# DÁIL ÉIREANN

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## AN COMHCHOISTE UM SHLÁINTE

## JOINT COMMITTEE ON HEALTH

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*Dé Céadaoin, 6 Nollaig 2017*

*Wednesday, 6 December 2017*

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Tháinig an Comhchoiste le chéile ag 9 a.m.

The Joint Committee met at 9 a.m.

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Comhaltaí a bhí i láthair/Members present:

| Teachtaí Dála/Deputies | Seanadóirí/Senators |
|---|---|
| Bernard J. Durkan, | Colm Burke. |
| Billy Kelleher, | |
| Margaret Murphy O'Mahony, | |
| Kate O'Connell. | |

Teachta/Deputy Michael Harty sa Chathaoir/in the Chair.

## Business of Joint Committee

**Chairman:** I propose that we deal with housekeeping matters in private session. Is that agreed? Agreed.

*The joint committee went into private session at 9.10 a.m. and resumed in public session at 9.37 a.m.*

## Medical Practitioners (Amendment) Bill 2017: Discussion

**Chairman:** The purpose of this morning's meeting is to undertake detailed scrutiny of the Medical Practitioners (Amendment) Bill 2017. In this, the first of two sessions, we will engage with Deputy Kelleher and in the second session we will meet with officials from the Department of Health. On behalf of the committee, I welcome Deputy Kelleher, accompanied by Dr. Jean O'Sullivan, consultant in emergency medicine at Tallaght hospital.

I draw the attention of witnesses to the fact that by virtue of section 17(2)(*l*) of the Defamation Act 2009, witnesses are protected by absolute privilege in respect of their evidence to the committee. However, if they are directed by the committee to cease giving evidence on a particular matter and they continue to so do, they are entitled thereafter only to a qualified privilege in respect of their evidence. They are directed that only evidence connected with the subject matter of these proceedings is to be given and they are asked to respect the parliamentary practice to the effect that, where possible, they should not criticise or make charges against any person, persons or entity by name or in such a way as to make him, her or it identifiable.

I advise witnesses that any opening statements they have made to the committee may be published on the committee's website after the meeting. Members are reminded of the longstanding parliamentary practice to the effect that they should not comment on, criticise or make charges against a person outside the Houses or an official either by name or in such a way as to make him or her identifiable.

I ask Deputy Kelleher to make his opening statement.

**Deputy Billy Kelleher:** I thank the Chair and the committee. I believe we are taking this under Standing Order 141(3) and that it will hopefully be reported to both Houses. The Medical Practitioners (Amendment) Bill 2017, if enacted, will require "practitioners to declare any income or gift received from medical suppliers or pharmaceutical companies to the Medical Council in statutory declaration annually."

Section 1 of the Bill provides definitions. Section 2 of the bill amends section 45 of the Medical Practitioners Act 2007 in three ways. Firstly it provides that "A registered medical practitioner shall on an annual basis, give to the Medical Council a statutory declaration signed by him or her giving particulars of all declarable income and gifts received from any medical equipment suppliers, its servants or agents, and or any pharmaceutical companies, its servants or agents, within the previous 12 months not before the 31st day of January of each year." Second, it provides that the Medical Council shall maintain a register of gifts and declarable income declared by each registered medical practitioner, which shall be published by the council annually in electronic form in a publicly accessible and searchable manner. It also provides that failure to comply with the provisions as outlined shall result in the registered medical prac-

titioner being the subject of a complaint under section 57 of the principal Act by the Medical Council. Section 3 provides the Short Title and commencement.

I will now outline for members the rationale behind the Bill. In 2016, €6.8 million was given directly to Irish doctors by pharmaceutical companies. The Health Service Executive has no record of any of this through the Standards in Public Office Commission. This obviously poses a number of questions, including ethical issues. First, patients deserve full transparency about how doctors make decisions about recommending new drugs for patients. All treatment should be based on international best evidence, free of any conflict of interest. Second, given the very large expenditure incurred on medication and other medical goods by the HSE, taxpayers need to know that large financial outlays are solely influenced by clinical outcomes and not by conflicted advice from doctors in receipt of concealed payments from companies in the medical arena. Third, the Revenue Commissioners ought to be informed about payments of €6.8 million to ensure fair compliance and collection of taxes. Incidentally, €10.6 million went directly to hospitals from drug companies and this will not be covered in the Bill. There is an onus, obviously, on the HSE to regulate this.

Earlier this year the *Irish Independent* reported that drug companies are paying the wages of a significant number of staff in the country's children's hospitals. Our Lady's Children's Hospital, Crumlin, confirmed to the newspaper that pharmaceutical companies pay for a nurse and a health and social care worker there. Tallaght hospital also confirmed that it has three junior doctors and two nurses whose salaries are funded by the drug companies.

The Irish Pharmaceutical Healthcare Association gathers information annually on payments or so-called transfers of value by its member companies to doctors, but an opt-out clause means many of the recipients are not identified. In other words, there is a voluntary code within the Irish Pharmaceutical Healthcare Association, and it will publish payments, or what it calls transfers of value, to doctors, but only if the doctor allows it to be published. They can opt out if they request to do so. According to the *Irish Medical Times*, in 2016 only 55% of doctors who were in receipt of funding from pharmaceutical companies actually declared it.

The Minister for Health ordered a review late last year after claims that up to one third of senior HSE clinicians are in receipt of money from pharmaceutical companies. The Health Service Executive responded to the Minister by saying that it did not know whether any of its senior staff have received direct payments from pharmaceutical companies. The HSE investigation failed to establish whether any payments were made, and found uncertainty as to whether existing rules were even being followed.

The pharmaceutical companies fund posts in many hospitals, and the HSE was unable to answer a parliamentary question seeking specific details in February this year. In the reply, the deputy national director of the acute hospital division said that information requested was not held centrally by the acute hospitals division, and while the deputy national director also liaised with the hospital groups on this information, it was not available currently in a consistent standard format. Clearly, there is a lack of information, even within the HSE, on the staff that it employs.

Professor Michael Barry, of the National Centre for Pharmacoeconomics, NCPE, told *The Sunday Business Post* in November 2016 that he believes payments from industry are influencing prescribing habits in Ireland. He said doctors were prescribing more costly branded medicines here than doctors in other countries. He said: "What is going on should not be happening. We need to stop making excuses for this." There are also indications of public support

for changing the current situation. A poll on *thejournal.ie* revealed 89% of respondents did not believe that doctors should continue to receive payments from pharmaceutical companies.

All positions of employment in the Health Service Executive across all grade categories where the minimum salary point is equal to or above the minimum point of grade VIII have been prescribed in regulations as designated positions of employment for the purposes of the Ethics in Public Office Acts 1995 and 2001. However, in view of the fact that the HSE was unable to answer parliamentary questions, and given the HSE's response to the Minister for Health that it does not know whether any of its senior staff have received direct payments from pharmaceutical companies and whether existing rules were being followed, it is clear that rules need to be strengthened. Currently, the Medical Council does not ask doctors about any conflicts of interest when they are registering each year.

I will now outline the legislation on which the Bill is modelled. In the United States, the Physicians Payments Sunshine Act came into force in 2010. The Sunshine Act, as it is known, requires manufacturers of drugs, medical devices, biological and medical supplies covered by the three federal health care programs Medicare, Medicaid and the state children's health insurance program, SCHIP, to collect and track all financial relationships with physicians and teaching hospitals and to report these data to the centres for Medicare and Medicaid services, CMS. The goal of the law is to increase the transparency of financial relationships between health care providers and pharmaceutical manufacturers and to uncover potential conflicts of interest. The bill allows states to enact additional requirements, as six states already had industry-pay disclosure laws.

France, Portugal, Belgium, Denmark and Slovakia are EU states with primary legislation governing such donations. In the United Kingdom this issue is still a huge problem with little clarity on where the money goes. It is an issue that is being debated quite vigorously. The British *Daily Telegraph* reported on 30 June this year that,"Cash and hospitality given by the pharmaceutical industry to doctors has increased to more than £116 million a year, despite a drive to make the practice more transparent ... Experts ... called for a change in the law to bring Britain in line with the US where doctors are forced to publish all potential conflicts of interest."

Doctors have to renew their Medical Council registration every year. It is an easy online process. It would be relatively simple to add a question asking for disclosure on payments on the renewal portal. It may require a little IT work, but this could then generate an annual report of all submissions made. The Medical Council will have to inform members of the sanctions faced if they fail to disclose payments. This can be done via its newsletter, so it is unlikely to give rise to additional costs.

I refer to the financial implications of this measure. It it hoped this will have the potential to ensure that the only drug treatments chosen by all doctors are those with clinical efficacy, thereby reducing expenditure on pharmaceuticals nationally. Declaration of payments could also mean that the Revenue Commissioners will have greater knowledge of any payments and it may serve as a revenue-raising measure.

Before I yield to Dr. O'Sullivan, I will make a final point. I am not inferring anything about the professional integrity of our clinicians, but there is an issue that has to be addressed. We must ensure that there is absolute transparency in payments received, or transfers of value, as they are called. Between all of the moneys and the transfers of value, almost €30 million a year is transferred from the pharmaceutical industry to health care organisations, health care professionals and advocacy groups. As medical technologies and medicines evolve, for example,

through the development of fourth generation and orphan drugs, there will be an incremental increase in the cost to the Exchequer. The very least that patients deserve is transparency and the assurance that all medicines are being prescribed for medical efficacy. The taxpayer should also be entitled to ensure that he or she is getting value for money.

**Dr. Jean O'Sullivan:** I will reiterate what Deputy Kelleher has said. The key reason this Bill is so important is that it will give patients full assurance that any decision made to start them on new treatment or new therapy is made purely on clinical grounds and is based purely on best available international evidence and peer-reviewed research, as opposed to any conflict of interest. It is important that patients and general practitioners have full access to any conflict of interest. When we see reports in the media that there are staff working in public hospitals who are fully funded by pharmaceutical companies, patients and their families need to know that the staff treating them are acting purely on best international clinical practice as opposed to being funded by pharmaceutical companies. It is really about transparency. There is nothing wrong with pharmaceutical companies funding research or new treatments, but it is important that it is fully transparent. Similarly, when the HSE drug bill is so colossal, I think it is important that taxpayers know that the decisions to buy different drugs or to use different drugs in hospitals at their expense are made purely on the best clinical evidence that is available internationally and for no other reason.

**Chairman:** Does the Bill address the issue of staff in hospitals?

**Deputy Billy Kelleher:** No. It primarily addresses health care professionals who prescribe. It is acknowledged by ourselves, in the briefing paper compiled by the Oireachtas Library and Research Service and in the comments made by the Minister in the Dáil, that it might be necessary to broaden the scope of this Bill to include doctors, other prescribers, other health care professionals and employees at the higher echelons. Senior officials are obliged to declare under the Standards in Public Office Act.

**Chairman:** Is the Deputy open to such expansion?

**Deputy Billy Kelleher:** I am open to amendments being made or an expansion of my Bill. We do not want to be over-prescriptive. We want to embrace all views and opinions to ensure that the legislation goes through. We want to ensure that the Bill is legally sound and, more importantly, is transparent when it comes to the prescription of medicines and use of medical devices and equipment in this country.

**Chairman:** I suggest that we take questions from individual members now rather than bank questions. I call Deputy Murphy O'Mahony to commence.

**Deputy Margaret Murphy O'Mahony:** I commend my colleague, Deputy Kelleher, on bringing forward his Bill. I also commend him on his work as Opposition spokesperson on health. I have a few questions. Will medical practitioners have to declare everything? Will there be a lower or upper limit or is everything included? Does Deputy Kelleher envisage that the legislation, when enacted, will have an effect on the ability to access and avail of orphan drugs? Is the Bill broad enough to cover the issue of hospital staff being on the payroll of pharmaceutical companies?

**Deputy Billy Kelleher:** The definitions section of the Bill outlines:

> "declarable income" means any money or other form of payment that a medical practitioner receives from a medical equipment supplier, its servants or agents, or pharmaceutical

company and its servants or agents above the value of €600.

There is potential for people to circumvent the provision by making multiple donations that amount to less than the threshold of €600. The select committee may amend the provision on Committee Stage to ensure that one must aggregate the sums of money. In terms of the issue of pharmaceutical companies paying for nurses or hospital and other health care professionals, primarily the money would be seen as a gift. Obviously, we gift to the entity where the nurses work, for example.

**Deputy Margaret Murphy O'Mahony:** What if they are drawing it to themselves?

**Deputy Billy Kelleher:** We might broaden the scope of the legislation. The current provision is quite restrictive as it purely refers to health care professionals. One could argue that the requirement should be already mandatory as the HSE reports and publishes details on the people who work in hospitals but are paid by pharmaceutical companies.

The third issue raised by the Deputy was orphan drugs. I do not believe that my Bill will have an impact on the availability of orphan drugs, primarily because one would hope that all drugs are prescribed for their clinical efficacy and effectiveness. There is a larger debate on the availability of orphan drugs and how they are funded, as witnessed by this committee on a regular basis. In general, orphan drugs, four-generation drugs, other high-tech drugs and medical devices are not covered by my Bill as it primarily relates to a payment to a health care professional. The purpose of my Bill is to ensure that if there is prescribing or use of medical devices by health care professionals that it is done for the right reasons.

**Deputy Margaret Murphy O'Mahony:** Dr. O'Sullivan said the same thing. I thank the Deputy for his replies.

**Deputy Bernard J. Durkan:** I welcome the Bill and compliment Deputy Kelleher on bringing it forward. The legislation covers direct payments. To what extent are indirect or hidden payments, such as holidays abroad, covered in the legislation? Does the legislation apply directly across the board? Are there areas that do not come under its remit? In some locations, it might still be possible to circumnavigate legislation. Will this new legislation thwart such an activity?

In terms of the pharmaceutical sector, I presume the legislation identifies and covers instances whereby free and extensive amounts of samples are provided to a practitioner. I ask without meaning to get at GPs. It is possible that a person could circumnavigate the rules in that fashion. Maybe the drug companies or manufacturers of certain equipment may make a contra deal whereby it appears that the donor owed the recipient for implied services.

**Deputy Billy Kelleher:** The Bill states: " 'gift' means any voluntary transfer of money, grant for research, bursary, service or property without compensation above the value of €600.". Again, there is an acknowledgement in terms of the broad debate around the Bill that there may be a requirement to consider the matter in more detail on Committee Stage. Like everything else, having sponsored a Private Members' Bill, unlike the Government, we do not have access to the Office of the Attorney General. I am quite sure that there may be a need to tighten the provision. Primarily, the legislation seeks to ensure that a gift is defined in such a way that companies cannot circumvent the provision. The legislation does not imply that people continually abuse the provision. We simply want to give confidence by including direct payments, gifts and other transfers of value.

It is critically important that we continue to encourage and foster innovation, research and development, close collaboration between clinicians and universities, and that pharmaceutical companies conduct research and produce medical devices, drugs and medicines, which is all very positive. My legislation simply seeks to bring transparency to the heart of such work.

One cannot legislate for ethics and morality. People are obliged to behave in an ethical manner. In terms of contra deals, some of these are already governed in legislation, particularly under the criminal code.

**Dr. Jean O'Sullivan:** As Deputy Kelleher said, there is a difference between direct and indirect payments. The Bill seeks to make everything transparent and remove ambiguity about what is a gift, payment and salary. The reason we wanted to amend the Medical Practitioners Act and involved the Medical Council is because we wanted to ensure there would be quite a serious sanction for anybody who did not declare a gift or financial reward given by a pharmaceutical company.

**Senator Colm Burke:** I thank the Deputy for bringing forward the Bill. I agree it is extremely important to have transparency. However, it is also important for all parts of the health care sector to co-operate. Sometimes for a matter to progress, such as funding a nurse in a particular facility, it is important to highlight that the service being offered would not be offered except for the availability of the nurse. It is one of the problems in areas of rare diseases and where small numbers of people are affected by a particular medical complaint. If a medical consultant were trying to progress a particular area only to find that the scrutiny was too severe from his point of view, would it then put a restriction on trying to develop new services? While there is a need for transparency, I am concerned that people might shy away from getting involved in this area.

On advances in medicine, in fairness to nursing, medical and administrative staff, they have pushed out the boat themselves rather than it coming from national level. Sometimes they need the assistance of a third party to push that boat out. Can we be overly restrictive as well? Does the witness have a concern about that?

I refer also to conferences abroad, which sometimes are subsidised by medical suppliers or medical pharmaceutical companies. There are advantages but there is also the disadvantage in that the practitioner may then feel an obligation to use that particular product. Is it intended that this Bill would also cover something like that? I am not saying where the trip is totally free, as in a person goes to a conference in the UK on a particular area of medicine and new advances are disclosed at that conference. The drug company might subsidise the flight or the accommodation. Is the witness saying that under this Bill that will have to be fully disclosed? We might get some clarification on that.

**Deputy Billy Kelleher:** In terms of posts being paid for by pharmaceutical companies, we do not want to discourage charity or philanthropy. Certainly, that is something we all laud, applaud and encourage. All we are saying is that in the event of such posts being paid for, that it would be publicly declared. That would be the purpose. It is not actually defined in this Bill but I think that has been mentioned in the debates in the Dáil, on Second Stage, that there would be a requirement to declare these things in order that people know. However, there would be nothing beyond that.

In terms of scrutiny of clinicians and researchers, 60 Senators and 158 Deputies have to fill a statutory declaration form every year. It is not that onerous. This certainly would not even

be as onerous as that. Anything with a value of more than €600 would have to be declared. If a person attending a conference abroad is subsidised, it would have to be worked out if there was a value in that subsidy, and if it was greater than €600, that person would have to declare it. Is that onerous? I do not think that would be over-difficult for people to do once a year when they are registering with the Medical Council. It is important, if people are travelling abroad and going to conferences and if they are being paid for by pharmaceutical industries or medical device companies, that it is declared. There is nothing beyond that. We do not need to have any further detail other than the fact that it is declared. I hope that it would not be onerous.

In terms of research, when we look at where we are in terms of research in this country, there have been great strides made in recent years. It has been the policy of Governments in general and even more so in recent times in the whole area of tax reliefs for research and development. There is a general acceptance that we are reasonably good at attracting these companies into the country and we are reasonably good at the co-operation between clinicians, universities and industry in terms of research and innovation. We have been very good at that until recently. There has been, it could be argued, a bit of slippage in recent times. Primarily that is about funding, reimbursements of drugs, clinical trials and all that flows from that. At the heart of all of this is the requirement to know that there is absolute transparency. If academia and pharmaceutical companies are coming together and clinicians are actively involved as well, we are asking that they declare an interest and nothing beyond that. We do not need to know the detail. If it is more than €600, it must be declared.

**Dr. Jean O'Sullivan:** I will answer Senator Burke's question about conferences. If doctors have to declare that they were sponsored in going to a conference or to a meeting, it would probably take the pressure off them to feel in any way conflicted to support that particular drug or that particular treatment. As Deputy Kelleher said it is not about stopping research or stopping sponsorship of education. It is really about making this so transparent that patients, their families and general practitioners can know that if a patient is started on a new treatment, it was purely for clinical reasons and not for any other hidden reasons. It is really about transparency. It is not about stopping research or education at all.

**Deputy Kate O'Connell:** I thank Deputy Kelleher for bringing this Bill forward. I am all for it. This will lead to greater confidence in optimum treatment being given to patients. It is also important from a taxpayer point of view, because of the huge drug bill we have, to make sure that people are getting the best value for their money. I have one issue about the medical equipment supplier and diabetic testing kits. These are regularly given out free to clinics by companies, not necessarily to an individual practitioner but to a diabetic clinic or a GP surgery. The unit is given free but the cost is in the consumable, in the diabetic strips. I have long felt the price of them is a bit of a racket. Does this cover that? If a company decides to supply the eastern or northern region with a particular brand of testing kit, is this going to deal with that issue? I have just come up with that and I understand if the Deputy does not have an answer for me right now.

**Deputy Billy Kelleher:** No, that is okay.

**Deputy Kate O'Connell:** In general, I am all for this. The onus falls on the medical practitioner to make the declaration with regard to the subsidy for, as Senator Burke brought up, foreign travel. Would that not lead to a little bit of inconsistency in self-declaration? Should the onus not fall on the pharmaceutical company? If it is dealing with 100 doctors that it is bringing to the UK for a conference, would it not be handier if the pharmaceutical company was responsible for netting down the actual donation amount as opposed to the practitioner doing

the sums? There would be 100 different sums done on the side of the practitioners. I am just trying to tease out things that might emerge through this.

**Deputy Billy Kelleher:** In terms of diabetic testing equipment, if it is not a direct transfer of value to the clinician himself or herself, it probably would not be governed under this legislation as it is drafted. Primarily, the transfer of value would be to the patients. We can get into the detail at some stage. If the doctor is charging for the use of that equipment, then that would be covered.

**Deputy Kate O'Connell:** They are often given free to the patient.

**Deputy Billy Kelleher:** The equipment is.

**Deputy Kate O'Connell:** Yes. The patient is therefore getting the financial benefit. It has a knock-on effect, however, because that patient is then restricted to using a particular product and the person prescribing the strips is the doctor. I do not think the legislation covers that.

**Deputy Billy Kelleher:** I do not believe that would be covered in this legislation as it stands. I mentioned that earlier. Some €10.7 million went directly to hospitals from drug companies and other entities, and that is not covered in this Bill.

**Deputy Kate O'Connell:** We will have to do another Bill.

**Deputy Billy Kelleher:** We could just broaden the scope of this Bill. It is important that we accept that there might be a need to broaden this Bill, and that has been referred to by the Minister in his observations, and in those of the Minister of State, Deputy Byrne, as well.

**Deputy Kate O'Connell:** What is the value of the subsidy that the pharmaceutical company would be responsible for netting down?

**Deputy Billy Kelleher:** There is a voluntary code among pharmaceutical companies to declare, but the individual in receipt of the gift can decline to publish his or her name. If a doctor does not want his or her name to be publicised, he or she can decline. There is no statutory obligation. That is a difficulty. A pharmaceutical company could be taking many clinicians abroad. Some people would allow their name to be publicly declared and others would not. In that instance there would be no transparency.

**Deputy Kate O'Connell:** If this all happens, the drug company will organically say that the value of this, from Dublin to London, is €50, €100, €150 or €750. The companies will probably help out the administrators.

**Deputy Billy Kelleher:** A value will be put on a trip. It will be said that the trip is being subsidised by a certain amount, and therefore a company is either under the limit or over the limit in terms of the obligation to declare, if this legislation were to be passed

**Deputy Kate O'Connell:** We want to make it as easy as possible for them.

**Deputy Billy Kelleher:** Yes. The companies would not have to run around and count every receipt. It would be done. I do not believe it is onerous.

**Senator Colm Burke:** I fully support the Bill, but it is important that the message is not sent out that we are concerned that everyone is on the take for his or her own benefit, and that this legislation is not for the benefit of the patient. It is important to say that the vast majority

of medical practitioners and practising nurses work to the best of their abilities for the benefit of the patient. Sometimes those people get very frustrated with the lack of response from the HSE or the Department of Health and then rely on the support of the private sector to progress an issue. It is important that we emphasise that this is about transparency and not about restricting the funding available.

**Deputy Billy Kelleher:** I believe that this would help, and the reason I say that is because it would remove the potential for the public or individuals to have a view that there are conflicts. There is no doubt that as we look into the future, we will see much more international co-operation in terms of clinicians travelling abroad to conferences, being peer-reviewed across the globe and interacting with colleges in other countries. Much of this will be funded by medical companies, pharmaceutical companies and medical device companies. There is nothing wrong with that. It is part and parcel of how we have evolved in terms of research and innovation. Many of the most wonderful drugs, equipment and devices which save and change lives have been developed through that process. It works very effectively. The problem is the transparency element. As more and more drugs come on the market across the globe, companies are obligated, because of the advances to fund greater amounts of medical devices, medicines and equipment, to adjust to transparency. In the longer term, it would be good for all individuals involved in the provision of health care to be obliged to declare so that everybody will be on an equal footing. If a number of clinicians get on a plane and go abroad, and some are declaring and some are not, that can lead to immediate suspicions, whereas if everyone on the plane has declared, all those issues are resolved.

**Chairman:** There are overt transfers of value and more subtle transfers of value. On educational activities, apart from educational activities that occur abroad, there are substantial educational activities that occur in Ireland which are sponsored by pharmaceutical companies. For example, a lecture may be sponsored by a company, the topic of which is a drug which is particularly related to that company, and this is portrayed as an educational evening for doctors, consultants or GPs. How could that be approached in this Bill?

A pharmaceutical company may exert a subtle influence by sponsoring a specialist nurse. There may be a dermatology nurse who visits a practice once a month or once every three months to review particular dermatological conditions and suggest treatments which invariably are produced by the sponsoring company.

It is happening more regularly now that companies are going into nursing homes and carrying out dietary and nutritional assessments on the residents in that nursing home and suggesting food supplements which are invariably produced by that company. Ethics were mentioned earlier, and I would have a difficulty with the ethics of such behaviour.

On the sponsoring of equipment, in many public hospitals now, and this has been discussed in the Committee on the Future of Healthcare and in this committee, there is a mix between public and private patients. Many companies are now sponsoring a unit or a respiratory lab or cardiology lab. They may also be employing the nurses who are running that lab. There is a temptation for physicians to use that lab inordinately for their private patients. There is a conflict there. Can this Bill be expanded to cover that?

There are influences in the pharmaceutical world where companies will offer certain discounts to pharmacies to dispense one generic product instead of another. There is a subtle influence on the pharmaceutical industry in terms of prescribing. Perhaps Deputy Kelleher could address those issues.

**Deputy Billy Kelleher:** The medical device industry funding equipment, a unit or personnel would not be covered by this particular Bill unless the doctor is making personal gains from it. If he or she is working within the unit, there is no material benefit. However, if he or she is charging people to use that facility, that would be seen as a gift because there would be a gain to the health care professional in that circumstance. If a nurse is being funded by a pharmaceutical company and is in a hospital, there is no material gain to an individual clinician if he or she is working in the same unit and just doing his or her job. If there was a direct transfer to that clinician because that nurse was being paid by the pharmaceutical industry it would have to be seen as a gift or a transfer of value under this legislation. That would require more thorough scrutiny on Committee Stage.

**Chairman:** Will the Deputy speak about the educational evenings sponsored by companies?

**Deputy Billy Kelleher:** It would be hard to argue that there would be a gift or a transfer of value if a person is just attending a lecture subsidised by a pharmaceutical company. If there is a transfer of value, for example, in a situation where a GP or a clinician is getting something more than education or information from it, it would have to be declared. If they are merely attending an evening I would suggest that it is not necessary to declare that. It would be highly unlikely that the evening would be worth more than €600.

**Chairman:** That depends on the wine.

**Deputy Billy Kelleher:** The Chairman raised an important point and this is why it should be teased out. The last thing one wants to do is sterilise interactions between research, pharmaceutical industries, academia, etc. People should not have to count the number of glasses of wine they had wondering if they had tipped over the threshold of €600.

**Deputy Kate O'Connell:** That would be great wine.

**Deputy Billy Kelleher:** That is why we have a high threshold. Some people will argue that this threshold is much too high, because it could mean that multiple gifts worth less than €600 could be received over the course of a year and none of them would have to be declared. As I have said, we do not want to be onerous in this, but we want the Bill and its intent to be embraced. We can modify it to ensure that those issues are addressed, or that other areas not covered by the Bill are included in it.

**Chairman:** On behalf of the committee, I thank Deputy Kelleher for appearing. I also thank Dr. Jean O'Sullivan for coming in to give her expert evidence.

**Deputy Billy Kelleher:** I thank the Chairman.

*Sitting suspended at 10.21 a.m. and resumed at 10.24 a.m.*

**Chairman:** On behalf of the committee, I welcome Ms Mary Jackson and Mr. Eugene Lennon of the Department of Health. I draw the attention of witnesses to the fact that by virtue of section 17(2)(*l*) of the Defamation Act 2009, witnesses are protected by absolute privilege in respect of their evidence to the committee. However, if they are directed by the committee to cease giving evidence on a particular matter and they continue to so do, they are entitled thereafter only to a qualified privilege in respect of their evidence. They are directed that only evidence connected with the subject matter of these proceedings is to be given and they are asked to respect the parliamentary practice to the effect that, where possible, they should not criticise or make charges against any person, persons or entity by name or in such a way as to

make him, her or it identifiable.

I also advise that any opening statement witnesses make to the committee may be published on the committee's website after this meeting. Members are reminded of the long-standing parliamentary practice to the effect that they should not comment on, criticise or make charges against a person outside the House or an official either by name or in such a way as to make him or her identifiable. I will now ask Ms Jackson to make her opening statement.

**Ms Mary Jackson:** I am a principal officer in the governance and clinical indemnity unit in the Department of Health. Mr. Eugene Lennon is principal officer in the medicines and controlled drugs unit. I thank the committee for the opportunity to provide the Department of Health's observations on the Medical Practitioners (Amendment) Bill 2017 at this scrutiny stage of the Bill.

By way of background, as we heard from Deputy Kelleher, this Private Members' Bill was published in March 2017. The Bill would require medical practitioners to declare any income or gift received from medical suppliers or pharmaceutical companies which exceeds €600 in value to the Medical Council in a statutory declaration annually. It was introduced on Second Stage on 19 October 2017.

The Minister for Health, Deputy Simon Harris, strongly agrees with the general principles behind this Bill. There should be transparency about transactions between commercial interests and health care providers so that the public can be assured that health care providers recommend treatment or administer appropriate care based solely on clinical evidence and experience and in the best interests of their patients and patient safety.

The tabling of this proposed legislation is timely. There have been a number of similar developments across Europe in this important area since 2010, when the Physician Payments Sunshine Act was first introduced in the United States. Under that legislation, the pharmaceutical industry must report relationships with doctors and teaching hospitals to the government-run programmes Medicaid and Medicare. In France, disclosure under similar legislation covers relationships with all health professionals and associations representing them, scientific societies, patients' associations and the press. In the Netherlands, a Healthcare Transparency Register was introduced in 2013 to disclose payments and gifts to health professionals from pharmaceutical companies. This publicly accessible register was extended in 2016 to cover medical devices also.

In examining reports on the laws, regulations and codes across Europe, we observe that the self-regulatory code on transfers of value from pharmaceutical companies to health care professionals and health care organisations of the European Federation of Pharmaceutical Industries and Associations, EFPIA, is common to all countries. As we have heard already, however, one of the shortcomings of this code is that health care professionals may choose not to allow their individual details to be published. This means that there is not full transparency, as only the composite totals of payments to those individuals is then published. Furthermore EFPIA and its member associations represent only part of the pharmaceutical industry.

In Ireland the Irish Pharmaceutical Healthcare Association, IPHA, applies this code to 44 of its members. In 2016, €30 million was provided to Irish health care organisations and health care professionals by EFPIA. Of this sum, however, just over €7 million went to health care professionals, while €10 million was directed to health care organisations. The balance of €12.6 million was directed to clinical trials and research and development. In addition, because

of the voluntary nature of the code, we understand that only around half of health care professionals in Ireland permit their information to be published.

We thus have problems with transparency. Other countries have experienced the same problems, with some health professionals choosing not to register transfers of value. To address this, some countries, such as the UK, have introduced anti-corruption laws. Interestingly, Scotland is considering the introduction of sunshine-type regulation, and the Scottish Parliament has debated it quite recently. There are also so-called "sunshine laws", or regulations similar to those enacted in the US, in the Netherlands, Belgium, Denmark and Portugal.

The current proposal is straightforward, requiring doctors to make a declaration to the Medical Council every year on funding and supports received from commercial interests. The definitions and terminology in the Bill require amendment to become consistent with existing Irish and European pharmaceutical and medical device legislation. We also believe the scope of the Bill may be too narrow to achieve the overall objective of transparency, as it limits transparency to doctors only, while other health professionals and health care organisations are also involved. If we are to consider broadening the scope, we should also look at where the register should be located and maintained.

Another relevant question is whether the register should be populated by the recipients of transfers of value or by those providing them. We question whether it would not be better to set up a register in an alternative location to the Medical Council in order that there would be the potential to cover transfers of value to other health professionals and health care organisations.

I will now make some specific comments on the Bill. In section 1, the definition of "declarable income" as "money or other form of payment" is too narrow. A transfer of value can be monetary, such as a fee for service or loan for the purchase of a device, but it can also be a non-monetary benefit, such as a flight, a registration fee or hotel accommodation. The reference to the term "gift" needs to be checked to ensure that it does not conflict with advertising regulations which allow for free samples to be provided in certain circumstances.

The terms "medical equipment" and "supplier" are not recognised terms under EU or Irish legislation. The term "medical device", which is used in existing legislation, includes medical equipment. On the term "supplier", EU legislation on medical devices defines a "manufacturer" as a "natural or legal person who manufactures or fully refurbishes a device or has a device designed, manufactured or fully refurbished and markets that device under its name or trade mark". EU legislation also defines a "distributor" and "authorised representative", but there is no definition of "supplier". We must be very careful around the consistency of definitions in the legislation.

There is no definition of "pharmaceutical company" in EU medicines legislation. EU legislation refers to "marketing authorisation", which means approval to market a medicine, and there is a lengthy definition of a marketing authorisation. Companies are known as "marketing authorisation holders", where the company or other legal entity is granted approval to market a medicine in one, several or all EU member states.

We suggest that a value of above €600 may be too high. This figure is set at a total of €500 per annum in the Netherlands. Similar legislation in other jurisdictions sets much lower threshold values, in some cases as low as €25. In addition, as the legislation is currently worded, it does not pick up on multiple payments to a medical practitioner of less than €600 which together would breach the threshold. For example, a doctor could receive two or more payments

of €400 each without breaching the legislation.

The Bill refers to the Statutory Declarations Act 1938 as the means by which doctors would declare the gifts and supports received. We may need to look at this because a statutory declaration under that legislation involves a person making a statutory declaration in front of either a notary, a commissioner for oaths or a peace commissioner.

Section 2 of the Bill proposes amending section 8 of the Medical Practitioners Act 2007 to mandate that doctors would make an annual declaration to the Medical Council of any declarable income or gifts, which would be placed on a publicly accessible register. Failure to do so would result in a complaint being made to the council. The onus of collecting annual declarations from doctors of their supports or gifts from commercial interests and placing this information on a publicly accessible register would create a new function for the council. Currently the council does not deal with pharmaceutical or medical device legislation, so if it is to maintain and respond appropriately to declarations received, it will have to build competence in this area. It already has a very challenging role in regulating around 21,800 medical practitioners and in promoting good professional practice in the interest of public safety. It also deals with complaints, which may be escalated to its fitness to practise committee. These may in turn result in a medical practitioner being removed from the register. Since the commencement of the Medical Practitioners (Amendment) Act 2017, on 6 November last, the council must also check that all medical practitioners, on applying to be placed on the council's register and on annual renewal of registration, have minimum levels of clinical indemnity cover. While Deputy Kelleher has said this change is a simple process within the Medical Council, maintaining this register will be another function on top of what is quite a challenging role for it in supervising the clinical competence and the clinical oversight of doctors.

The proposed Bill puts the burden on doctors to report. Approaches in other jurisdictions require pharmaceutical and medical device companies to report on their affiliations and financial relationships. Recognising that the objective of this Bill can be met by different approaches, we believe more time should be taken to consider these options, fully examining the benefits and drawbacks of each to adopt legislation which is robust, fair and achieves the objective of transparency for the public. We do not want circumvention of any legislation that we put in place. The options for changing the scope depend on whether it should be the payer or the receivers of transfers of value who populate the register.

We have identified five potential options, and there are probably more. The current option of making the Medical Council the holder of the register is one. Option 2 would be for it still to apply only to doctors but for a register to be established elsewhere and have commercial interests populate the information on the doctors to whom they provide transfers of value. Another option would be to extend the scope of the Bill to all health care professionals, including nurses, pharmacists, dentists and allied health professionals. As we have heard already, there are definitely transfers of value to nurses but, I think, to all of the others as well. Option 4 would be to extend the scope of Bill to cover all health care professionals and health care organisations in the public system. We have heard again this morning that the transfers of value may be to hospitals and other facilities. Extending the scope to that would cover those transactions. Another option would be to extend the scope to cover all health care professionals and health care providers in both the public and private health care systems.

A major consideration is where the register of transfers of value should be located and maintained. We pose the following questions. Should the register relate to doctors only and be the responsibility of the Medical Council, as per the current legislation? Should it be established

where all health professionals can be registered, as it would not make sense that each regulator would set up a separate register? Should there be a national register which includes transfers of value to health care organisations as well as health care professionals? Should the Health Information and Quality Authority, HIQA, which oversees standards within the health care system, hold the register, or should it be the Health Products Regulatory Authority, HPRA, which already has responsibility for regulation of pharmaceuticals and medical devices? Should the register be located in the HSE, if it is only publicly funded agencies that are covered, or the Department of Health, or indeed an independent entity external to all of those I have listed?

The cost of setting up and maintaining the register could be significant, so a costing model is needed to assess the respective costs of the options proposed and to find the optimum solution. The legislation may be too ambitious in including medical devices at the very outset. It may be prudent to commence with pharmaceuticals only, test the workability of the system and then extend the scope as soon as possible thereafter to medical devices, because of the different regulatory regime applying to both areas. This stepwise approach worked well in the Netherlands.

I hope the Department's comments are helpful and constructive. The Bill gives the opportunity to address a gap in legislation, which we all want to see happen and which many other European states are in the process of addressing. With robust legislative scrutiny and consultation, the resultant legislation will be based on the best models in place in other jurisdictions and what would work best for Ireland. The committee may wish to consider inviting other witnesses such as the HSE, the Pharmaceutical Society of Ireland and other regulators to advise on the best fit for this legislation. The obstacles to effective regulation of this area must be overcome through consultation and collaboration with the relevant parties, who wish to see full transparency in the interest of best patient care. I would like to reaffirm that the Minister and the Department strongly agree with the principles underpinning this Bill. We are committed to working with Deputy Kelleher and his legislative advisers on this important proposal.

I thank the Chair. My colleague and I will be happy to answer any follow-up questions.

**Deputy Billy Kelleher:** I thank Ms Jackson for her observations on the Bill as proposed. I note her reaffirmation that the Minister and the Department strongly agree with the principles underpinning this Bill, and her Department's commitment to working with me and my advisers on the proposal. I personally do not mind who takes ownership of this Bill. Is the Department drafting legislation at the moment or is it looking at alternative options to this Bill? I do not particularly want to pursue this legislation in order that I can go around with a feather in my cap, saying that I have a Bill on the Statute Book. I am interested in the outcome of the Bill. If there is a parallel process happening and we can bring the two proposals together, that might help the Department if it is looking to bring forward legislation.

The witness raised the question of registering recipients versus registering suppliers. Deputies have to declare to the Standards in Public Office Commission. We have to declare gifts as recipients. Why should it be the case that the provider of the gift would be obliged to declare, rather than the recipient? One could argue that both should be obliged to declare. There would then be absolute transparency, in the sense that one could be checked against the other.

Obviously I can accept that there would be a cost involved in establishing a register. However, it should be a fairly straightforward operation using software. We do not need fancy, elaborate offices with teams of people. This would be a register that would be filled out online and made available for public inspection. I do not know whether a very elaborate system is required in other countries or whether the Department has even assessed how other countries have

set up a register, who oversees it, or under what agency it is located, such as other countries' equivalent to the Medical Council.

Is there a role for the European Union in drafting a directive on this?

**Ms Mary Jackson:** The Department is not currently drafting alternative or parallel legislation. When the Deputy's Bill was published, we got approval from the Government to support it and examine its scope. For it to move to the Department, we would have to ask for further Government approval. It is not on our legislative agenda at the moment. We are happy with whatever works. The good thing about this legislation is that we are all in unison about what we want, and we want what is best. We can discuss with the Minister and with Deputy Kelleher what the best way forward on it is, but the Department would have to get approval from the Government to move on this legislation.

Registering the providers of gifts or monetary transfers would provide a much more comprehensive register than one recording all the individual recipients. Where the proposal made by the Irish Pharmaceutical Healthcare Association, IPHA, works well is in ensuring 100% transparency where entities are concerned, as far as we know. It is the individuals that are blocking their information. If there was full transparency concerning all transfers of value, then it would be equitable and no single group would be distinct in having to declare their information.

**Deputy Billy Kelleher:** Is Ms Jackson saying that an entity, for example, a pharmaceutical company, would actually declare the amount transferred to individuals?

**Ms Mary Jackson:** It would declare transfers both to individuals and to entities.

**Deputy Billy Kelleher:** Would the individuals be named?

**Ms Mary Jackson:** Let us say that €30 million in transfers of value came from 44 companies here in Ireland last year. That €30 million would be listed. Then everybody would be treated in the same way. That can be achieved by registering the suppliers of the transfers of value as opposed to their recipients.

The Department has not done any research on the cost of a register. Dr. O'Sullivan had the same report that we have found in our scoping of this legislation. We need to check the logistics involved with other countries where this has been put in place. There are probably different models depending on how the regulators in those countries have achieved the goal of transparency.

Perhaps Mr. Lennon would like to say something about the role of the EU. There is quite a lot of legislation on advertising that would be relevant.

**Mr. Eugene Lennon:** There are already regulations on advertising of prescribed medicines. These come from an EU directive, Directive 2001/83/EC. This proposal goes further than that. It deals with gifts and transfers of money. The EU has some role, but if we were to look for a new directive, we would be talking about a number of years. The EU would carry out an impact assessment, make a proposal, negotiate over a number of years, and then give some time to implement. Taking the route of national legislation may be the quickest way of making some sort of progress on this.

Regarding cost, what we want ultimately is a register that is very transparent and very searchable. We do not want a situation where there are lots of individual entries. We would

like to be able to look up an individual consultant or an individual entity and see all payments from all sources. Some work would be involved in building that. There may also be some work in policing any register or system we set up. We cannot presume that people are always fully honest in these matters, and it will be necessary to check the information that is provided. I am not saying that this would be a great cost, but we do need to make some estimate.

Where such registers are based varies between different countries. In some cases it is with the regulator of the particular profession. In other cases it can be with the medicines agency or some other entity in the country. I agree that the bulk of prescribing is done by medical practitioners, but as we have heard, there are other health professionals who may receive transfers of value. Would it be appropriate, then, to house the register in the Medical Council or somewhere more central?

There is also the question of transfers of value to health care organisations. Once our concern goes beyond doctors, the Medical Council may not be the best or most appropriate place. However, we agree very much with the principle of the Bill.

**Deputy Bernard J. Durkan:** In most legislation, we look for a downside. To what extent has the Department tested any negative effect which this legislation might have on the delivery of services to patients, institutions or whatever the case may be? On the €600 total, is it not a simple thing to insert in the legislation a clause to the effect that a cumulative amount of €600 is the threshold?

I have often looked back over the years at ways in which we, as Members of the Oireachtas, have had to declare our interests, and I am sure other public servants have had to declare their interests. One would often wonder how come a particular organisation did not see fit to reward A, B and C. Why were some people left out? I say that because if a system is in place in which some members involved in the delivery of a service are rewarded in a particular fashion by a donor, it has the effect of skewing the delivery of services, whether they are health, administrative or education services. Has that aspect been examined and, if so, to what extent?

Is there any possibility the Bill might be seen as a further obstacle in the delivery of services, particularly in health, which is a very sensitive area at present and one fraught with a great deal of difficulty? Is it possible that someone will come back to us in a year or two and say the Bill prevented the provision of particular services? I do not say that in opposition to the proposed Bill but simply to inquire about what might happen in particular circumstances.

**Chairman:** I presume the purpose of the Bill is to have ethical standards applied and to have transparency and accountability.

**Deputy Billy Kelleher:** Yes.

**Chairman:** If a doctor, nurse or other health professional is in receipt of support from a pharmaceutical company or the pharmaceutical industry, it may be very legitimate support but the Bill is concerned with it being upfront, transparent and accountable. In health research, there are researchers who put a declaration of interest at the end of their papers saying that a particular company assisted in the sponsorship of the research or in some other way. They are being ethical, transparent and accountable for how the research was funded. It is not to inhibit the pharmaceutical industry in the delivery of medical services but to ensure that the person or entity is upfront and declares that interest. That is the real purpose of the Bill. How does the Deputy view his Bill in light of the comments that have been made today?

**Deputy Billy Kelleher:** Is it appropriate for me to comment?

**Chairman:** I will ask the witnesses first and perhaps the Deputy can address it through questions.

**Deputy Bernard J. Durkan:** Deputy Kelleher could then comment on their comments.

**Ms Mary Jackson:** Deputy Durkan made a point about the untold effects of the legislation. The Chairman also mentioned it. The last thing we want to do is stifle the clinical trials and the very important clinical work that is going on which is legitimately sponsored by a number of companies in order to advance medicine. As part of the scrutiny process, that needs to be checked. One way would be to get some witnesses with experience in this area of clinical trials because there may be genuine reasons some aspects of those transfers of value or information about the people they are going to need to be confidential. Witnesses who have the competence or expertise to address that would be useful. Part of the scrutiny process is to make sure that what we introduce has no untold effects. We question whether it is equitable that only doctors would be on this register when it could be the representative organisations of the doctors or the hospitals. We must examine the untold consequences of going down any particular route. We need to be sure which is the best way to achieve what we all want. We support proceeding with the Bill. We can share information on what we have done to scope out the various aspects of the Bill and the Minister can talk to Deputy Kelleher to see how it can be moved forward.

**Deputy Billy Kelleher:** I do not want to burden the Department with the challenges connected to this legislation or by bringing witnesses from the Department before the committee on a regular basis. I assume there is an acceptance that we need to have transparency in view of the Physician Payments Sunshine Act in the United States and the fact that countries in Europe have either drafted or passed legislation. It is statute in some countries in the European Union so there is an acceptance around it. The Chairman, Ms Jackson, Mr. Lennon and Deputy Durkan were right. We do not want to stifle or put obstacles in the way of the creative genius in research and development in medicine, medicinal devices and pharmaceuticals. When I was Minister of State in the then Department of Enterprise, Trade and Employment, I saw the innovation that comes from the collaborative work of academia, clinicians and the industry. I do not want to stymie it. A transparency clause or legislation would unburden people. They could embrace industry and get really involved with it knowing it is upfront and transparent and that anyone can inspect it. The last thing we need is for people to go through back doors and carry out research without transparency.

**Chairman:** I thank Deputy Kelleher. Do the witnesses have any comments?

**Mr. Eugene Lennon:** I do not know whether the committee intends to call further witnesses but when its report is published, the Department will study it and the Minister will be happy to speak to Deputy Kelleher about how we can advance the Bill.

**Ms Mary Jackson:** Deputy Kelleher mentioned the legislation across Europe. Most member states know what they are doing but Ireland does not so we need to do something.

**Chairman:** On behalf of the committee, I thank Ms Jackson and Mr. Lennon for coming in this morning. I thank Deputy Kelleher for sponsoring the Bill.

The joint committee adjourned at 10.57 a.m. until 9 a.m. on Wednesday, 13 December 2017.