medical corruption. The experts interviewed stated that there were
201 currently three major categories of countermeasures to oppose medical corruption in China. The
202 experts agreed that imposing fines and criminal penalties was the easiest and best preventative
203 measure to curb institutional medical corruption.

204 However, many experts also pointed out that this type of regulation was not ideal because it
205 was poorly structured. Punitive policies for medical corruption, including fines and imprisonment,
206 did not effectively restrain bribers, nor were they uniformly rigorous. For example, the fine
207 amount set by the Anti-unfair Competition Law (1993), 10,000 RMB (approximately \$1,450) and
208 200,000 RMB (approximately \$29,000), is too small to effectively restrain bribers. Although the
209 Anti-unfair Competition Law was newly amended in February 2017 to increase the fine amount to
210 10% to 30% of illegal revenue obtained, experts believe that this is still too small to be effective.
211 Moreover, because firms usually pay these fines, bribers are not effectively deterred from
212 conducting illegal activities. Additionally, penalties imposed on those making and accepting
213 bribes are strikingly different depending on their affiliation to different types of institutions.
214 Penalties are usually milder for parties associated with multinational firms compared to those
215 associated with domestic firms. Lastly, individuals working in public health institutions (i.e.
216 physicians) receive greater punishment than individuals working in private health institutions, as

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4 217 they are regarded as civil servants of China.

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6 218 *Evaluation of related health policy regulations*

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8 219 *a. The establishment of the National Reimbursement Drug List (NRDL) and the Essential Drug*

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11 220 *List (EDL)*

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14 221 The government created the National Reimbursement Drug List (NRDL) so it could select the

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16 222 highest therapeutic and cost-efficient drugs. Though being listed on the NRDL is positive

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18 223 development for drug producers, because listed drugs are paid completely or at least in part by

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20 224 China's Health Insurance Department, being listed also means that there is higher scrutiny of its

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22 225 prices. The Essential Drug List (EDL), as part of the NRDL, was established in 2009 with the

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24 226 purpose of selecting essential drugs to be made available in all public health facilities, with

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26 227 particular emphasis on elemental health institutions[26]. Additionally, health institutions are

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28 228 required to obey the "zero-profit drug" policy, meaning the EDL drugs must be sold at purchasing

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30 229 prices[5]. Experts said that by far, this policy helped proper prescription of drugs and further

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32 230 reduce the space for medical corruption.

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38 231 However, most experts noted that regarding policy design, the main problem was that the

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40 232 initial established lists contained limited(i.e. for the EDL, there were only 307 kinds of drugs)

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42 233 kinds of drugs for the whole nation, and always needed big change in nearly all provinces. But the

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44 234 selection of drugs in various provinces was lack of scientific criteria. The experts proposed that

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46 235 when revising the list by province, new corruption space would easily come into being. Since the

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48 236 provincial selection was set by leaders in the health bureau without use of the necessary scientific

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50 237 processes and criteria, many pharmaceutical firms may have interfered in the process, leading to

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52 238 corruption. Many of the drugs on the NRDL that are not on the EDL can still be sold at prices 15%

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4 239 higher than the purchasing price, which means health institutions, particularly hospitals, have
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6 240 opportunities to create alliances with pharmaceutical firms for illegal profits. Usually, hospitals
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8 241 will purchase drugs that are not on the NRDL if they generate profits.
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11 242 *b. The new program for centralized purchase of pharmaceuticals*

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14 243 Centralized purchase policy was proposed as early as 2000 as a means of restraining health
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16 244 institutions' power to directly negotiate and purchase drugs from the pharmaceutical companies.
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18 245 This policy set a separate third-party committee as the purchasing entity, though still usually
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20 246 affiliated with the health bureau. However, it was not well executed and many hospitals can still
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22 247 buy drugs directly. And not until 2009, the new centralized purchase policy was released by
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24 248 China's Ministry of Health and made specific regulations to shift purchasing power from public
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26 249 hospitals to the governments. Specifically, it is the provincial committees' obligation to select
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28 250 suppliers through a competitive bidding process and then distribute the products to all hospitals
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30 251 under their jurisdiction. According to the new policy, drugs are competitively tendered at the
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32 252 provincial levels. It is also reported that central purchasing programs at the provincial level have
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34 253 reduced drug prices by 30% in Beijing[31], 41% in Hebei[32], and 46% in Shandong[33].
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41 254 Although studies showed that decreasing the cost of medicines might reduce the corruption
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43 255 space, experts pointed out there were still two problems with the purchasing committees. First, in
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45 256 many provinces, the committees that manage the purchasing platforms are not independent. Most
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47 257 of these committees are affiliated with the health bureau. In some areas, there is not even a formal
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49 258 committee in which the responsibilities are assumed by different departments under the health
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51 259 bureau. In this case, buck-passing would occur between various departments. Undoubtedly, this
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53 260 easily may lead to the monopoly. Experts proposed that if a central selection committee has the
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4 261 monopoly power, then it's easy to see that medical firms may bribe key decision makers in the
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6 262 selection process. Second, experts indicated that there were defects in the criteria for bidding.
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8 263 Many indexes were difficult for bidding judges to quantify and evaluate. For instance, choices for
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11 264 judges in the index of clinical effect and security are typically listed as "obviously superior to
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13 265 others," "a little superior to others," "similar to others," and "worse than others." The lack of
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16 266 scientific and quantified standards provide chances for bidding judges to participate in corruption.
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18 267 Another major problem with the bidding criteria is that they usually overemphasize the weight of
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21 268 price. Sometimes, in order to win, bidding companies set bidding prices lower than actual cost
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23 269 prices of drugs. This may lead to the bidding companies reducing the quality of their drugs. For
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26 270 example, the cost price per kilo of the drug radix isatidis was 3.7 RMB, but the bidding price was
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28 271 only 1.4 RMB—far lower than the actual cost. So the companies used the apple peel instead of
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31 272 radix isatidis. The principle of those with lower price win may also induce bidding companies to
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33 273 make the alliance to provide artificially lowered prices when bidding and share the profits
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36 274 afterwards, leading to a disruption of the competitive market balance.

275 *Evaluation of reporting scheme for medical corruption in China*

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41 276 In late 2013, the Chinese central government responded that ethical regulations should be used to
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43 277 curb medical corruption. The "Establishment of Commercial Bribery Records in the Purchase and
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46 278 Sale of Medicines and devices" then came into being[28]. This reporting scheme for Commercial
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48 279 Bribery Records blacklists "manufacturers, operators or distributors" involved in commercial
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51 280 bribery, and instructs health administrative departments to discipline responsible persons,
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53 281 including physicians (who may lose their licenses).

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56 282 However, experts noted that the biggest problem with this reporting scheme was that it was
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4 283 poorly executed in the past few years. Only a few provinces have released the records of illegal
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6 284 commercial bribery, and of these limited released records, many were outdated. It remains to be
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8 285 seen if this policy will have real impact at the provincial and local levels from an ethical
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11 286 perspective.

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14 15 16 288 **Quantitative evaluation of regulations on institutional medical corruption in China**

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18 289 As shown in Table 2, although the Supreme People's Court of China required courts to report
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20 290 verdicts to the online system since 2010, we found that until 2013, there was only a small number
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22 291 of released verdicts. Most of the verdicts (80.06%) were from the Basic People's Courts. We were
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24 292 surprised to find that in most cases, bribes were above 100,000 RMB, and in 11.31% of the cases,
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26 293 individuals taking bribes received more than 1,000,000 RMB. Usually, individuals taking bribes
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28 294 were from public hospitals. Among these individuals were physicians, directors and deans of
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30 295 different departments, and officers from the health bureaus. In addition, most of the criminal
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32 296 activities reported had been undetected for a long time, with 58.53% of corruption behaviors
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34 297 lasting more than 5 years. This indicates that the inspection policies are not strict.

35 36 37 38 39 40 41 298 **DISCUSSION**

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43 299 Our evaluation showed that while many of China's regulations on medical corruption operate well,
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45 300 they still have many problems. Compared to other countries implementing policies to curb
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47 301 medical corruption, China implements relatively mild penalties that do not abide by a
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49 302 "zero-tolerance" policy. In the United States, if pharmaceutical firms promoted drugs unlawfully,
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51 303 they will receive great fines. For instance, we can look to cases concerning atypical antipsychotics.
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54 304 In 2010, the multinational pharmaceutical company Astra-Zeneca paid \$520 million for illegally

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4 305 marketing the drug Seroquel for uses not approved by the Food and Drug Administration by
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6 306 paying kickbacks to physicians. In 2012, Johnson & Johnson settled for \$1.2 billion on charges of
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8 307 off-label promotion and failure to disclose information on adverse reactions to the drug
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11 308 Risperdal[19]. According to Public Citizen[34], from 1991 to 2012, drug companies have paid \$30
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13 309 billion in criminal fines in the United States for Medicare fraud, unlawful drug promotion,
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15 310 kickbacks, monopoly practices, and the concealment of study findings. In China, the fines for
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17 311 medical corruption are much smaller. Even the shocking multinational case of GSK's bribery in
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19 312 2013 ended with the highest fine being 30 billion RMB (approximately 4.36 billion US dollar)
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21 313 [35]. If the fine amounts are not significantly increased, it will remain profitable for drug
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23 314 companies to engage in corruption practices that undermine public health[3].
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29 315 Although the Chinese government strived to reduce medical corruption by establishing the
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31 316 NRDL and EDL, our evaluation showed that without scientific and fair criteria for drug selection,
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33 317 it is difficult to resolve problems related to modifying these lists and with the defective bidding
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35 318 process. In many developed countries, health technology assessment has also been used to the
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37 319 selection of drug plans by comparing drug costs with their therapeutic benefits. This has become
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39 320 central in determining the prices of pharmaceutical products. Health technology assessment was
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41 321 also proven to be effective in establishing the modalities for access and reimbursement of drugs
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43 322 [22]. This technology makes evidence-based medicine (rather than marketing-based medicine)
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45 323 central to the architecture of the pharmaceutical market because it directly aligns financial
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47 324 incentives with improving health outcomes. Thereby, the health technology assessment should be
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49 325 applied to facilitate Chinese governments' decision making as soon as possible.
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56 326 Our results showed that problems with the central purchasing program were related to the lack
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4 327 of independent committees and the monopolies created by local health bureaus. To effectively
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6 328 solve these problems, many developed countries use marketization management of pharmaceutical
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8 329 products purchasing. Originated in the US, an entity called Group Purchasing Organization (GPO)
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10
11 330 is one kind of purchasing platform in the market. The GPO is created to leverage the purchasing
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13 331 power of a group of businesses to obtain discounts from vendors based on the collective buying
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15 332 power of the GPO members. The GPOs are intermediary agencies, and health organizations can
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17 333 voluntarily sign up to be a member of any GPO in US. It was found that GPO can help effectively
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19 334 prevent medical corruption[36]. However, while many large cities in China such as Shanghai and
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21 335 Beijing have tried to establish independent GPOs, still, it was not mature[37], which can't well
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23 336 functioned to curb the medical corruption.

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28 337 Overall, the reason for improper use of drugs should also be attributed to physicians and
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30 338 patients. Physicians may be indifferent to high prices of drugs if prescribed pharmaceutical
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32 339 products or inspections make them profitable. Additionally, when patients buy pharmaceutical
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34 340 products on the NDRL, they rarely pay the full price themselves. To restrict the behaviors of
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36 341 physicians and patients, the health insurance department should not only supervise the current
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38 342 payment budget for public hospitals, but also design effective regulations to inspect authenticity of
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40 343 therapies [38]. In Germany, the United States, and other countries, insurance institutions, usually
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42 344 health insurance companies, can trace the behavior of physicians or hospitals. Most drug coverage
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44 345 systems in these countries can specify which drugs will be reimbursed through methods such as
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46 346 managing drug formularies or requiring generic products to be used when available[22]. Some
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48 347 states in the US now require the full disclosure of every payment received by physicians from
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50 348 drug companies[19]. These policies impose restriction on physicians.

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4 349 Miller(2013) notes that companies initiate most corporate social responsibility initiatives to
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6 350 avoid negative reputational consequences that may induce greater burden than the illegal earned
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8 351 profits. Accreditation, certification, and rating systems have proven useful in curbing medical
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11 352 corruption to a certain extent, as these systems help align market forces with trustworthy
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13 353 practices[23]. However, under the "Guanxi" society where relationship plays an important role in
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16 354 China[39], the reporting system for medical corruption is not well executed. To improve this
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18 355 situation, we suggest that the adverse results should be made open to the public compulsorily.

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21 356 As revealed by much of the literature, the root of institutional corruption lies first and foremost
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23 357 in the fact that physicians' remuneration is set at a low level in China[39-40]. Low compensation
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25 358 may lead to physicians taking significant payments for high-cost diagnostic and therapeutic
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27 359 interventions in China. Therefore, this issue must be tackled by improving the financial incentives
28
29 360 for physicians and the moral environment within China's health reform. Finally, the main
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31 361 limitations of this study were related to the quantitative section. Though the quantitative data from
32
33 362 the online system were helpful in supporting the qualitative data, the small sample size may have
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35 363 caused the low reliability error.

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42 43 44 365 **CONCLUSIONS**

45
46 366 Our study found that though China has made efforts to tackle institutional medical corruption in
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48 367 drug procurement for many years, corruption issues continue to be a concern. In analyzing the
49
50 368 current regulations, we found that existing countermeasures such as fines, imprisonment penalties,
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52 369 health policy regulations, and reporting schemes, still have many defects. We suggest creating
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54 370 more rigorous legislation and well-functioning administrative mechanisms that select drugs for the
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4 371 NRDL or EDL and establish prices using scientific criteria. We also suggest more rigorously
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6 372 supervising health insurance departments in China. To address the root of medical corruption
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8 373 however, the financial structure of physicians' income should be adjusted within China's health
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11 374 reform.

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14 15 16 376 **Abbreviations**

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18 377 NRDL: National Reimbursement Drug List

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20 378 EDL: Essential Drug List

21 22 379 **Acknowledgements**

23
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35
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37 38 387 **Authors' contributions**

39
40 388 Conceived and designed the experiments: JWS, ZXW and LYS. Analysed the data: JWS, RL and
41
42 389 CXW. Contributed reagents/materials/analysis tools: HJ, YX and NNL. Wrote the paper: JWS and
43
44 390 LYS.

45 46 391 **Data sharing statement**

47
48 392 All relevant data from the "China Judgements Online" can be shared to the public.

49 50 393 **Competing interests**

51
52 394 The authors have declared that they have no competing interests.

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Table 1 Experts' evaluation on existing countermeasures for restraining institutional medical corruption

	Countermeasures	Content	Structure	Process	Outcome
1	Fines and criminal penalties ruled by the "Penal Law"(Amended, 2006), the "Anti-unfair Competition Law"(1993), and the "Interim Provisions on Anti-commercial bribery"(1996)	Financial fines, imprisonment, and cancellation of physician licenses	(1)The fines are not high enough to effectively restrain bribery. (2)The punishment differs strikingly when bribers or bribees are in different institutions	(1) It is well implemented	(1) Imposing fines and criminal penalties is the easiest and most direct way to restrain medical corruption
2	Health policy regulations, especially those regarding drugs				
2.1	The establishment of the National Reimbursement Drug List (NRDL, 2000) and the Essential Drug List (EDL, 2009)	To select the most therapeutic and economical drugs by the government	(1)The initial lists are incomplete. The adjustment of the lists may induce corruption	(1) Many of the drugs on the NRDL can still be sold at prices higher than the purchasing price; (2) Hospitals will only purchase drugs that are not on the NRDL if they generate profits.	(1) It makes the drugs on the lists under the government's high supervision; (2) The "zero-profit drug" policy for the EDL can shrink the benefit space
2.2	The new centralized purchase policy(2009)	Public tenders, bidding, and auction processes relating to the purchase of drugs are mostly operated by provincial governments	(1)Usually, the purchasing committee is affiliated with the health bureau, and purchasing decision is not made independently. Additionally, many areas have one purchasing institute, leading to monopoly of drug procurement (2)There are many defects in the selection criteria	(1) From 2009 according to the strict regulation by national Health Bureau, the purchasing of drugs or equipment has normal process for execution	(1) Shifting purchasing power from public hospitals to governments can reduce medical corruption to a large extent
3	Reporting scheme for medical corruption(2013)	Establishment of a reporting and record-keeping scheme of commercial bribery records	(1) The reporting scheme focuses on adverse behaviors. A comprehensive rating system to rating the companies' reputation should be established	(1)The reporting scheme is poorly implemented	(1) The public can be a constraint force for the corruption

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Table 2 Verdicts involving institutional medical corruption from "China Judgements Online" (N=336)

Variable	Classification	n	(%)
Year of verdicts	2013	15	4.46
	2014	105	31.25
	2015	64	19.05
	2016	152	45.24
Level of the court	Supreme people's court	4	1.19
	Intermediate people's court	63	18.75
	Basic people's court	269	80.06
Amount of money involved in the bribery(RMB)	[14,900-100,000)	87	25.89
	[100,000-500,000)	164	48.81
	[500,000-1,000,000)	47	13.99
	[1,000,000-2,000,000)	16	4.76
	[2,000,000-6,959,000)	22	6.55
Institutions of individuals taking bribes	Hospitals	307	91.37
	Health bureaus	33	9.82
Time span of the committed corruption(year)	[1-2)	15	4.46
	[2-5)	124	36.90
	[5-10)	158	47.02
	[10-15]	39	11.61

STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of *cross-sectional studies*

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	2
		(b) Provide in the abstract an informative and balanced summary of what was done and what was	2-3
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	3-6
Objectives	3	State specific objectives, including any prespecified hypotheses	6-7
Methods			
Study design	4	Present key elements of study design early in the paper	7
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	8
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection of participants	8
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	8
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	8
Bias	9	Describe any efforts to address potential sources of bias	9
Study size	10	Explain how the study size was arrived at	8
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	8-9
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	8-9
		(b) Describe any methods used to examine subgroups and interactions	8-9
		(c) Explain how missing data were addressed	8-9
		(d) If applicable, describe analytical methods taking account of sampling strategy	N/A
		(e) Describe any sensitivity analyses	N/A
Results			

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Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	N/A
		(b) Give reasons for non-participation at each stage	N/A
		(c) Consider use of a flow diagram	N/A
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	10
		(b) Indicate number of participants with missing data for each variable of interest	N/A
Outcome data	15*	Report numbers of outcome events or summary measures	10-14
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg 95% confidence interval). Make clear which confounders were adjusted for and why they were included	N/A
		(b) Report category boundaries when continuous variables were categorized	N/A
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	N/A
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	N/A
Discussion			
Key results	18	Summarise key results with reference to study objectives	14
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	17
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	14-17
Generalisability	21	Discuss the generalisability (external validity) of the study results	17-18
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	18

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at www.strobe-statement.org.

BMJ Open

Moving towards a better path? A cross sectional examination of China's reforms to remedy medical corruption from pharmaceutical firms

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Moving towards a better path? A cross sectional examination of China's reforms to remedy medical corruption from pharmaceutical firms

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4 31 **Moving towards a better path? A cross sectional**
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6 32 **examination of China's reforms to remedy medical**
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8 33 **corruption from pharmaceutical firms**
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12 34 **ABSTRACT**
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15 35 **Objectives:** Few studies have systematically examined the effects of the existing regulations for
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17 36 alleviating corruption. This study assesses the effectiveness of China's reforms to curb medical
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19 37 corruption.
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24 38 **Methods:** Using semi-structured key informant interviews, we designed the evaluation questions
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26 39 and examined the effect of the existing different kinds of countermeasures to oppose medical
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28 40 corruption based on the Donabedian model. Using the quantitative data from the online database
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30 41 of the "China Judgements Online", which lists the case verdicts related to medical corruption, we
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32 42 also showed the tendency, characteristics and seriousness of medical corruption in recent years.
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37 43 **Results:** Since 1990s, China has implemented three main categories of countermeasures to oppose
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39 44 medical corruption: fines and criminal penalties, health policy regulations and reporting scheme
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41 45 policy. First, the level of fines and criminal penalties for medical corruption behaviors may not be
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43 46 sufficient. Second, health policy regulations are also insufficient because although the National
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45 47 Reimbursement Drug List(NRDL) and Essential Drug List(EDL) were implemented, they were
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47 48 incomplete and created more opportunities for corruption. Additionally, the new program that
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51 50 independent, and the selection criteria for bidding lacked scientific evidence. Third, reporting
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4 51 scheme for Commercial Bribery Records by the health bureau is executed poorly. Lastly,
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6 52 quantitative data from "China Judgements Online" showed no obvious decrease of institutional
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8 53 medical corruption in recent years, and most criminals committed crimes for a long time before
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11 54 getting caught.

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14 55 **Conclusions:** Although existing countermeasures have exerted certain effects according to the
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16 56 Chinese experts, much improvement is needed. Fundamentally, financial incentives for
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18 57 hospitals/physicians and the health insurance system should be improved.

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22 58 **Keywords:** Medical corruption; Evaluation; Effectiveness; China

23 24 25 26 59 **Strengths and limitations**

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29 60 ● This study systematically examined the effects of existing regulations for curbing medical
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31 61 corruption in China.
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33 62 ● Using mainly qualitative data from interviews with experts, supported by the quantitative
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35 63 data from "China Judgements Online" that release the case verdicts about medical corruption,
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37 64 this study examined the effects comprehensively.
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39 65 ● The main limitations of this study were related with its data collection, since the selected
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41 66 interviewed experts were mostly from Shanghai and the quantitative data from the online
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43 67 system had a small sample size.

44 45 46 47 68 **INTRODUCTION**

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53 69 Medical corruption is pervasive across cultures and endemic in countries regardless if they are
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55 70 small or large, poor or rich, or capitalist or socialist[1-3]. Though medical corruption is costly for

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4 71 all countries, it seems to be an especially prevalent problem in developing and transitional
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6 72 economies where public resources are scarce, such as China[4]. Since the China's reform and
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8 73 opening up policy in 1979, public hospitals in urban and rural areas have remained under central
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11 74 government ownership. However, they were required to undertake a large degree of responsibility
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13 75 for financing money and administering institutions. This responsibility for healthcare financing
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15 76 required hospitals to rely more on the sale of services, drug prescriptions, and medical
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17 77 examinations to produce revenues[5]. The National Development and Reform Commission's price
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19 78 guidelines for basic health services(routine examinations, surgeries, standard diagnostic tests, and
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21 79 pharmaceuticals in health institutions) required prices to be low enough so services would be
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23 80 affordable for patients. Moreover, hospitals were prohibited from earning more than 15% markup
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26 81 from regulated tests and drugs[6]. However, the privatization of healthcare financing combined
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28 82 with price regulation put most public hospitals in China at serious financial risk[5-6]. To
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31 83 compensate for the retrenchment of government health outlays, many public hospitals in China
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33 84 began to earn revenue illegally through alliances with the pharmaceutical firms to procure
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35 85 pharmaceuticals and medical equipment. Meanwhile, pharmaceutical companies prefer
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37 86 establishing special arrangements for the hospitals since competition with other pharmaceutical
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39 87 companies is costly. Since the penalty cost is much lower than the illegal profit, special
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41 88 arrangements with hospitals creates a win-win situation for both entities[7,8-9]. Gradually,
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43 89 medical bribery permeated the health sectors in China[7, 10].
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51 90 The illicit bribery from pharmaceutical firms to hospitals and health professionals or officials can
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53 91 lead to the medical corruption. Usually, certain pharmaceutical firms' practices corrupt medical
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55 92 research, the production of medical knowledge, the practice of medicine, drug safety, and the
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4 93 administration's oversight of pharmaceutical marketing, etc.[11]. It was estimated that in the
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6 94 United States, the pharmaceutical industry spent up to \$42 billion in promotion every year, or on
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8 95 average, \$61,000 per physician, to influence their prescribing habits and generate profits[12]. In
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11 96 China in the 2000s, numerous incidents regarding medical corruption emerged and exposed the
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13 97 severity of corruption in China's healthcare industry[7]. For instance, in 2013, all public hospitals
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15 98 in Zhangzhou, Fujian Province were reported to be involved in medical corruption. A total of
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17 99 1,088 doctors and 133 administrators from 73 hospitals in Zhangzhou were found to be taking
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19 100 bribes and kickbacks from pharmaceutical firms that amounted to \$3.34 million[13]. In this study,
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21 101 we focused on the type of medical corruption resulting from pharmaceutical firm practices.
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23 102 Usually, the interactions between pharmaceutical companies and hospitals or physicians are
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25 103 guided by their financial interests, and can be in the form of drug or device promotion, kickbacks,
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27 104 and/or financial incentives to influence physician prescribing behaviors[14-15]. Studies showed
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29 105 that medical corruption negatively impacts the health care system by undermining the quality of
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31 106 healthcare, leading to inappropriate treatments, raising the cost of care, and damaging
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33 107 physician-patient relationships[10, 6-18].
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41 108 Confronted with severe medical corruption, many countries have implemented various
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43 109 anti-corruption strategies, such as fines and penalties[19], reform of tax policy for pharmaceutical
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45 110 companies[20], health regulations by insurance institutions(i.e. new forms of prescription drug
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47 111 pricing)[9, 21-22], and improvement of accreditation, certification, and rating systems[23-24].
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51 112 However, due to the varying characteristics of health systems and severity of medical corruption
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53 113 in different countries, the solutions usually differ by country. In China, the government began
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55 114 implementing a wave of activities to combat medical corruption as early as 1990s. In detail, there

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4 115 are three categories of solutions: fines and criminal penalties, health policy regulations and
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6 116 reporting scheme policy. Specifically, (1)the fines and criminal penalties created by legal and
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8 117 regulatory bodies, such as the "Penal Law"(Amended, 2006), "Anti-unfair Competition
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11 118 Law"(1993) and "Interim Provisions on Anti-commercial bribery"(1996)[25], as part of its health
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13 119 care reforms, (2)There are health policies that aim to reduce possible corruption in the process of
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15 120 drug selection and procurement, including the establishment of the National Reimbursement Drug
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18 121 List(NRDL, 2000) and the Essential Drug List(EDL, 2009). The NRDL was established by a
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20 122 national medicine selection system. Drugs on the NRDL have a subsidized price, but are also
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22 123 highly scrutinized. As a part of the national reimbursed drug list, the essential drugs are selected to
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24 124 ensure the accessibility and quality of basic drugs available in health institutions[26]. The second
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26 125 regulation by the health department is the new program required by the China Food and Drug
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28 126 Administration since 2009[27]. The program centralizes purchase of pharmaceuticals and controls
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30 127 costs by public tenders, bidding, and auction processes. (3) Finally, the National Health Bureau
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32 128 created a reporting scheme for commercial bribery records. Regional health bureaus must blacklist
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34 129 "manufacturers, operators or distributors" involved in commercial bribery, and instruct health
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36 130 administrations to discipline responsible persons in the health institutions and pharmaceutical
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38 131 companies[28].
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46 132 Though much information has been accumulated on how to develop regulations and
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48 133 countermeasures that restrain medical corruption in various countries[1-2,4,8,11], there is little
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50 134 research systematically examines the effects of these regulations on the elimination or alleviation
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52 135 of medical corruption from pharmaceutical firms specifically. Thereby, with the understanding
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54 136 that Chinese leadership is combating rampant corruption within its society, this study sought to
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4 137 assess whether China's reforms to curb medical corruption were effective in the procurement of
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6 138 medicines and devices. This study can help improve and foster better therapeutic and practical
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8 139 innovations to combat medical corruption in the Chinese health sector. Additionally, we think this
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11 140 study may provide recommendations to other developing countries that may be suffering from
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13 141 similar problems during economic and social transition periods.

142 **METHODS**

143 **Analytic framework**

144 Through literature review, we collected various forms of countermeasures. Additionally, we
145 consulted with the experts to reveal other regulations for medical corruption in China that were
146 not exposed through the literature review to ensure the completeness of these countermeasures.
147 These measures were then classified into three categories, with help from experts, based on the
148 rigidity of implementation. Fines and criminal penalties were executed by the law sectors in which
149 the punishments were very strict. Health policy regulations were issued by the national or local
150 health departments and usually provided guidance. The reporting scheme for the medical
151 corruption was not strict and its execution was loosely implemented.

152 Second, to examine the effects of existing countermeasures for curbing medical corruption, we
153 formulated an interview instrument based on the Donabedian model[29]. The Donabedian model
154 provides a framework to evaluate the effects of countermeasures on curbing medical corruption in
155 three categories: structure, process, and outcomes. Questions designed for experts were related to
156 the design of the regulations(structure), their implementation(process), and their

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4 157 effectiveness(outcomes). Main discussion questions about the evaluation were as follows: How
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6 158 would you describe each kind of regulation for curbing medical corruption, including its design,
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8 159 execution/implementation, and effectiveness in China?
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12 160 In addition, to support the evaluation, particularly the "outcome" section of the framework, we
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14 161 analyzed quantitative data of current medical corruption in China. Experts were also asked to
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16 162 identify any countermeasures in other countries that can help end medical corruption in China.
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20 163 **Data source**

21 22 23 24 164 *Qualitative data*

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27 165 To evaluate the current countermeasures for medical corruption in China, we chose experts that
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29 166 attended a professional forum in Shanghai about preventing and curbing medical corruption. All
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31 167 16 interviewees were experts in the field of health economics and health policy. However, only 12
32
33 168 of the experts agreed to participate. Eight experts were from universities in the city of Shanghai,
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35 169 and four experts were officers in drug procurement agencies in Shanghai and Beijing. Interviews
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37 170 were conducted from March 1, 2017 to April 9, 2017.
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43 171 *Quantitative data*

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47 172 There is no specific and sound reporting system for medical corruption in China currently.
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49 173 Therefore, to reflect the current state of medical corruption in China, we referred to "China
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51 174 Judgements Online," a national online database of case verdicts. The database, established in 2010
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53 175 by the Supreme People's Court, contains case verdicts from every field. When the system was
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3 176 initially established, only the serious verdicts released by the Supreme People's Court were
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6 177 required to be released. As of 2013, the local and intermediate courts in different provinces were
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8 178 also encouraged to send verdicts to this system[30]. We retrieved case verdicts related to medical
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11 179 corruption that occurred from January 1, 2010 to December 31, 2016 using the keywords
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13 180 "medical," "corruption," and "health institution". We collected data starting from 2010, the year in
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16 181 which the online system was launched. However, since the government did not require verdicts to
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18 182 be uploaded into the system until 2013, we discarded data before 2013 and used data from 2013 to
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21 183 2016. We found a total of 856 related verdicts. Though the sample size of the verdicts online was
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23 184 relatively small, the data uploaded provided a representative sample from each province.

185 **Data analysis**

186 Two trained researchers analyzed the qualitative data using NVivo10 to sort the interview answers.
187 The Donabedian model was used as an a priori organizational framework. Using a hierarchical
188 coding structure, the researchers deductively identified all themes, then coded and analyzed those
189 that were relevant. In addition, we conducted a literature review of medical corruption governance
190 in both developing and developed countries to search for methods to curb medical corruption in
191 China.

192 When screening the verdicts from "China Judgements Online", we first eliminated duplicate cases.
193 Second, we asked two of the authors(JWS and RL), who are health policy experts, to carefully
194 conduct a review of the verdicts. As part of the criteria, verdicts needed to depict institutional
195 medical corruption specifically relating to the procurement of drugs and devices. After conducting
196 two rounds of review, we kept a total of 336 verdicts for descriptive analysis of the current status

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4 197 of medical corruption in China. In our analysis, we reviewed the year the verdict was released, the
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6 198 level of the court that decided the verdict, the amount of illegal money involved, the institutions
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8 199 bribed, and the time period when the corruption took place.

200 **Ethics statement**

201 All research activities were conducted with integrity and in line with generally accepted ethical
202 principles. Verbal consent forms for participation and publication were obtained from all
203 interviewees.

204 **RESULTS**

205 **Qualitative evaluation on regulations for institutional medical corruption in China**

206 *Evaluation of fines and criminal penalties*

207 As early as 1990s, China has strived to establish more effective laws to curb medical corruption.
208 In the 2000s, China implemented more health reforms to restructure the health care system. The
209 experts interviewed stated that there were currently three major categories of countermeasures to
210 oppose medical corruption in China(Table 1). The experts agreed that imposing fines and criminal
211 penalties was the easiest and best preventative measure to curb institutional medical corruption.
212 However, many experts also pointed out that this type of regulation was poorly structured.
213 Punitive policies for medical corruption, including fines and imprisonment, did not effectively
214 restrain bribers, nor were they uniformly rigorous. For example, the fine amount set by the
215 Anti-unfair Competition Law(1993), 10,000RMB(approximately \$1,450) and
216 200,000RMB(approximately \$29,000), was too small to effectively restrain bribers. Although the

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4 217 Anti-unfair Competition Law was newly amended in February 2017 to increase the fine amount
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6 218 from 10% to 30% of illegal revenue obtained, experts believe that this fine is still too small to be
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8 219 effective. Moreover, because firms usually pay these fines, bribers are not effectively deterred
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11 220 from conducting illegal activities. Additionally, penalties imposed on those making and accepting
12
13 221 bribes are strikingly different depending on their affiliation to different types of institutions.
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15 222 Penalties are usually milder for parties associated with multinational firms compared to those
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17 223 associated with domestic firms. Lastly, individuals working in public health institutions (i.e.
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19 224 physicians) receive greater punishment than individuals working in private health institutions, as
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21 225 they are regarded as civil servants of China.
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25 226 *Evaluation of related health policy regulations*

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28 227 *a. The establishment of the National Reimbursement Drug List(NRDL) and the Essential Drug*
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30 228 *List(EDL)*

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33 229 The government created the National Reimbursement Drug List(NRDL) so it could select the
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35 230 highest therapeutic and cost-efficient drugs. Though being listed on the NRDL is a positive
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37 231 development for drug producers, being listed also means that there is higher scrutiny of its prices
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39 232 because listed drugs are paid completely or at least in part by China's Health Insurance
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41 233 Department. The Essential Drug List(EDL), as part of the NRDL, was established in 2009 with the
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43 234 purpose of selecting essential drugs to be made available in all public health facilities, with
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45 235 particular emphasis on grassroots health institutions[26]. Additionally, health institutions are
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47 236 required to obey the "zero-profit drug" policy, meaning the EDL drugs must be sold at purchasing
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49 237 prices[5]. Experts said that this policy helped proper prescription of drugs and further reduce the
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51 238 space for medical corruption to a certain extent.
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4 239 Most experts noted that the main problem with this policy design was that the initial established
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6 240 lists contained limited(i.e. for the EDL, there were only 307 kinds of drugs) drugs for the whole
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8 241 nation, and varied widely between provinces. However, the selection of drugs in various provinces
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11 242 lacked scientific criteria. The experts proposed that when revising the list by province created
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13 243 opportunities for new corruption. Since the provincial selection was set by leaders in the health
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15 244 bureau without necessary scientific processes and criteria or effective supervision, it was easy for
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17 245 the pharmaceutical firm to interfere. For example, the selection of drugs was corrupt because
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19 246 pharmaceutical firms were able to bribe experts. Many of the drugs on the NRDL that are not on
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21 247 the EDL can still be sold at prices 15% higher than the purchasing price, which means health
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23 248 institutions, particularly hospitals, have opportunities to create alliances with pharmaceutical firms
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25 249 for illegal profits. Usually, hospitals will purchase drugs that are not on the NRDL if they generate
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27 250 profits.

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33 251 *b. The new program for centralized purchase of pharmaceuticals*

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36 252 Centralized purchase policy was proposed in 2000as a means of restraining health institutions'
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38 253 power to directly negotiate and purchase drugs from the pharmaceutical companies. This policy
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40 254 set a separate third-party committee as the purchasing entity that was usually affiliated with the
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42 255 health bureau. However, the policy was not properly executed and many hospitals were still able
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44 256 to buy drugs directly. A new centralized purchase policy was not released until 2009 by China's
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46 257 Ministry of Health that made specific regulations to shift purchasing power from public hospitals
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48 258 to the governments. Specifically, it is the provincial committees' obligation to select suppliers
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50 259 through a competitive bidding process and then distribute the products to all hospitals under their
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52 260 jurisdiction. According to the new policy, drugs are competitively offered at the provincial levels.
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261 Central purchasing programs at the provincial level have reduced drug prices by 30% in
262 Beijing[31], 41% in Hebei[32], and 46% in Shandong[33].

263 Although studies show that decreasing the cost of medicines might reduce corruption , experts
264 pointed out there were still two problems with the purchasing committees. First, in many
265 provinces, the committees that manage the purchasing platforms are not independent. Most of
266 these committees are affiliated with the health bureau. In some areas, there is an informal
267 committee in which the responsibilities are assumed by different departments under the health
268 bureau. In this case, buck-passing would occur between various departments and could easily lead
269 to a monopoly. Experts proposed that if a central selection committee has the monopoly power,
270 then t medical firms may easily bribe key decision makers in the selection process. Secondly,
271 experts indicated that there were defects in the criteria for bidding. Many indexes were difficult
272 for bidding judges to quantify and evaluate. The lack of scientific and quantified standards
273 provides chances for bidding judges to participate in corruption. Another major problem with the
274 bidding criteria is that they usually overemphasize the weight of price. Sometimes, in order to win,
275 bidding companies set bidding prices lower than actual cost prices of drugs. This may lead to the
276 bidding companies reducing the quality of their drugs. For example, the cost price per kilo of the
277 drug radix isatidis was 3.7 RMB, but the bidding price was only 1.4 RMB—far lower than the
278 actual cost. Thus, the company used apple peel instead of radix isatidis. Requiring companies to
279 bid for the lowest price may artificially lowered prices and share profits afterwards, leading to a
280 disruption of the competitive market.

281 *Evaluation of reporting scheme for medical corruption in China*

282 In late 2013, the Chinese central government stated that ethical regulations should be used to curb

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4 283 medical corruption. The government created the "Establishment of Commercial Bribery Records
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6 284 in the Purchase and Sale of Medicines and Devices"[28]. This reporting scheme for Commercial
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8 285 Bribery Records blacklists "manufacturers, operators or distributors" involved in commercial
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11 286 bribery, and instructs health administrative departments to discipline responsible persons,
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13 287 including physicians, who may lose their licenses.

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16 288 However, experts noted that the biggest problem with this reporting scheme was that it was poorly
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18 289 executed. Only a few provinces have released the records of illegal commercial bribery, and of
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20 290 which, many were outdated. It remains to be seen if this policy will have real impact at the
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22 291 provincial and local levels from an ethical perspective.
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293 **Quantitative evaluation of regulations on institutional medical corruption in China**

31 294 As shown in Table 2, although the Supreme People's Court of China required courts to report
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33 295 verdicts to the online system since 2010, until 2013, there was only a small number of released
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35 296 verdicts. Most of the verdicts(80.06%) were from the Basic People's Courts. In most cases, bribes
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37 297 were above 100,000 RMB, and in 11.31% of the cases, bribes were more than 1,000,000 RMB.
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39 298 Usually, individuals, such as physicians, directors, deans of departments from public hospitals,
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41 299 and officers from the health bureaus, were taking bribes from pharmaceutical firms. In addition,
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43 300 most of the criminal activities reported had been undetected for a long time, with 58.53% of
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45 301 corruption behaviors lasting more than 5 years.
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52 **DISCUSSION**

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54 302 Our evaluation on the experts' interviews, supported by the quantitative data from "China
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4 304 Judgements Online", showed that while many of China's regulations on medical corruption
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6 305 operate well, problems persist. Compared to other countries implementing policies to curb medical
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8 306 corruption, China implements relatively mild penalties that do not abide by a strict "zero-tolerance"
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11 307 policy. In the United States, if pharmaceutical firms promoted drugs unlawfully, they would
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13 308 receive great fines. For instance, we can look to cases concerning a typical antipsychotics. In 2010,
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15 309 the multinational pharmaceutical company Astra-Zeneca paid \$520 million for illegally marketing
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17 310 the drug Seroquel for uses not approved by the Food and Drug Administration by paying
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19 311 kickbacks to physicians. In 2012, Johnson & Johnson settled for \$1.2 billion on charges of
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21 312 off-label promotion and failure to disclose information on adverse reactions to the drug
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23 313 Risperdal[19]. According to Public Citizen[34], from 1991 to 2012, drug companies have paid \$30
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25 314 billion in criminal fines in the United States for Medicare fraud, unlawful drug promotion,
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27 315 kickbacks, monopoly practices, and the concealment of study findings. In China, the fines for
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29 316 medical corruption are much smaller. Even the shocking multinational case of GSK's bribery in
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31 317 2013 ended with the highest fine being 30 billion RMB(approximately 4.36 billion US dollar)[35].
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33 318 If the fine amounts are not significantly increased, it will remain profitable for drug companies to
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35 319 engage in corruption practices that undermine public health[3].
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43 320 Although the Chinese government strived to reduce medical corruption by establishing the NRDL
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45 321 and EDL, our evaluation showed that without scientific and fair criteria for drug selection, it is
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47 322 difficult to resolve problems related to modifying these lists and the flawed bidding process. In
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49 323 many developed countries, health technology assessment has also been used to select drug plans
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51 324 by comparing drug costs with their therapeutic benefits. This has become central in determining
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53 325 the prices of pharmaceutical products. Health technology assessment was also proved to be
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4 326 effective in establishing the modalities for access and reimbursement of drugs[22]. This
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6 327 technology makes evidence-based medicine(rather than marketing-based medicine) central to the
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8 328 architecture of the pharmaceutical market because it directly aligns financial incentives with
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11 329 improving health outcomes. Thereby, the health technology assessment should be applied to
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13 330 facilitate Chinese governments' decision-making as soon as possible.

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16 331 Our results showed that problems with the central purchasing program were related to the lack of
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18 332 independent committees and the monopolies created by local health bureaus. To effectively solve
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20 333 these problems, many developed countries use marketization management of pharmaceutical
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22 334 products purchasing. Created in the US, an entity called Group Purchasing Organization(GPO) is
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24 335 one kind of purchasing platform in the market. The GPO leverages the purchasing power of a
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26 336 group of businesses to obtain discounts from vendors based on the collective buying power of the
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28 337 GPO members. The GPOs are intermediary agencies, and health organizations can voluntarily
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30 338 sign up to be a member of any GPO. It was found that GPOs can help effectively prevent medical
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32 339 corruption[36]. However, while many large cities in China such as Shanghai and Beijing have
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34 340 tried to establish independent GPOs[37], their efforts are still immature and thereby insufficient to
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36 341 curb medical corruption.

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39 342 Miller(2013) notes that companies initiate most corporate social responsibility initiatives to avoid
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41 343 negative reputational consequences due to the illegal earned profits. Accreditation, certification,
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43 344 and rating systems have proven useful in curbing medical corruption to a certain extent, as these
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45 345 systems help align market forces with trustworthy practices[23]. However, since its execution is
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47 346 not supervised, the reporting system for medical corruption is not properly executed. To improve
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49 347 this situation, we suggest that companies should be required to be open transparent to the public
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4 348 about the adverse results of their illegal activities.
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7 349 As revealed by much of the literature, the root of difficulties to curb medical corruption may first
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9 350 lie in the financial pressure on public hospitals. The privatization of healthcare financing
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11 351 combined with price regulation put most public hospitals in China at serious financial risk. Under
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13 352 this condition, hospitals/physicians' remuneration is set at a low level in China[38-39]. Meanwhile,
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15 353 the financial subsidies for the public health institutions were not sufficient. For instance, the EDL
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17 354 was established to curb medical corruption and health institutions are required to obey the
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19 355 "zero-profit drug" policy on essential drugs. Fiscal policy also required local governments to
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21 356 provide enough subsidies to public health institutions. However, the fiscal subsidies were not
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23 357 sufficient or not provided by the local government in many parts of China[40]. All in all, although
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25 358 many of the countermeasures were proposed and implemented, under the background of financial
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27 359 pressure, the consistent low compensation may lead to hospitals/physicians receiving bribes from
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29 360 pharmaceutical companies, since the penalty cost for both of them is much lower than the illegal
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31 361 profit[7,8-9]. Second, the weak Chinese insurance market may fuel medical corruption and
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33 362 weaken current countermeasures. The insurance market in China is composed of the social
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35 363 medical insurance provided by the government(90% coverage) and the private insurance(<10%
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37 364 coverage)[41]. However, because many of the drugs, especially the imported drugs from
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39 365 multinational corporations, are not on the NRDL and are not covered by the social medical
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41 366 insurance, and exacerbated by the weak private insurance in China, there is room for corrupt
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43 367 payoffs to be added into the price of many of these drugs. For instance, usually, patients are
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45 368 willing to pay more for foreign drugs than for ones from domestic suppliers[3]. Therefore, these
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47 369 issues must be tackled by improving the proper financial incentives for hospitals/physicians and
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4 370 perfecting the health insurance system within China's health reform.
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7 371 There were a few limitations to this study. First, there may be selection bias since the selected
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9 372 experts were mostly from Shanghai. Second, though the quantitative data from the online system
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11 373 "China Judgements Online" were helpful in supporting the qualitative data, the small sample size
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13 374 of the released verdicts about medical corruption may not accurately reflect the effects of the
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15 375 current countermeasures. More data is needed to conduct a more robust evaluation.
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18 19 376 **CONCLUSIONS**

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21 377 Our study found that though China has made efforts to tackle institutional medical corruption in
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23 378 drug procurement for many years, corruption issues continue to be a concern. In analyzing the
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25 379 qualitative material on the subject by Chinese health policy experts and quantitative data from the
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27 380 online database, we found that existing countermeasures such as fines, imprisonment penalties,
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29 381 health policy regulations, and reporting schemes, still have many defects. We suggest creating
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31 382 more rigorous legislation and well-functioning administrative mechanisms to select drugs for the
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33 383 NRDL or EDL and to establish prices using scientific criteria. To address the root of medical
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35 384 corruption however, we suggest improving the financial incentives for hospitals/physicians and
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37 385 the health insurance system within China's health reform.
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45 46 387 **Abbreviations**

47
48 388 NRDL: National Reimbursement Drug List

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50 389 EDL: Essential Drug List

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53
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55

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2
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398 **Authors' contributions**

399 Conceived and designed the experiments: JWS, ZXW and LYS. Analysed the data: JWS, RL and
400 CXW. Contributed reagents/materials/analysis tools: HJ, YX and NNL. Wrote the paper: JWS and
401 LYS.

402 **Data sharing statement**

403 All relevant data from the "China Judgements Online" can be shared to the public.

404 **Competing interests**

405 The authors have declared that they have no competing interests.

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512 Table 1 Experts' evaluation on existing countermeasures for restraining institutional medical corruption

	Countermeasures	Content	Structure	Process	Outcome
1	Fines and criminal penalties ruled by the "Penal Law"(Amended, 2006), the "Anti-unfair Competition Law"(1993), and the "Interim Provisions on Anti-commercial bribery"(1996)	Financial fines, imprisonment, and cancellation of physician licenses	(1)The fines are not high enough to effectively restrain bribery. (2)The punishment differs strikingly when bribers or bribees are in different institutions	(1)It is well implemented	(1)Imposing fines and criminal penalties is the easiest and most direct way to restrain medical corruption
2	Health policy regulations, especially those regarding drugs				
2.1	The establishment of the National Reimbursement Drug List (NRDL,2000) and the Essential Drug List(EDL, 2009)	To select the most therapeutic and economical drugs by the government	(1)The initial lists are incomplete. The adjustment of the lists may induce corruption	(1)Many of the drugs on the NRDL can still be sold at prices higher than the purchasing price; (2)Hospitals will only purchase drugs that are not on the NRDL if they generate profits.	(1) It makes the drugs on the lists under the government's high supervision; (2) The "zero-profit drug" policy for the EDL can shrink the benefit space
2.2	The new centralized purchase policy(2009)	Public tenders, bidding, and auction processes relating to the purchase of drugs are mostly operated by provincial governments	(1)Usually, the purchasing committee is affiliated with the health bureau, and purchasing decision is not made independently. Additionally, many areas have one purchasing institute, leading to monopoly of drug procurement (2)There are many defects in the selection criteria	(1)From 2009 according to the strict regulation by national Health Bureau, the purchasing of drugs or equipment has normal process for execution.	(1)Shifting purchasing power from public hospitals to governments can reduce medical corruption to a large extent
3	Reporting scheme for medical corruption(2013)	Establishment of a reporting and record-keeping scheme of commercial bribery records	(1)The reporting scheme focuses on adverse behaviors. A comprehensive rating system to rating the companies' reputation should be established	(1)The reporting scheme is poorly implemented	(1)The public can be a constraint force for the corruption

Table 2 Verdicts involving institutional medical corruption from "China Judgements Online" (N=336)

Variable	Classification	n	(%)
Year of verdicts	2013	15	4.46
	2014	105	31.25
	2015	64	19.05
	2016	152	45.24
Level of the court	Supreme people's court	4	1.19
	Intermediate people's court	63	18.75
	Basic people's court	269	80.06
Amount of money involved in the bribery(RMB)	[14,900-100,000)	87	25.89
	[100,000-500,000)	164	48.81
	[500,000-1,000,000)	47	13.99
	[1,000,000-2,000,000)	16	4.76
	[2,000,000-6,959,000)	22	6.55
Institutions of individuals taking bribes	Hospitals	307	91.37
	Health bureaus	33	9.82
Time span of the committed corruption(year)	[1-2)	15	4.46
	[2-5)	124	36.90
	[5-10)	158	47.02
	[10-15]	39	11.61

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Superieur (ABES)

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STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of *cross-sectional studies*

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	2
		(b) Provide in the abstract an informative and balanced summary of what was done and what was	2-3
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	3-6
Objectives	3	State specific objectives, including any prespecified hypotheses	6-7
Methods			
Study design	4	Present key elements of study design early in the paper	7
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	8
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection of participants	8
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	8
Data sources/measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	8
Bias	9	Describe any efforts to address potential sources of bias	9
Study size	10	Explain how the study size was arrived at	8
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	8-9
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	8-9
		(b) Describe any methods used to examine subgroups and interactions	8-9
		(c) Explain how missing data were addressed	8-9
		(d) If applicable, describe analytical methods taking account of sampling strategy	N/A
		(e) Describe any sensitivity analyses	N/A
Results			

Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	N/A
		(b) Give reasons for non-participation at each stage	N/A
		(c) Consider use of a flow diagram	N/A
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	10
		(b) Indicate number of participants with missing data for each variable of interest	N/A
Outcome data	15*	Report numbers of outcome events or summary measures	10-14
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg 95% confidence interval). Make clear which confounders were adjusted for and why they were included	N/A
		(b) Report category boundaries when continuous variables were categorized	N/A
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	N/A
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	N/A
Discussion			
Key results	18	Summarise key results with reference to study objectives	14
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	17
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	14-17
Generalisability	21	Discuss the generalisability (external validity) of the study results	17-18
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	18

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at www.strobe-statement.org.

BMJ Open

Moving towards a better path? A mixed-method examination of China's reforms to remedy medical corruption from pharmaceutical firms

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Secondary Subject Heading:	Ethics, Health economics, Health services research
Keywords:	Medical corruption, Evaluation, Effectiveness, China

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1 Moving towards a better path? A mixed-method 2 examination of China's reforms to remedy medical 3 corruption from pharmaceutical firms

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Moving towards a better path? A mixed-method examination of China's reforms to remedy medical corruption from pharmaceutical firms

ABSTRACT

Objectives: Few studies have systematically examined the effects of the existing regulations for alleviating corruption in China. This study assesses the effectiveness of China's reforms to curb medical corruption.

Methods: We used mixed methods for the evaluation of existing countermeasures. First, qualitative informant interviews based on the Donabedian model were conducted to obtain experts' evaluation of various kinds of countermeasures. Second, by using data from "China Judgements Online", we analyzed the occurrence trend and characteristics of the medical corruption cases in recent years to reflect the overall effects of these countermeasures in China.

Results: Since 1990s, China has implemented three main categories of countermeasures to oppose medical corruption: fines and criminal penalties, health policy regulations, and reporting scheme policy. Information from the interviews showed that first, the level of fines and criminal penalties for medical corruption behaviors may not be sufficient. Second, health policy regulations are also insufficient. Although the National Reimbursement Drug List(NRDL) and Essential Drug List(EDL) were implemented, they were incomplete and created additional opportunities for corruption. Moreover, the new program that centralized the purchase of pharmaceuticals found that most purchasing committees were not independent, and the selection criteria for bidding lacked scientific evidence. Third, reporting scheme for Commercial Bribery Records by the health

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4 50 bureau was executed poorly. In addition, quantitative online data showed no obvious decrease of
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6 51 institutional medical corruption in recent years, and most criminals committed crimes for a long
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8 52 time before getting detected, which further demonstrated the low effectiveness of the above
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11 53 countermeasures.

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14 54 **Conclusions:** Although existing countermeasures have exerted certain effects according to
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16 55 Chinese experts, more rigorous legislation and well-functioning administrative mechanisms are
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18 56 needed. Fundamentally, financial incentives for hospitals/physicians and the health insurance
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20 57 system should be improved.

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22 58 **Keywords:** Medical corruption; Evaluation; Effectiveness; China

23 24 25 59 **Strengths and limitations**

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31 60 ● This study systematically examined the effects of existing regulations for curbing medical
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33 61 corruption in China.
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36 62 ● Using mainly qualitative data from interviews with experts, supported by the quantitative
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38 63 data from "China Judgements Online" that release the case verdicts about medical corruption,
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40 64 this study examined the effects comprehensively.
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43 65 ● The main limitations of this study were related with its data collection, since the selected
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45 66 interviewed experts were mostly from Shanghai and the quantitative data from the online
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47 67 system had a small sample size.

48 49 50 51 68 **INTRODUCTION**

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55 69 Medical corruption is pervasive across cultures and endemic in countries regardless if they are

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4 70 small or large, poor or rich, or capitalist or socialist[1-3]. Though medical corruption is costly for
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6 71 all countries, it seems to be an especially prevalent problem in developing and transitional
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8 72 economies where public resources are scarce, such as China[4]. Since the China's reform and
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11 73 opening up policy in 1979, public hospitals in urban and rural areas have remained under central
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13 74 government ownership. However, they were required to undertake a large degree of responsibility
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15 75 for financing money and administering institutions. This responsibility for healthcare financing
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17 76 required hospitals to rely more on the sale of services, drug prescriptions, and medical
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19 77 examinations to produce revenues[5]. The National Development and Reform Commission's price
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21 78 guidelines for basic health services(routine examinations, surgeries, standard diagnostic tests, and
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23 79 pharmaceuticals in health institutions) required prices to be low enough so services would be
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25 80 affordable for patients. Moreover, hospitals were prohibited from earning more than 15% markup
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27 81 from regulated tests and drugs[6]. However, the privatization of healthcare financing combined
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29 82 with price regulation put most public hospitals in China at serious financial risk[5-6]. To
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31 83 compensate for the retrenchment of government health outlays, many public hospitals in China
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33 84 began to earn revenue illegally through alliances with the pharmaceutical firms to procure
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35 85 pharmaceuticals and medical equipment[3,7,8]. Meanwhile, pharmaceutical companies prefer
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37 86 establishing special arrangements for the hospitals since competition with other pharmaceutical
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39 87 companies is costly. Since the penalty cost is much lower than the illegal profit, special
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41 88 arrangements with hospitals creates a win-win situation for both entities[7,9-10]. Gradually,
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53 90 The illicit bribery from pharmaceutical firms to hospitals and health professionals or officials can
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56 91 lead to the medical corruption. Usually, certain pharmaceutical firms' practices corrupt medical
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4 92 research, the production of medical knowledge, the practice of medicine, drug safety, and the
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6 93 administration's oversight of pharmaceutical marketing, etc.[11]. It was estimated that in the
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8 94 United States, the pharmaceutical industry spent up to \$42 billion in promotion every year, or on
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11 95 average, \$61,000 per physician, to influence their prescribing habits and generate profits[12]. In
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13 96 China in the 2000s, numerous incidents regarding medical corruption emerged and exposed the
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15 97 severity of corruption in China's healthcare industry[7]. For instance, in 2013, all public hospitals
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17 98 in Zhangzhou, Fujian Province were reported to be involved in medical corruption. A total of
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20 99 1,088 doctors and 133 administrators from 73 hospitals in Zhangzhou were found to be taking
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23 100 bribes and kickbacks from pharmaceutical firms that amounted to \$3.34 million[13]. In this study,
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25 101 we focused on the type of medical corruption resulting from pharmaceutical firm practices.
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28 102 Usually, the interactions between pharmaceutical companies and hospitals or physicians are
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30 103 guided by their financial interests, and can be in the form of drug or device promotion, kickbacks,
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32 104 and/or financial incentives to influence physician prescribing behaviors[14-15]. Studies showed
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34 105 that medical corruption negatively impacts the health care system by undermining the quality of
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36 106 healthcare, leading to inappropriate treatments, raising the cost of care, and damaging
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38 107 physician-patient relationships[8, 6-18].
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44 108 Confronted with severe medical corruption, many countries have implemented various
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46 109 anti-corruption strategies, such as fines and penalties[19], reform of tax policy for pharmaceutical
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48 110 companies[20], health regulations by insurance institutions(i.e. new forms of prescription drug
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50 111 pricing)[10,21-22], and improvement of accreditation, certification, and rating systems[23-24].
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53 112 However, due to the varying characteristics of health systems and severity of medical corruption
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56 113 in different countries, the solutions usually differ by country. In China, the government began

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4 114 implementing a wave of activities to combat medical corruption as early as 1990s. In detail, there
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6 115 are three categories of solutions: fines and criminal penalties, health policy regulations and
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8 116 reporting scheme policy. Specifically, (1)the fines and criminal penalties created by legal and
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11 117 regulatory bodies, such as the "Penal Law"(Amended, 2006), "Anti-unfair Competition
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13 118 Law"(1993) and "Interim Provisions on Anti-commercial bribery"(1996)[25], as part of its health
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16 119 care reforms, (2)There are health policies that aim to reduce possible corruption in the process of
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18 120 drug selection and procurement, including the establishment of the National Reimbursement Drug
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20 121 List(NRDL, 2000) and the Essential Drug List(EDL, 2009). The NRDL was established by a
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23 122 national medicine selection system. Drugs on the NRDL have a subsidized price, but are also
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25 123 highly scrutinized. As a part of the national reimbursed drug list, the essential drugs are selected to
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28 124 ensure the accessibility and quality of basic drugs available in health institutions[26]. The second
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30 125 regulation by the health department is the new program required by the China Food and Drug
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32 126 Administration since 2009[27]. The program centralizes purchase of pharmaceuticals and controls
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35 127 costs by public tenders, bidding, and auction processes. (3) Finally, the National Health Bureau
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38 128 created a reporting scheme for commercial bribery records. Regional health bureaus must blacklist
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40 129 "manufacturers, operators or distributors" involved in commercial bribery, and instruct health
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43 130 administrations to discipline responsible persons in the health institutions and pharmaceutical
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45 131 companies[28].

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48 132 Though much information has been accumulated on how to develop regulations and
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50 133 countermeasures that restrain medical corruption in various countries[1-2,4,9,11], there is little
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53 134 research that systematically examines the effects of these regulations on the elimination or
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56 135 alleviation of medical corruption from pharmaceutical firms specifically. Thereby, with the

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3 136 understanding that Chinese leadership is combating rampant corruption within its society, this
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6 137 study sought to assess whether China's reforms to curb medical corruption were effective in the
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8 138 procurement of medicines and devices. This study can help improve and foster better therapeutic
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11 139 and practical innovations to combat medical corruption in the Chinese health sector. Additionally,
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13 140 we think this study may provide recommendations to other developing countries that may be
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16 141 suffering from similar problems during economic and social transition periods.
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142 **METHODS**

143 **Analytic framework**

144 Through literature review, we collected various forms of countermeasures. Additionally, we
145 consulted with the health system experts to reveal other regulations for medical corruption in
146 China that were not exposed through the literature review to ensure the completeness of these
147 countermeasures. These measures were then classified into three categories, with help from
148 experts, based on the rigidity of implementation. Fines and criminal penalties were executed by
149 the law sectors in which the punishments were very strict. Health policy regulations were issued
150 by the national or local health departments and usually provided guidance. The reporting scheme
151 for the medical corruption was not strict and its execution was loosely implemented.

152 Second, to examine the effects of existing countermeasures for curbing medical corruption, we
153 formulated an interview instrument based on the Donabedian model[29]. The Donabedian model
154 provides a framework to evaluate the effects of countermeasures on curbing medical corruption in
155 three categories: structure, process, and outcomes. Questions designed for experts were related to

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4 156 the design of the regulations(structure), their implementation(process), and their
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6 157 effectiveness(outcomes). Main discussion questions about the evaluation were as follows: How
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8 158 would you describe each kind of regulation for curbing medical corruption, including its design,
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11 159 execution/implementation, and effectiveness in China?

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14 160 To quantitatively support the evaluation, we analyzed released online data of current medical
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16 161 corruption cases in China to reflect the overall effects of the countermeasures. In addition, experts
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18 162 were also asked to identify any countermeasures in other countries that can help end medical
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20 163 corruption in China.

21 22 23 24 25 164 **Data source**

26 27 28 165 *Qualitative data*

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32 166 To evaluate the current countermeasures for medical corruption in China, we chose experts that
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34 167 attended a professional forum in Shanghai about preventing and curbing medical corruption. All
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36 168 sixteen interviewees were experts in the field of health economics and health policy. However,
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38 169 only twelve of the experts agreed to participate. Eight experts were from universities in the city of
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40 170 Shanghai, and four experts were officers in drug procurement agencies in Shanghai and Beijing.
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43 171 Interviews were conducted from March 1, 2017 to April 9, 2017.

44 45 46 172 *Quantitative data*

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51 173 There is no specific and sound reporting system for medical corruption in China currently.
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54 174 Therefore, to reflect the current state of medical corruption in China, we referred to "China
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4 175 Judgements Online," a national online database of case verdicts. The database, established in 2010
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6 176 by the Supreme People's Court, contains case verdicts from every field. When the system was
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8 177 initially established, only the serious verdicts released by the Supreme People's Court were
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11 178 required to be released. As of 2013, the local and intermediate courts in different provinces were
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13 179 also encouraged to send verdicts to this system[30]. We retrieved case verdicts related to medical
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15 180 corruption that occurred from January 1, 2010 to December 31, 2016 using the keywords
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18 181 "medical," "corruption," and "health institution". We collected data starting from 2010, the year in
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21 182 which the online system was launched. However, since the government did not require verdicts to
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23 183 be uploaded into the system until 2013, we discarded data before 2013 and used data from 2013 to
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25 184 2016. We found a total of 856 related verdicts and after selection, 336 verdicts relating to the
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28 185 procurement of drugs and devices were kept. Though the sample size of the verdicts online was
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31 186 relatively small, the data uploaded provided a representative sample from each province.

32 33 34 187 **Data analysis**

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37 188 Two trained researchers analyzed the qualitative data using NVivo 10 to sort the interview answers.
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40 189 The Donabedian model was used as an a priori organizational framework. Using a hierarchical
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42 190 coding structure, the researchers deductively identified all themes, then coded and analyzed those
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45 191 that were relevant. In addition, we conducted a literature review of medical corruption governance
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47 192 in both developing and developed countries to search for methods to curb medical corruption in
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50 193 China.

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53 194 When screening the verdicts from "China Judgements Online", we first eliminated duplicate cases.
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56 195 Second, we asked two of the authors(JWS and RL), who are health policy experts, to carefully

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4 196 conduct a review of the verdicts. As part of the criteria, verdicts needed to depict institutional
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6 197 medical corruption specifically relating to the procurement of drugs and devices. After conducting
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8 198 two rounds of review, we kept a total of 336 verdicts for descriptive analysis of the current status
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11 199 of medical corruption in China. In our analysis, we reviewed the year the verdict was released, the
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13 200 level of the court that decided the verdict, the amount of illegal money involved, the institutions
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15 201 bribed, and the time period when the corruption took place.

18 202 **Ethics statement**

20 203 All research activities were conducted with integrity and in line with generally accepted ethical
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22 204 principles. Verbal consent forms for participation and publication were obtained from all
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24 205 interviewees.

26 206 **RESULTS**

28 207 **Qualitative evaluation on regulations for institutional medical corruption in China**

30 208 *Evaluation of fines and criminal penalties*

32 209 As early as 1990s, China has strived to establish more effective laws to curb medical corruption.
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34 210 In the 2000s, China implemented more health reforms to restructure the health care system. The
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36 211 experts interviewed stated that there were currently three major categories of countermeasures to
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38 212 oppose medical corruption in China(Table 1). The experts agreed that imposing fines and criminal
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40 213 penalties was the easiest and best preventative measure to curb institutional medical corruption.
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42 214 However, many experts also pointed out that this type of regulation was poorly structured.
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44 215 Punitive policies for medical corruption, including fines and imprisonment, did not effectively

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4 216 restrain bribers, nor were they uniformly rigorous. For example, the fine amount set by the
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6 217 Anti-unfair Competition Law(1993), 10,000 RMB(approximately \$1,450) and 200,000
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8 218 RMB(approximately \$29,000), was too small to effectively restrain bribers. Although the
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11 219 Anti-unfair Competition Law was newly amended in February 2017 to increase the fine amount
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13 220 from 10% to 30% of illegal revenue obtained, experts believe that this fine is still too small to be
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15 221 effective. Moreover, because firms usually pay these fines, bribers are not effectively deterred
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17 222 from conducting illegal activities. Additionally, penalties imposed on those making and accepting
18
19 223 bribes are strikingly different depending on their affiliation to different types of institutions.
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21 224 Penalties are usually milder for parties associated with multinational firms compared to those
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23 225 associated with domestic firms. Lastly, individuals working in public health institutions(i.e.
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25 226 physicians) receive greater punishment than individuals working in private health institutions, as
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27 227 they are regarded as civil servants of China.

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33 228 *Evaluation of related health policy regulations*

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36 229 *a. The establishment of the National Reimbursement Drug List(NRDL) and the Essential Drug*
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38 230 *List(EDL)*

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41 231 The government created the National Reimbursement Drug List(NRDL) so it could select the
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43 232 highest therapeutic and cost-efficient drugs. Though being listed on the NRDL is a positive
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45 233 development for drug producers, being listed also means that there is higher scrutiny of its prices
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47 234 because listed drugs are paid completely or at least in part by China's Health Insurance
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49 235 Department. The Essential Drug List(EDL), as part of the NRDL, was established in 2009 with the
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51 236 purpose of selecting essential drugs to be made available in all public health facilities, with
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53 237 particular emphasis on grassroots health institutions[26]. Additionally, health institutions are

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4 238 required to obey the "zero-profit drug" policy, meaning the EDL drugs must be sold at purchasing
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6 239 prices[5]. Experts said that this policy helped proper prescription of drugs and further reduce the
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8 240 space for medical corruption to a certain extent.

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11 241 Most experts noted that the main problem with this policy design was that the initial established
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13 242 lists contained limited(i.e. for the EDL, there were only 307 kinds of drugs) drugs for the whole
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15 243 nation, and varied widely between provinces. However, the selection of drugs in various provinces
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17 244 lacked scientific criteria. The experts proposed that when revising the list by province created
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19 245 opportunities for new corruption. Since the provincial selection was set by leaders in the health
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21 246 bureau without necessary scientific processes and criteria or effective supervision, it was easy for
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23 247 the pharmaceutical firm to interfere. For example, the selection of drugs was corrupt because
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25 248 pharmaceutical firms were able to bribe experts. Many of the drugs on the NRDL that are not on
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27 249 the EDL can still be sold at prices 15% higher than the purchasing price, which means health
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29 250 institutions, particularly hospitals, have opportunities to create alliances with pharmaceutical firms
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31 251 for illegal profits. Usually, hospitals will purchase drugs that are not on the NRDL if they generate
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33 252 profits.

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41 253 *b. The new program for centralized purchase of pharmaceuticals*

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43 254 Centralized purchase policy was proposed in 2000 as a means of restraining health institutions'
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45 255 power to directly negotiate and purchase drugs from the pharmaceutical companies. This policy
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47 256 set a separate third-party committee as the purchasing entity that was usually affiliated with the
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49 257 health bureau. However, the policy was not properly executed and many hospitals were still able
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51 258 to buy drugs directly. A new centralized purchase policy was not released until 2009 by China's
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53 259 Ministry of Health that made specific regulations to shift purchasing power from public hospitals

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4 260 to the governments. Specifically, it is the provincial committees' obligation to select suppliers
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6 261 through a competitive bidding process and then distribute the products to all hospitals under their
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8 262 jurisdiction. According to the new policy, drugs are competitively offered at the provincial levels.
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11 263 Central purchasing programs at the provincial level have reduced drug prices by 30% in
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13 264 Beijing[31], 41% in Hebei[32], and 46% in Shandong[33].

16 265 Although studies show that decreasing the cost of medicines might reduce corruption, experts
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18 266 pointed out there were still two problems with the purchasing committees. First, in many
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20 267 provinces, the committees that manage the purchasing platforms are not independent. Most of
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22 268 these committees are affiliated with the health bureau. In some areas, there is an informal
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24 269 committee in which the responsibilities are assumed by different departments under the health
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26 270 bureau. In this case, buck-passing would occur between various departments and could easily lead
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28 271 to a monopoly. Experts proposed that if a central selection committee had the monopoly power,
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30 272 then medical firms may easily bribe key decision makers in the selection process. Secondly,
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32 273 experts indicated that there were defects in the criteria for bidding. Many indexes were difficult
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34 274 for bidding judges to quantify and evaluate. The lack of scientific and quantified standards
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36 275 provides chances for bidding judges to participate in corruption. Another major problem with the
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38 276 bidding criteria is that they usually overemphasize the weight of price. Sometimes, in order to win,
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40 277 bidding companies set bidding prices lower than actual cost prices of drugs. This may lead to the
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42 278 bidding companies reducing the quality of their drugs. For example, the cost price per kilo of the
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44 279 drug radix isatidis was 3.7 RMB, but the bidding price was only 1.4 RMB - far lower than the
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46 280 actual cost. Thus, the company used apple peel instead of radix isatidis. Requiring companies to
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48 281 bid for the lowest price may artificially lowered prices and share profits afterwards, leading to a

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4 282 disruption of the competitive market.
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7 283 *Evaluation of reporting scheme for medical corruption in China*
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9 284 In late 2013, the Chinese central government stated that ethical regulations should be used to curb
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11 285 medical corruption. The government created the "Establishment of Commercial Bribery Records
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13 286 in the Purchase and Sale of Medicines and Devices"[28]. This reporting scheme for Commercial
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15 287 Bribery Records blacklists "manufacturers, operators or distributors" involved in commercial
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17 288 bribery, and instructs health administrative departments to discipline responsible persons,
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19 289 including physicians, who may lose their licenses.
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24 290 However, experts noted that the biggest problem with this reporting scheme was that it was poorly
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26 291 executed. Only a few provinces have released the records of illegal commercial bribery, and of
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28 292 which, many were outdated. It remains to be seen if this policy will have real impact at the
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30 293 provincial and local levels from an ethical perspective.
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34 294 **Quantitative evaluation of regulations on institutional medical corruption in China**

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37 295 As shown in Table 2, although the Supreme People's Court of China required courts to report
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39 296 verdicts to the online system since 2010, until 2013, there was only a small number of released
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41 297 verdicts. However, there was no obvious decrease of institutional medical corruption from 2013 to
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43 298 2016. Most of the verdicts(80.06%) were from the Basic People's Courts. In most cases, bribes
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45 299 were above 100,000 RMB(74.11%), and in 11.31% of the cases, bribes were more than 1,000,000
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47 300 RMB. Usually, more of the individuals(physicians, directors, deans of departments) who took
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49 301 bribes were from hospitals(91.37%). In addition, most of the criminal activities reported had been
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51 302 undetected for a long time, with 58.63% of corruption behaviors lasting five years or more before
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3 303 being detected.
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7 304 **DISCUSSION**
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9 305 Our evaluation on the experts' interviews, supported by the quantitative data from "China
10 306 Judgements Online", showed that while many of China's regulations on medical corruption
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12 307 operate well, problems persist. Compared to other countries implementing policies to curb medical
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14 308 corruption, China implements relatively mild penalties that do not abide by a strict "zero-tolerance"
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16 309 policy. In the United States, if pharmaceutical firms promoted drugs unlawfully, they would
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18 310 receive great fines. For instance, we can look to cases concerning a typical antipsychotics. In 2010,
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20 311 the multinational pharmaceutical company Astra-Zeneca paid \$520 million for illegally marketing
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22 312 the drug Seroquel for uses not approved by the Food and Drug Administration by paying
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24 313 kickbacks to physicians. In 2012, Johnson & Johnson settled for \$1.2 billion on charges of
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26 314 off-label promotion and failure to disclose information on adverse reactions to the drug of
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28 315 Risperdal[19]. According to Public Citizen[34], from 1991 to 2012, drug companies have paid \$30
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30 316 billion in criminal fines in the United States for Medicare fraud, unlawful drug promotion,
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32 317 kickbacks, monopoly practices, and the concealment of study findings. In China, the fines for
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34 318 medical corruption are much smaller. Even the shocking multinational case of GSK's bribery in
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36 319 2013 ended with the highest fine being 30 billion RMB(approximately 4.36 billion US dollar)[35].
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38 320 If the fine amounts are not significantly increased, it will remain profitable for drug companies to
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40 321 engage in corruption practices that undermine public health[3].
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51 322 Although the Chinese government strived to reduce medical corruption by establishing the NRDL
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53 323 and EDL, our evaluation showed that without scientific and fair criteria for drug selection, it is
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4 324 difficult to resolve problems related to modifying these lists and the flawed bidding process. In
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6 325 many developed countries, health technology assessment has also been used to select drug plans
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8 326 by comparing drug costs with their therapeutic benefits. This has become central in determining
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11 327 the prices of pharmaceutical products. Health technology assessment was also proved to be
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13 328 effective in establishing the modalities for access and reimbursement of drugs[22]. This
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16 329 technology makes evidence-based medicine(rather than marketing-based medicine) central to the
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18 330 architecture of the pharmaceutical market because it directly aligns financial incentives with
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21 331 improving health outcomes. Thereby, the health technology assessment should be applied to
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23 332 facilitate Chinese governments' decision-making as soon as possible.

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26 333 Our results showed that problems with the central purchasing program were related to the lack of
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28 334 independent committees and the monopolies created by local health bureaus. To effectively solve
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30 335 these problems, many developed countries use marketization management of pharmaceutical
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32 336 products purchasing. Created in the US, an entity called Group Purchasing Organization(GPO) is
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34 337 one kind of purchasing platform in the market. The GPO leverages the purchasing power of a
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36 338 group of businesses to obtain discounts from vendors based on the collective buying power of the
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38 339 GPO members. The GPOs are intermediary agencies, and health organizations can voluntarily
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41 340 sign up to be a member of any GPO. It was found that GPOs can help effectively prevent medical
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43 341 corruption[36]. However, while many large cities in China such as Shanghai and Beijing have
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46 342 tried to establish independent GPOs[37], their efforts are still immature and thereby insufficient to
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49 343 curb medical corruption.

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53 344 Miller(2013) notes that companies initiate most corporate social responsibility initiatives to avoid
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56 345 negative reputational consequences due to the illegal earned profits. Accreditation, certification,

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4 346 and rating systems have proven useful in curbing medical corruption to a certain extent, as these
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6 347 systems help align market forces with trustworthy practices[23]. However, since its execution is
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8 348 not supervised, the reporting system for medical corruption is not properly executed. To improve
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11 349 this situation, we suggest that companies should be required to be open transparent to the public
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13 350 about the adverse results of their illegal activities.

16 351 As revealed by much of the literature, the root of difficulties to curb medical corruption may first
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18 352 lie in the financial pressure on public hospitals. The privatization of healthcare financing
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20 353 combined with price regulation put most public hospitals in China at serious financial risk. Under
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22 354 this condition, hospitals/physicians' remuneration is set at a low level in China[38-39]. Meanwhile,
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24 355 the financial subsidies for the public health institutions were not sufficient. For instance, the EDL
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26 356 was established to curb medical corruption and health institutions are required to obey the
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28 357 "zero-profit drug" policy on essential drugs. Fiscal policy also required local governments to
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31 358 provide enough subsidies to public health institutions. However, the fiscal subsidies were not
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33 359 sufficient or not provided by the local government in many parts of China[40]. All in all, although
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35 360 many of the countermeasures were proposed and implemented, under the background of financial
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37 361 pressure, the consistent low compensation may lead to hospitals/physicians receiving bribes from
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39 362 pharmaceutical companies, since the penalty cost for both of them is much lower than the illegal
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41 363 profit[7,9-10]. Second, the weak Chinese insurance market may fuel medical corruption and
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43 364 weaken current countermeasures. The insurance market in China is composed of the social
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45 365 medical insurance provided by the government(90% coverage) and the private insurance(<10%
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47 366 coverage)[41]. However, because many of the drugs, especially the imported drugs from
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49 367 multinational corporations, are not on the NRDL and are not covered by the social medical
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4 368 insurance, and exacerbated by the weak private insurance in China, there is room for corrupt
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6 369 payoffs to be added into the price of many of these drugs. For instance, usually, patients are
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8 370 willing to pay more for foreign drugs than for ones from domestic suppliers[3]. Therefore, these
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11 371 issues must be tackled by improving the proper financial incentives for hospitals/physicians and
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13 372 perfecting the health insurance system within China's health reform.

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16 373 There were a few limitations to this study. First, there may be selection bias since the selected
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18 374 experts were mostly from Shanghai. Second, though the quantitative data from the online system
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20 375 "China Judgements Online" were helpful in supporting the qualitative data, the small sample size
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22 376 of the released verdicts about medical corruption may not accurately reflect the effects of the
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24 377 current countermeasures. More data is needed to conduct a more robust evaluation.

25 26 27 28 29 378 **CONCLUSIONS**

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31 379 Our study found that though China has made efforts to tackle institutional medical corruption in
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33 380 drug procurement for many years, corruption issues continue to be a concern. In analyzing the
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35 381 qualitative material on the subject by Chinese health policy experts and quantitative data from the
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37 382 online database, we found that existing countermeasures such as fines, imprisonment penalties,
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39 383 health policy regulations, and reporting schemes, still have many defects. We suggest creating
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41 384 more rigorous legislation and well-functioning administrative mechanisms to select drugs for the
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43 385 NRDL or EDL and to establish prices using scientific criteria. To address the root of medical
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45 386 corruption however, we suggest improving the financial incentives for hospitals/physicians and
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47 387 the health insurance system within China's health reform.

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54 55 56 389 **Abbreviations**

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3 390 NRDL: National Reimbursement Drug List

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5 391 EDL: Essential Drug List

6
7 392 **Acknowledgements**

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9 393 We sincerely acknowledge and appreciate the interviewees and institutions' contributions to this study.

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20
21 400 **Authors' contributions**

22 401 Conceived and designed the experiments: JWS, ZXW and LYS. Analysed the data: JWS, RL and
23 402 CXW. Contributed reagents/materials/analysis tools: HJ, YX and NNL. Wrote the paper: JWS and
24 403 LYS. Revised the paper: JWS and LYS.

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28 404 **Data sharing statement**

29 405 All relevant data from the "China Judgements Online" can be shared to the public.

30
31 406 **Competing interests**

32 407 The authors have declared that they have no competing interests.

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Table 1 Experts' evaluation on existing countermeasures for restraining institutional medical corruption

	Countermeasures	Content	Structure	Process	Outcome
1	Fines and criminal penalties ruled by the "Penal Law"(Amended, 2006), the "Anti-unfair Competition Law"(1993), and the "Interim Provisions on Anti-commercial bribery"(1996)	Financial fines, imprisonment, and cancellation of physician licenses	(1)The fines are not high enough to effectively restrain bribery; (2)The punishment differs strikingly when bribers or bribees are in different institutions	(1)It is well implemented	(1)Imposing fines and criminal penalties is the easiest and most direct way to restrain medical corruption
2	Health policy regulations, especially those regarding drugs				
2.1	The establishment of the National Reimbursement Drug List (NRDL, 2000) and the Essential Drug List(EDL, 2009)	To select the most therapeutic and economical drugs by the government	(1)The initial lists are incomplete. The adjustment of the lists may induce corruption	(1)Many of the drugs on the NRDL can still be sold at prices higher than the purchasing price; (2)Hospitals will only purchase drugs that are not on the NRDL if they generate profits.	(1) It makes the drugs on the lists under the government's high supervision; (2) The "zero-profit drug" policy for the EDL can shrink the benefit space
2.2	The new centralized purchase policy(2009)	Public tenders, bidding, and auction processes relating to the purchase of drugs are mostly operated by provincial governments	(1)Usually, the purchasing committee is affiliated with the health bureau, and purchasing decision is not made independently. Additionally, many areas have one purchasing institute, leading to monopoly of drug procurement; (2)There are many defects in the selection criteria	(1)From 2009 according to the strict regulation by national Health Bureau, the purchasing of drugs or equipment has normal process for execution.	(1)Shifting purchasing power from public hospitals to governments can reduce medical corruption to a large extent
3	Reporting scheme for medical corruption(2013)	Establishment of a reporting and record-keeping scheme of commercial bribery records	(1)The reporting scheme focuses on adverse behaviors. A comprehensive rating system to rating the companies' reputation should be established	(1)The reporting scheme is poorly implemented	(1)The public can be a constraint force for the corruption

Table 2 Verdicts involving institutional medical corruption from "China Judgements Online" (N=336)

Variable	Classification	n	(%)
Year of verdicts	2013	15	4.46
	2014	105	31.25
	2015	64	19.05
	2016	152	45.24
Level of the court	Supreme people's court	4	1.19
	Intermediate people's court	63	18.75
	Basic people's court	269	80.06
Amount of money involved in the bribery(RMB)	[14,900-100,000)	87	25.89
	[100,000-500,000)	164	48.81
	[500,000-1,000,000)	47	13.99
	[1,000,000-2,000,000)	16	4.76
	[2,000,000-6,959,000)	22	6.55
Institutions of individuals taking bribes	Hospitals	307	91.37
	Health bureaus	33	9.82
Time span of the committed corruption(year)	[1-2)	15	4.47
	[2-5)	124	36.90
	[5-10)	158	47.02
	[10-15]	39	11.61

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STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of *cross-sectional studies*

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	2
		(b) Provide in the abstract an informative and balanced summary of what was done and what was	2-3
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	3-6
Objectives	3	State specific objectives, including any prespecified hypotheses	6-7
Methods			
Study design	4	Present key elements of study design early in the paper	7-8
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	8
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection of participants	8
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	9-10
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	8-9
Bias	9	Describe any efforts to address potential sources of bias	9
Study size	10	Explain how the study size was arrived at	8
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	10
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	10
		(b) Describe any methods used to examine subgroups and interactions	8-9
		(c) Explain how missing data were addressed	8-9
		(d) If applicable, describe analytical methods taking account of sampling strategy	N/A
		(e) Describe any sensitivity analyses	N/A
Results			

Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	N/A
		(b) Give reasons for non-participation at each stage	N/A
		(c) Consider use of a flow diagram	N/A
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	8
		(b) Indicate number of participants with missing data for each variable of interest	N/A
Outcome data	15*	Report numbers of outcome events or summary measures	10-15
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg 95% confidence interval). Make clear which confounders were adjusted for and why they were included	N/A
		(b) Report category boundaries when continuous variables were categorized	N/A
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	N/A
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	N/A
Discussion			
Key results	18	Summarise key results with reference to study objectives	15
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	18
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	15-18
Generalisability	21	Discuss the generalisability (external validity) of the study results	17-18
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	19

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at www.strobe-statement.org.