מאיירס-ג'וינט-ברוקדייל
MYERS-JDC-BROOKDALE
مايرس - جوينت - بروكديل

1974-2014

SMOKLER CENTER FOR HEALTH POLICY RESEARCH

RESEARCH REPORT

Legislation to Promote Transparency in the Relationship between Physicians and Pharmaceutical Companies

Rachel Nissanholtz-Gannot ✦ Ariel Yankellevich ✦ Nurit Nirel

The study was funded by the Israel National Institute for Health Policy Research

RR-701-16

Legislation to Promote Transparency in the Relationship between Physicians and Pharmaceutical Companies

Rachel Nissanholtz-Gannot Ariel Yankellevich Nurit Nirel

The study was funded by the Israel National Institute for Health Policy Research

Jerusalem February 2016

Editor: Ronit Ben-Nun
English translation (executive summary): Naomi Halsted
Layout and print production: Leslie Klineman

Myers-JDC-Brookdale Institute
Smokler Center for Health Policy Research
P.O.B. 3886
Jerusalem 9103702, Israel

Tel: (02) 655-7400
Fax: (02) 561-2391

Website: http://brookdale.jdc.org.il
e-mail: brook@jdc.org.il

Executive Summary

The relationship between physicians and pharmaceutical companies (PCs) is an integral part of the health system. Much has been written about this relationship, which does, in many ways, oil the wheels of the health system, inter alia by funding research and the work of medical organizations such as patients' associations. However, the fact that the development of medicine is intertwined with the development of the pharmaceutical industry means that there are also considerable ethical issues of concern to policymakers all over the world, including Israel. First and foremost among these is the fear of the influence on the practices of physicians and other players in the health system and on health spending and medical care.

This mutually dependent relationship – and the dilemmas it poses – require the health systems in Israel and abroad to examine the impact on the individual physician, and on the entire system, and to put safeguards in place.

This study seeks to examine the implications of recent Israeli legislation (requiring public reporting of contributions) on the relationship between physicians and PCs, as reflected in the statements of stakeholders in this area, and to ascertain the role of this legislation in the regulatory environment in Israel. The study also examines the attitudes of stakeholders towards the relationship between physicians and PCs and the best way for the system to address the ethical dilemmas raised.

Background

The proposed approaches to regulating the relationship fall into two categories:

1. ***Self-regulation*:** A voluntary arrangement among the parties involved, which establishes ethical rules for managing the relationship. Such regulation between medical organizations and PC associations exists in both Israel and other countries.
2. ***State regulation*:** A regulatory arrangement, usually achieved through legislation, which sets rules for the relationship. Examples of this type of legislation include the Sunshine Acts that exist in the United States and France. The legislation stipulates the obligation to report and publish details of all payments or payment in-kind transferred to physicians by the PCs. In 2010, Section 40A of the National Health Insurance Law was passed, stipulating that manufacturers of drugs and medical equipment must report all donations over NIS 2,500 paid to any party working in the fields of health or medicine to the Minister of Health by March 1st every year. The law also requires all beneficiaries of such donations to report the donations they have received. Importantly, legislation usually sets clear limits in order to address various problems. In this case, the legislature had the choice of legislating to fix limits, e.g., to limit the amount of the donation or the relationship. However, it chose a different path and passed legislation to encourage transparency, on the assumption that where there is transparency, there will be healthier management and better ways of addressing problems that arise in this context.

The impact of this legislation on the stakeholders has been examined in a handful of studies conducted in several states in the United States. They have shown that the requirement to report donations from the

PCs to physicians does not reduce the prescribing of medication nor does it reduce the undesirable influence that the PCs have over physicians. Prior to this study, the impact of legislation on the practices of the relevant parties had not been examined in Israel, and it was therefore imperative to do so.

Study Goal

The study goal was to examine the following:

- Has there been a change in recent years in the relationship between physicians and the PCs? And if so, what has been the nature of the change?
- Has legislation affected the relationship between physicians and the PCs? And if so, how?
- What is the best way to regulate this relationship?

Study Methods

Two instruments were used:

1. ***Open in-depth interviews (semi-structured)*** with 42 senior representatives of the parties involved: Ministry of Health, health plans, PCs, medical associations, patients' associations and journalists reporting on health services. The interviews lasted about an hour and discussed the perceived impact of the legislation and initiatives for self-regulation on the relationship as well as the respondents' attitudes towards regulation. The interviews were analyzed using the Narralizer program with a focus on identifying central themes corresponding to the study goals.
2. ***Analysis of 3 databases*** containing information about donations and funds transferred from the PCs to parties within the health system: This analysis was done in order to examine patterns of change in the amounts of the donations and the purpose for which they were made in the wake of the legislation. The information is available to the public on the website of each organization.
    - ***Ministry of Health database*:** The database was created in 2009 and contains information about financial donations from PCs to health organizations.
    - ***Israel Medical Association (IMA) database:*** The database sets out the amounts that have been received by the Association's specialist societies since 2009 and the purpose for which they were given.
    - ***Pharma-Israel reports of donations:*** Since 2011, Pharma-Israel has published an annual report of donations setting out the amounts of donations and the purpose for which they were given. The reports show distribution of donations by beneficiary organizations and include information about the purpose of the donations.

The Ministry of Health database includes reports required by law from various health organizations including pharmaceutical and medical equipment companies, hospitals, health plans and patients associations. The IMA database includes reports from specialist societies not all of which are required by law to report directly to the Ministry of Health database. Furthermore, in principle, the IMA database should also include donations received from commercial organizations that are not concerned with health, such as banks and food companies. Pharma-Israel only has reports on companies that are

members of organizations, but the reporting is in-depth and includes analyses by amount and purpose of the donation.

Study Findings

Attitudes towards the Relationship between Physicians and PCs

Different Viewpoints on the Relationship between Physicians and PCs: From an Inevitable Fact to a Contribution to the Health System

Most of the respondents believe that not only is the relationship inevitable, but also that it is essential and good for the system. They claim that the relationship is based on mutual dependency reflected in the fact that the PCs need the physicians in order to develop drugs, while the physicians (and the health system as a whole) need the knowledge and financial resources of the PCs in order to conduct studies and gain information about medical innovations in their respective fields.

Accordingly, most of the respondents reported that completely discontinuing the relationship would be harmful to the health system and the quality of medicine in Israel, since there would be no funding for research and in-service training, and innovative treatments would not reach Israel. They argue that the relationship has advantages, such as:

- ***Sharing of knowledge and professional discourse:*** The PCs have the most comprehensive knowledge about the drugs they develop and therefore the ability (and some would argue, the responsibility) to explain to the physicians and teach them about their products in the best way possible. Some of the respondents expressed greater reservations, noting that the involvement of the PCs in medical "education" is a "necessary evil" or is "imperfect, but better than nothing," since most of the physicians do not spend much time updating themselves about developments in their field. On the physicians' side, physicians deal with patients and meet needs that are not necessarily known to the PC's. They can share information about side effects, complaints or requests of patients. The PC's need these feedback to refine their products and to address issues they were not aware of during the research.
- ***Additional financial resources:*** The relationship brings more resources both to the system and to individual physicians. PCs inject financial resources into the health system. The two main areas in which PC funding is perceived to be essential to the system, in view of inadequate public funding, are research and continuing medical education (CME). Additionally, it is important to physicians to attend international conferences, where they are exposed to cutting-edge developments, and active participation in such conferences enables them to provide a more effective service to their patients. The PCs fund a substantial proportion of these trips.

The respondents who support the relationship note that the challenge is in finding the correct balance so as to achieve a "win-win" situation not only for these two sides, but also for the service providers (health plans and hospitals) and the public.

Minority Opinion: Opposition to the Relationship

Only a small minority of respondents oppose any form of relationship between physicians and the PCs and they themselves do not accept any support from the companies. They do not share the majority opinion that breaking off contact would be harmful to the health system. On the contrary, they support a ban on contact between the physicians and PCs and emphasize its inherent dangers and negative impact on the health system. Their view is that, in a perfect world, the PCs would manufacture quality products, publish full information about them and compete amongst themselves over quality and price, rather than try to influence physicians through gifts and money to prescribe their products.

Inherent Dangers in the Relationship

Although most of the respondents are aware of the clear advantages of the relationship, almost all acknowledge that it could have some negative effects:

1. Influence on the Physicians' Agenda

The health system's increasing dependence on PC funding gives the PCs the power to unduly influence the agenda in the medical world and to affect the emphases in basic research and the relationships with institutions that approve drugs, such as the FDA. Consequently, certain fields and activities that are not profitable are liable to be marginalized in the medical discourse and any criticism of the dominant discourse may be subject to efforts to silence it.

2. Influence on Physicians' Prescribing Practices

The influence of the PCs over the prescribing practices of physicians may have implications not only for the quality of care (biased medical judgment and preference for an inferior drug), but also for its cost. The doctors have an obligation to provide the best treatment to patients. Some physicians, particularly those in hospitals, may prescribe expensive drugs (marketed by the PCs) without considering the cost to the system or the situation of the patients themselves, who sometimes have difficulty paying for them. It is possible that in some cases, a less expensive drug would have been just as effective.

The PCs try to market their products and encourage the physicians to prefer prescribing them in many ways, and respondents related to several of them, as follows:

- ***Publicity***
  - ***Providing information to physicians:*** A small minority of the respondents are against the practice to get medical information from pharma representatives, while most expressed ambivalence towards the practice. While recognizing the importance of getting information from these representatives, when it updates physicians about new drugs, they have concerns about blind faith of many physicians in the information provided.
  - ***Providing disinformation about rival and generic drugs:*** The practice of providing false information about rival drugs was reported by some respondents in this context, even though it is illegal. Another strategy implemented even by the research based pharmaceutical companies, which was noted by the respondents, is fear mongering among the physicians and casting doubts about generic drugs.

- ***Contacting family physicians:*** Some of the respondents noted that it is easier for the PCs to influence family physicians than to influence specialists because the family physicians deal with a broad range of drugs and cannot remember everything about all of them. Moreover, they do not have the time to update themselves about innovations in every area that they work in.

- ***Offering gifts:*** These include pens, mugs, and small logo items and may also include medical and office equipment, expensive personal gifts and flights to overseas conferences with a high standard of hospitality including a range of attractions. In this area, the respondents noted mainly the success of regulatory measures and restrictions that the companies and employers impose in order to limit and regulate this practice. Some of the respondents, mainly those who oppose or are critical of the contact between physicians and the PCs, referred directly to the effect that offering gifts has on physicians' decision-making, arguing that gifts may influence physicians because they produce a sense of obligation and a need to repay the "debt."

- ***Distributing samples:*** The interviews reveal a range of opinions in the medical world over the main roles of samples distributed by PCs to physicians. Those who support this practice argue that it gives the physicians the opportunity to try out new drugs and accumulate knowledge about them, makes them accessible to populations who cannot afford them, enables the physicians to test their effectiveness and see how they are tolerated by specific patients and saves medical institutions (the hospitals and health plans) money. On the other hand, those against distributing samples argue that the practice encourages the use of expensive medicines including those that are not in the benefits package (increasing the costs to the health plans), creates prescribing practices that favor those drugs and encourage brand loyalty, and, marginally, encourages the illegal sale of drugs (physicians selling samples to their patients).

3. Influence on Opinion Leaders

The fabric of the reciprocal relations between physicians and PCs includes several other interested parties, chiefly senior physicians and key opinion leaders. These physicians have status and prestige and can influence the prescribing practices of less senior physicians as well as the decision-making of regulators and the health package committee. For this reason, the PCs consider it important to invest in them by funding lectures and research, and offering payment for consultancy. These contacts fall outside of jurisdiction of the law since they are not considered to be donations. Some respondents argue that this practice is a means of circumventing the law.

The Other Side of the Coin: What Physicians Expect from the PCs

There is another side to the attempts by the PCs to influence decision-making among physicians and that is the expectations and behavior of the physicians. Some of the respondents, mainly senior executives at the PCs, claim that some physicians take advantage of the PCs' dependency on them for personal gain and behave in an unethical, sometimes even impudent manner. They claim that the problem is partially due to the fact that the physicians, particularly the more senior of them, are finding it hard to get used to the new regulatory environment, which sets limits to the relationship with the PCs and sets rigid rules for communication between them.

Attitudes towards the Nature of Regulation of the Relationship – State Regulation vs. Self-Regulation

Although most of the respondents believe that the problem is not serious, almost all think that there is a need for regulation. However, there are differences of opinion as to the extent of regulation required and as to who has responsibility and authority for it. The main models of regulation, as revealed in the interviews, are: Self-regulation, state regulation, and regulation by the employer. The perceived pros and cons of each of these models as reported by the respondents are consistent with what is found in the literature.

Self-Regulation

Those in favor of self-regulation claim that regulation must be based on ethical rules that have developed from the bottom up, from the field, and are agreed upon by all concerned. The advantages of self-regulation, as reported by its supporters are as follows:

- ***Knowledge of the situation in the field:*** Compared with the regulators, both sides are better acquainted with the issues and problems in the field and are therefore better placed than the legislature to determine ethical rules that will be proportional and acceptable to all.
- ***Agreement rather than coercion:*** Regulation of the relationship has to be based on reciprocal agreement between both sides of the relationship rather than imposed "from above." This step will increase the motivation of both sides to observe the rules.
- ***Over-regulation:*** Over-regulation, which is sometimes characteristic of state regulation, may be detrimental to some of the positive aspects of the relationship and have negative implications for the scientific cooperation between physicians and the PCs and their motivation to invest in Israel.
- ***Political motives of the legislature:*** The legislature's decision-making may be influenced by political considerations that are not compatible with the needs of the system, as perceived by those involved in the relationship.
- ***Weakness of the regulator and lack of enforcement:*** The legislature cannot effectively enforce the laws and procedures, particularly among the physicians, due to the organizational culture in the medical world, which encourages autonomy and independent thought.

State Regulation

Many respondents referred to the problems with self-regulation and were in favor of regulatory intervention by the state, noting its advantages compared with the disadvantages of self-regulation:

- ***Implications of regulation for the public:*** State regulation takes account of overall public considerations, as opposed to the ethical code of self-regulation, which – naturally – focuses on what the two parties want.
- ***Material temptations in the relationship:*** The material temptations in the relationship are too great to leave regulation in the hands of the interested parties.
- ***Voluntary regulation:*** The fact that self-regulation is voluntary means that enforcement depends on the goodwill of the two sides.

- ***Deterrent effect of legislation:*** Legislation has a greater deterrent effect than ethical codes because large companies prefer not to contravene the law even if they are opposed to it.
- ***Standardized rules of the game:*** Legislation creates standard rules that are equal for all and therefore prevents unfair competition, unlike an ethical code (convention) that is not binding on any party other than the signatories.
- ***The scale of investment does not depend on the nature of regulation:*** Those in favor of legislation reject the argument that over-regulation could be detrimental to the relationship and lower the level of medicine in Israel by reducing the scale of investment in …..

Regulation by the Employer / Provider Organization

Some of the respondents noted that regulation should originate with the employer (health plans and hospitals) and that the relationship should be between the PCs and the employers (as they are the major organizational providers of health care), rather than at the level of the individual physician. They argue that the employers have mechanisms for regulating the relationship and preventing unacceptable influences, such as a centralized inventory and a system of prioritization and control of prescriptions.

Attitudes to Legislation – from Apathy to Skepticism

Supporters of state regulation and self-regulation are unanimous in their appreciation of the importance of transparency in the relationship between physicians and PCs. They report that the Ministry of Health has adopted the idea of transparency and has sought to promote it through legislation since 2010. Insofar as the goal of legislation is to increase transparency, the respondents tend to support it. However, regardless of their organizational or professional affiliation, respondents expressed reservations and lack of confidence about the transition from theory to practical legislation, noting that the impact of legislation in Israel has not been felt – not in the sense of a decline in the extent of donations, nor in a change of norms in the relationship. These findings are similar to those in studies conducted in the United States.

The respondents gave a number of reasons for the minor impact of regulation, including:

- Lack of awareness that the legislation exists
- The ease with which it is possible to bypass the legislation
- The vagueness of the definition of "donation" for some of those who are required to report
- The absence of any enforcement
- Publishing the amounts of the donations is not a deterrent.
- Not all of the relevant parties are involved in the legislative process.

Studies conducted in the United States found similar reasons for the difficulties in implementing legislation, including – in addition – the difficulty of obtaining information on donations. In contrast, in Israel, this information is available and accessible on the Internet.

Origin of the Change: Increased Self-Regulation Worldwide

The interviews and the literature show that in recent years there has been an extensive change in the regulatory environment of the relationship at the international level. Most of the change is reflected in the fact that research based international PCs have adopted ethical codes that regulate and set limits to their contact with physicians. The physicians and employers also have additional regulatory arrangements.

The conceptual change stems in part from the ***international public outcry*** following highly publicized cases of unacceptable influence over physicians. The PCs feared financial damage resulting from the public criticism and responded, inter alia, by adopting ethical codes for the relationship and reinforcing internal regulation and control. Another factor leading to the change was the ***intervention of the legislatures in Western countries***. Countries such as the United States and United Kingdom passed stricter laws, such as the anti-corruption laws, and tightened regulation over the PCs, inter alia through reporting requirements.

Impact of the Worldwide Self-Regulation Trend on the Situation in Israel

The increased self-regulation of PCs at the international level has also been reflected in Israel. This is expressed in stricter ***control by corporate headquarters over the funds granted by the PCs to health organizations and care providers.*** Furthermore, Israel has an ethical code (convention) between the industry and the IMA, which sets ethical rules and norms for the relationship between physicians and PCs through agreement and cooperation among all involved in the relationship.

Regulation by the Employer

The move towards increased self-regulation also affects the employers, i.e., the hospitals and the health plans. The interviews reveal that in recent years the employers have taken the relationship with the PCs seriously and have taken steps to regulate it, such as:

- ***Attendance at conferences:*** Every hospital has a committee chaired by the hospital director or his deputy that decides which physicians may attend conferences. The committee discusses the request and examines the contents of the conference and level of hospitality. Payment for the travel expenses is made through the hospital's accounts department and not directly to the physician, as used to be the case.
- ***Greater supervision of medication prescribing:*** This is done by a computerized system that directs the physician to certain drugs according to internal prioritization by the health plan and requires him to request special authorization if he wishes to prescribe a different drug.

Changes in the Relationship – from a "Gift Economy" to a Contractual Relationship

Both in Israel and abroad, the relationship between physicians and the PCs has been undergoing a remarkable process of change. The "gift economy" has been reined in and greater attention is paid to considerations of visibility, as reflected in several areas:

- ***Contractual arrangements for donations and transfer of funds:*** In contrast to what used to be done, every transfer of funds to physicians and other parties in the health system is now rigorously checked and is based on a contractual agreement.
- ***Transfer of funds for overseas conferences via the employer:*** The PCs have stopped transferring funds directly to the physicians and they are required to transfer the money via the hospitals, health plans or medical associations.
- ***Lower level of hospitality:*** The hospitality offered by the PCs is more modest than it used to be and there has been a decline in the scale of the gifts and attractions.
- ***Ban on hospitality for spouses:*** The PCs no longer fund travel and hospitality for spouses at scientific conferences.
- ***Less vacation, more science:*** The PCs now make sure not to fund conferences that are basically junkets – e.g., those that take place over weekends. In addition, they make demands on the medical associations seeking their support for organizing conferences, for example to provide detailed budgets, provide a full report on how the money was used; and return surplus funds.
- ***Less influence on the content of conferences and fair disclosure:*** In recent years, the PCs have been less involved in the content delivered in specific lectures and when they are involved, the physicians note this as fair disclosure.
- ***Reduced number of samples:*** Some of the companies have entirely stopped supplying samples.
- ***Reduction in the number and value of gifts:*** In the past, expensive gifts were the norm. Today the companies make smaller gifts and sometimes, the gifts are subject to rules that limit their value.

With regard to the depth and significance of the changes, the interviews showed differences of opinion. Some respondents argued that these were real changes in the norms of the relationship, while others claimed that the changes were cosmetic and did not affect the substance of the relationship.

Different Viewpoints on the Path Ahead: From Transparency to Raising Awareness

Legislation and self-regulation are perceived to be partial, imperfect solutions. The respondents were asked their views of the continuation of the process and what solutions they proposed. Among the responses:

- ***Greater transparency through legislation:*** Most of the respondents believe increased transparency to be a desirable solution, or at least a step in the right direction. Some proposed broadening the areas for which the law demands reporting to include funds that are not considered donations by law. The initiators of the law at the Ministry of Health view Section 40A of the National Health Insurance Law to be the first stage in a long-term process of changing the norms in the relationship between physicians and the PCs.
- ***Increased self-regulation:*** Some respondents believe that the PCs and medical associations should increase self-regulation. These respondents, most of them representatives of the PCs and

physicians, share the belief that transparency is the preferred solution for problems in the relationship, but that this should be promoted by the physicians and PCs, rather than by the state through legislation.

- ***Establishing a joint fund:*** This model was brought up by leading authors in the literature, and almost half of the respondents referred to it. The mechanism by which the fund would be managed would be by concentrating all donations from the PCs and dividing the funds according to criteria fixed by the fund itself. This solution came up repeatedly in the interviews as well, although the respondents noted that there could be barriers to establishing such a fund for two main reasons: 1. The PCs would have very limited interest in donating to such a fund; 2. It would be difficult to create a single mechanism that would suit all the PCs.
- ***Including the subject of the relationship between physicians and PCs in medical education:*** Some respondents believe that the key to resolving this matter lies in education and they therefore propose including relevant contents in medical education as an integral part of the curriculum.

Analysis of Donation Reports

Ministry of Health

Ministry of Health reports on donations made by PCs to health providers are available for the years 2011-2012. The reports are divided into three levels, for each of which there is a donor report and a recipient report: Level 1 – Total amounts of donations by donor (the total amount that each company has donated) and recipient (the amount each organization has received). Level 2 – In addition to the name of the donor/recipient, specific amounts of donations given to each organization or amounts of donations received by each recipient. Level 3 – Purpose of each donation. The information in these reports indicates:

- ***An increase in the extent of overall donations from 2011 to 2012:*** The overall amount of donations reported between 2011 and 2012 indicates an increase from NIS 29.3 million to NIS 32.7 million. On the **receipt** side, the reports show a minor increase from NIS 41.2 million to NIS 41.4 million. The difference in the amounts of money reported by the organizations who receive donations and by the organizations who give it may be due to the fact that some of the donations do not go directly to the recipient but to the hotel or hospital concerned.
- ***The increase is not consistent:*** When we examine the increase at the level of the individual donor or beneficiary, it is hard to discern a clear trend for change. In some cases, there has been an increase in the amount of donations, in others a decline. For example, J-C Healthcare donated NIS 4.8 million in 2011 and NIS 6.3 million in 2012. In contrast, Roche Pharmaceuticals donated NIS 2.6 million in 2011 and NIS 1.7 million in 2012. The same mixed trend is observed on the beneficiary side. For example, the Association of Friends of the Tel Aviv Sourasky Medical Center (Ichilov) received donations totaling NIS 1 million in 2011 and NIS 1.1 million in 2012. On the other hand, the KMR company at Rambam hospital received NIS 2.8 million in 2011 and only NIS 2 million in 2012.

- ***Not all those required to report to the Ministry of Health actually do so:*** Many organizations are recorded as having received funds, but no report was received from them. This is particularly evident among patients associations, individual physicians and physicians associations.
- ***There is a discrepancy between the reported amounts of donations made and those received:*** For example in 2012, the donations report totaled NIS 32.7 million (an increase of 10% over the previous year), while the sums received totaled NIS 41.4.
- ***It is hard to know what the funds are actually earmarked for and to assess their proportionality.***
- ***With regard to the purpose of the donation, about half are defined as "other."***
- ***In some cases, there is a considerable disparity between the sum reported for 2011 and that for 2012.*** For example, Teva reported donations of NIS 1.7 million in 2011 and NIS 8.1 million in 2012, while Novartis reported donations of NIS 4.2 million in 2011 and NIS 250,631 in 2012. Similar disparities were found in the reports of donations received.

Pharma-Israel

Pharma-Israel has reports for 2011 and 2012, which include information about the donations made by its member organizations with distribution by various characteristics. However, the reports do not include distribution by companies. Furthermore, in contrast to the Ministry of Health and IMA reports, those of Pharma-Israel do not provide information about individual donations, but only the total amount of all donations by various categories. The Pharma-Israel reports show a small decline in the overall amount of donations, from NIS 21.2 million in 2011 to NIS 20.4 million in 2012. Importantly, the reports contain information about member companies only and this could be one of the reasons why these figures are lower than those appearing in the MOH reports.

Hospitals were the institutions that received the largest donations – NIS 11 million in 2011 and NIS 11.4 in 2012 – followed by patient organizations, with donations of NIS 5 million in 2011 and NIS 4 million in 2012.

Israel Medical Association (IMA)

IMA's reports were first published in 2009. Over the years, only 75 of the 189 specialty societies active in the IMA have reported. Reports are available from only 16 societies for all years between 2009 and 2012; data for the remaining societies is missing for certain years. As above, there is no clear trend among the societies with regard to change in the amount of donations. For example, while the amounts donated to the Israel Society of Anesthesiologists increased steadily from one year to the next (NIS 17,684 in 2009, NIS 51,928 in 2010, NIS 61,000 in 2011, and NIS 120,236 in 2012), the Israel Society of Obstetrics and Gynecology did not enjoy such an increase, and there was no consistent trend (NIS 169,985 in 2009, NIS 228,170 in 2010, NIS 128,199 in 2011 and NIS 84,267 in 2012). Note that in most cases, the reports fail to indicate the specific purpose of the donation (e.g., specific conference), giving only the general category.

Discussion

Changes in the Relationship between Physicians and the Pharmaceutical Companies

The study found that in recent years there have been a number of changes in the relationship, among the notable changes:

- Transition from a "gift relationship" to one based on contractual agreements. If in the past, the PCs handed out gifts to physicians and medical associations and transferred funds for activities, with no distinction as to what they were used for and to what extent, today the relationship with the PCs is based on detailed contracts setting out the amounts and purposes of the funds.
- A general change in the way the PCs work with physicians, with an emphasis on visibility and moderation.
- Reporting on donations – although it was found that during the 3 years since the reporting requirement was introduced there has been more reporting of donations, the trend regarding the amount of donations is mixed. In some cases, there been a modest increase in the amounts of the donations, while in others, the amount has declined. It is uncertain whether the reporting requirement has led to this situation. Furthermore, there is uncertainty as to the purpose of the donations.

Most of the respondents are of the opinion that the changes that have taken place are not the result of legislation in Israel, but rather of the ethical codes and rules of practice of the international companies that market their products in Israel.

Lack of Knowledge about the Israeli Legislation

Evidently, legislation in Israel has not attained the position that the legislature originally planned and it does not entirely fulfill its intended role. Many of the respondents believe that the legislation is not relevant to their daily lives. Furthermore, a considerable proportion of them reported that they were unfamiliar with the legislation and some did not even know what it addressed and what it stipulated. It should be emphasized that all of the respondents in this study are senior representatives in their fields. The fact that they do not have in-depth knowledge of the legislation or that they do not believe it to be relevant to them has implications for the organizations that they head.

Situation in Other Countries

The findings show that legislation in Israel does not fulfill its intended role as well as it should, nor does self-regulation, in the form of ethical codes for the PCs, respond to all the problems in the relationship between the companies and the physicians and it does not address the associated problems. The ethical code is not always clear and known to the public and it is unclear how it is possible to enforce it.

The above situation is not unique to Israel. Similar legislation in other countries has proved unsatisfactory as well. Studies conducted in the United States in the states that have adopted the Sunshine Acts have brought to light problems in implementation, including the facts that there is no easy access to information and that whatever information is available does not make it possible to

disclose patterns of payment or to understand to whom each payment has been donated. Another study has found that the PCs are still spending hefty sums on marketing to physicians and that the law has not reduced the problematic practices inherent in the relationship. Furthermore, it is unclear whether exposure is of any benefit to the patients, since they have no interest in information about monies transferred to their physicians.[1]

Looking Ahead

The foregoing raises the question of what can be done to reduce the impact of the said relationship on the entire health system. The directions proposed by the respondents – among them, greater transparency, setting up a joint donations fund, and broadening medical education – could constitute the basis for future discourse headed by the Ministry of Health, but in the initial stage, the legislature has to decide to what extent – if at all – to address the matter and to lead the way to the creation of restrictions on the relationship.

Assuming that the legislature in Israel decides to continue to act to set limits to the relationship and influence the behaviors of both sides, it is appropriate to formulate policy that can be implemented in two ways – by establishing norms and safeguards that would stabilize the threshold of appropriate behavior in the eyes of the legislature and by continuing to increase the information provided by the PCs to the legislature and to the public.

[1] Chimonas, S.; Rozario, N.M.; Rothman, D.J. 2010. "Show Us the Money: Lessons in Transparency from State Pharmaceutical Marketing Disclosure Laws." ***Health Services Research*** 45(1):98-114.

Acknowledgments

We received assistance preparing and conducting the study and writing this report from many people and we are grateful to all of them. We thank the respondents for giving us their time and responding patiently and seriously to the interview questions, for their ability to fine-tune questions that arose during the analysis of the data, and for introducing us to the important dilemmas discussed in the study.

We are grateful to our colleagues at the Myers-JDC-Brookdale Institute for reading drafts of the report and commenting on the study from interesting and innovative perspectives. Special thanks to Bruce Rosen for reading the material and for in-depth discussion of the subject. Thanks also to Ruth Waitzberg for checking information with her associates abroad, to Ronit Ben-Nun for editing the report, to Naomi Halsted for translating the executive summary, and to Leslie Klineman for preparing the report for publication.

Table of Contents