National Pensioners Federation | Fédération Nationale des Retraités
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1st Vice-President | Sam Wiese
2nd Vice-President | Bernie LaRusic
3rd Vice-President | Barb Mikulec
Member-at- Large | Kathleen Jamieson
Recording Secretary | Anette O'Connor

February 13, 2020

Executive Director,
PMPRB Consultations
CEPMB@pmprb-cepmb.gc.ca

Dear PMPRB Executive Director:

The National Pensioners' Federation is pleased to submit the enclosed submission commenting on the new Patented Medicines Price Review Board (PMPRB) regulations and their implementation. We are also pleased to have been invited by PMPRB to participate in in the consultation on the new regulations. The issues are complex and we benefitted from the informative presentations made by the PMPRB and the questions from the other participants. We see the changes as a major step forward toward to getting a universal single payer Pharmacare plan.

We hope that we will continue to be involved in any future consultations.

Please do not hesitate to call me if you have any questions.

Thank you.

Trish McAuliffe

President,
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Reconciling the Personal and the Political: Steps to implementing a sustainable universal Pharmacare plan and the challenge of ensuring equitable and timely access to new medicines.

A submission to the Patented Medicine Prices Review Board. by the National Pensioners' Federation.

Prepared by Kathleen Jamieson, February 14, 2020

1. Introduction

The National Pensioners' Federation (NPF) welcomes this opportunity to comment on the significant changes to the regulations in the 1985 Patent Act that will come into effect on July 1, 2020 and that will be implemented by the Patented Medicine Prices Review Board (PMPRB). Our comments and recommendations to PMPRB are submitted on behalf of the almost one million members of 350 seniors' groups, organizations, and individual members that NPF represents across Canada.

When the imminent changes to the Patent Act regulations were announced in the *Canada Gazette* on August 21, 2019 then federal Minister of Health, Ginette Petitpas-Taylor, said: "Today we take the biggest step to lower drug prices in a generation … these bold reforms will both make prescription drugs more affordable and accessible for all Canadians --- saving them an estimated $13 billion dollars in the next decade --- and lay the foundation for National Pharmacare." At the same time the Minister noted that "Canadians pay among the highest patented drug prices in the world after only the United States and Switzerland …[and] pay close to 25% more than people in other developed countries pay for the same drugs."[1]

The mandate of the PMPRB is to implement these "bold reforms" primarily through setting ceiling prices for new patented medicines. More specifically, it will employ three new measures: 1) Take an approach that looks at price in relation to its value and impact on the Canadian health care system; 2) Update the list of countries that Canada compares drug prices with to include only countries with similar social and economic systems; 3) Change current reporting requirements.

[1] https://www.canad/en-canada/health/news/2019/08/government-of-c...wer-drug-prices-and-lay-the-foundation-for-national-pharmacare.html

The agency is described by Health Canada as a quasi-judicial body that protects consumers and contributes to health care by ensuring that the manufacturers' prices of patented medicines are not excessive. PMPRB is part of the "arms-length" portfolio of the Minister of Health.

The PPMRB does not have jurisdiction over prices charged by wholesalers or pharmacies. Its overall purpose is "to protect and inform Canadians by ensuring that the prices of patented medicines sold in Canada are not excessive and by reporting on Pharmaceutical trends."[2] PMPRB is moving forward with the reforms by, among other things, changing the Canadian list of comparator countries by eliminating the US and Switzerland from Canada's list and using 11 OECD countries for price comparison.

Although PMPRB is seen as pivotal to the implementation of universal Pharmacare, it is one component in a number of federal/ provincial and territorial government decision-making entities that have some changing involvement in the pricing of, and Canadians' access to, patented drugs.

The Canadian Agency for Drugs and Technology in Health (CADTH) conducts a technical review of the efficacy of new drugs and informs the pricing decisions made by the PMPRB.[3] The Quebec-based Institut national d'excellence en santé et en services sociaux (INESSS) which has a similar function in Quebec may also be consulted. In addition, provincial and territorial governments created their own Pan-Canadian Pharmaceutical Alliance in 2010 to "conduct joint provincial/territorial/federal negotiations for brand name and generic drugs in Canada to achieve greater value for publicly funded drug programs and patients through the use of the combined negotiating power of participating jurisdictions."[4]

A new Canadian Drug Agency that is intended to provide oversight and possibly amalgamate all these disparate agencies was announced in the February 4, 2019 federal Budget which states that the Canadian Drug Agency will work with provinces, territories and stakeholders to create the Canadian Drug Agency that will:

- "Assess the effectiveness of new prescription drugs.
- Negotiate drug prices on behalf of Canada's drug plans.
- Recommend which drugs represent the best value-for-money for Canadians. "[5]

[2] pmprb-cepmb.gc.ca
[3] https://www.canada.ca/en/patented-medicine-prices-review/services/consultations/draft-guidelines.html#10
[4] https://canadaspremiers.ca/pan-canadian-pharmaceutical-alliance/
[5] https://budget.gc.ca/2019/docs/themes/pharmacare-assurance-medicaments-en.html

In June 2019 the federally-appointed Advisory Council Report on the Implementation of National Pharmacare also recommended the creation of a Canadian drug agency and outlined its possible scope.[6]

NPF supports all efforts to ensure a strong humanitarian and economic basis for implementing national, single payer universal Pharmacare and commends PMPRB for its initiative in consulting with and receiving submissions from NPF and other major citizen and labour groups on the proposed regulatory changes. It sees this approach as a step to more ongoing citizen involvement in deliberations by the varied government agencies involved in ensuring equitable access to new medicines.

2. Seniors as Equity-Seeking Stakeholders in Access to Patented Prescription Drugs

We seniors have a vested interest in promoting equitable access to prescription drugs whether they are patented or generic. But we are not all the same. Seniors can range in age from 60 to 100 years or more. Canadian seniors are also diverse in health status, culture, education, and income and these factors can affect their quality of life and life- span differently. Seniors with higher levels of education and higher incomes, for example, will have longer years in good health.[7] However, sooner or later we will all become frail and so all seniors become major stakeholders in this endeavour

Seniors are major users of prescription drugs --- connoisseurs you might say. According to CIHI, one in four Canadian seniors is prescribed ten or more drug classes per year and on average 5.9 different drug classes per year.[8] Seniors may have, or develop, age-related chronic illnesses and be dependent on patented medicines to maintain their quality of life, even to stay alive. Seniors with an age-related incurable or rare disease, such as multiple system atrophy, or Alzheimer's, for example, live in the hope that the remarkable advances in medical research now being made will lead to more effective symptom control or cures. Some seniors may ultimately choose programs to assist them in dying when medicine fails them.

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[6] https://www.canada.ca/en/health-canada/corporate/about-health-canad..dvisory-bodies/implementation-national-pharmacare/final-report.html

[7] Statistics Canada, Health Report January 15, 2020. *Socioeconomic disparities in life and health expectancy among the household population in Canada.* Tracey Bushnik et al. www150.statcan.gc.ca

[8] Canadian Institute for Health Information. *Drug use among seniors in Canada, 2016*.

Decisions made by PMPRB on timely and equitable access to new and effective drugs are experienced as being very personal and are critically important for all, old or young, with otherwise limited life spans or money.

3. PMPRB Decision-Making Tools

We appreciate federal efforts to ensure access to needed prescription drugs for all but we remain concerned about the extent to which decisions on managing drug funding levels and access appear to be based almost entirely on traditional economic measures and considerations such as GDP (Gross Domestic Product) and QALY (Quality-adjusted life year) that are not balanced by measures of social or environmental well-being.

QALY has been used for decades by health economists as a measure that combines in a single index number quality of life and the quantity of life lived or life expectancy. In essence, it's a convenient measure for allocating scarce resources.
However, as some scholars have noticed this index is reductionist. They note it does not capture all the benefits of a health care intervention or account for inequities or ethical concerns such as the role and values of the allocator of the resources. [9]

It seems possible that QUALY could be used to discriminate against some seniors who need a new medication but have fewer years of life left. It might also be used to discriminate against people from lower socio-economic groups and others who have shorter life expectancies. NPF believes that QALY and its underlying assumptions need to be examined and expanded to ensure that they support core Canadian values of fairness and equity in access to new patented medicines.

Gross Domestic Product (GDP) is an aggregate measure of economic performance and was never meant to measure societal well-being or the environment when it was developed by Nobel prize winning economist Simon Kuznets in the 1930s but it is often assumed to be able to do so today. Ninety years ago, Simon Kuznets, warned in a report to the US Congress: "The valuable capacity of the human mind to simplify a complex situation in compact characterization becomes dangerous when not controlled in terms of definitely stated criteria. With quantitative measurements especially, the definiteness of the result suggests, often misleadingly, a precision and simplicity in the outlines of the object measured."[10]

[9] Health Expectations, Vol.5, Issue 3, September 2002. *Resource allocation: social values and the QALY: a review of the debate and empirical evidence.* David L.P. Schwappach
[10] National Incomes 1929-1932. Senate Report no. 124, 73rd Congress, 2nd session.

More recently, Nobel-prizewinning economist, Joseph Stiglitz, noted "GDP is not a good measure of economic performance, and it's not a good measure of well-being." Together with Christine Lagarde, Head of the International Monetary Fund (IMF), and Erik Brynjolfsson of the Massachusetts Institute of Technology (MIT), Stiglitz argued at the 2016 World Economic Forum for a change in the way we measure both economic and social development. [11]

The National Pensioners' Federation believes that PPMRB has made a corporate choice to reify these two measures (QUALY and GDP) and that it may help to look more deeply into other measures that offer more balance such as the Human Development Index (HDI) or the 2013 OECD Better Life index.

That being said, NPF recognizes, that an important step to achieving our long-term goal of seeing public, single-payer, universal Pharmacare operating in our lifetimes is to control expenditures on patented drugs. And NPF also recognizes that in the face of the spiralling and unsustainable costs of new drugs to our public health care system and the efforts of large pharmaceutical companies to block any restrictions that can impact on profits to their shareholders, the work of PPMRB and its federal partners is absolutely essential.

4. Opponents of the amended PMPMB regulations and Universal Pharmacare

Two days after the federal government announced the amended PMPRB regulations in 2019, five large pharmaceutical companies filed a challenge to the amendments in federal court alleging that the changes were contrary to provisions of the Canadian constitution which they argue makes the provision of health care a provincial responsibility. [12]

Shortly after that, a separate lawsuit was launched in federal court by Innovative Medicines Canada (IMC), a drug industry lobby group, on behalf of 16 of its member companies, arguing that Canada cannot "fundamentally alter" the role of the PMPRB.[13]

An IMC industry spokesperson is quoted in their August 2019 media release as saying that they had been trying to work with Health Canada to find policy alternatives to the amendments for 2 years.

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These court cases and the apparent long-term ability of IMC and big pharmaceutical companies to lobby Health Canada on policy matters provide a chilling insight into the reach and power that the Pharmaceutical industry has in Canada.

Clearly these companies are taking steps to protect their profits; they also threaten dire consequences for Canadians if Canada does not toe their line. In so doing so they seem to believe they can nullify the will of the majority of the people of Canada who want and need universal single payer Pharmacare and who understand that bringing current drug spending under control in Canada is a necessary pre-condition for universal Pharmacare to become a reality.

The pharmaceutical industry does not stop at lobbying governments to protect their interests; it has increasingly involved patient groups and seniors' organizations in financial relationships that are influenced by commercial objectives. A *Globe and Mail* investigative report of December 2018 found that there was an extensive "web of influence between patient-advocates and Big Pharma" in Canada and that pharmaceutical companies' funding to patient advocacy groups, small or large, tends to coincide with the drugs up for technical review by the Canadian Agency for Drugs and Technology in Health (CADTH).[14]

Such influencing of patient groups is not confined to Canada. The British Medical Association Journal reported in May 2019 that £57 million had been donated by the drug industry to patient organizations in the UK between 2012 and 2016 and that "priority for funding is given to those groups supporting commercially high-profile conditions." [15]

In the US, a long-delayed Bill to limit the high costs of drugs was passed by Congress on December 12, 2019 but is not expected to pass in the Senate. Extensive lobbying by big Pharmaceutical companies has been identified as one reason.

5. Conclusion

NPF sees the role of the PMPRB as complex, challenging, and currently, at least, very powerful. It is one that requires it to balance many different factors that contribute to Canadians health and

[14] Globe and Mail, December 13, 2018. How a little-known agency reveals the web of influence between patient advocates and Big Pharma. https://www.theglobeandmail.com/canada/investigations/article-how-a-little known-agency-reveals the-web- of influence between-patient- advocates-and-Big-Pharma

[15] British Medical Journal, May22, 2019

quality of life as well as control the prices of new patented drugs. We believe it is an essential step in the journey to the implementation of a universal single payer Pharmacare plan.

In making its decisions, the PMPRB does not lack for support and advice from experts in advisory committee and working groups in economic and pharmaceutical fields of knowledge. This pharma-economic reasoning, we believe, needs to be balanced by applications from fields that consider social and individual well-being. An independent ethics committee also needs to be appointed and included in decisions-making. A specific recommendation and measure of fairness is that Canada should not lag behind other comparable countries in approving new patented drugs.

We support the PMPRB in carrying out all its responsibilities in an equitable way. However, we would like to remind all the agencies involved in making decisions on the allocation of health resources that seemingly impartial judgements or measures adopted by any public agency inevitably involve some present-day ethical and moral assumptions or state-of-knowledge judgements about the value to society of any person or group of persons. The use of QUALYs and the GDP in key decision-making on matters that are not solely economic are prime examples.

Implementing current federal policy objectives related to the federal PMPRB mandate and its role in moving Pharmacare forward while dealing with the intensive lobbying and the legal challenges of many large pharmaceutical companies and their allies may seem daunting. We believe, however, that Canada, unlike the US, is still not in thrall to the pharmaceutical industry and that the extensive public support that exists for a Universal Pharmacare plan will ensure that it becomes a reality very soon. It just has to be done right.

We, therefore, recommend that the ongoing work of PMPRB in making these critical decisions be transparent, and monitored and have an appeal board. The appeal board should be composed not only of academics and politicians but also of representatives of independent not for profit citizen groups that do not receive funding or any incentives from Pharmaceutical companies.

We offer our perspectives on these issues as seniors with decades of knowledge and experience of the benefits of, and the gaps in, our public health care system and also of the vagaries of the political process as a contribution to making universal, single-payer Pharmacare a reality for everyone living in Canada.

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[18] https://www.canada.ca/en/patented-medicine-prices-review/services/consultations/draft-guidelines.html#10
[19] https://canadaspremiers.ca/pan-canadian-pharmaceutical-alliance/
[20] https://budget.gc.ca/2019/docs/themes/pharmacare-assurance-medicaments-en.html
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5. Conclusion

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In making its decisions, the PMPRB does not lack for support and advice from experts in advisory committee and working groups in economic and pharmaceutical fields of knowledge. This pharma-economic reasoning, we believe, needs to be balanced by applications from fields that consider social and individual well-being. An independent ethics committee also needs to be appointed and included in decisions-making. A specific recommendation and measure of fairness is that Canada should not lag behind other comparable countries in approving new patented drugs.

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[29] Globe and Mail, December 13, 2018. How a little-known agency reveals the web of influence between patient advocates and Big Pharma.
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Implementing current federal policy objectives related to the federal PMPRB mandate and its role in moving Pharmacare forward while dealing with the intensive lobbying and the legal challenges of many large pharmaceutical companies and their allies may seem daunting. We believe, however, that Canada, unlike the US, is still not in thrall to the pharmaceutical industry and that the extensive public support that exists for a Universal Pharmacare plan will ensure that it becomes a reality very soon. It just has to be done right.

We, therefore, recommend that the ongoing work of PMPRB in making these critical decisions be transparent, supported and monitored by an appeal board. The appeal board should be composed not only of academics and politicians but also of representatives of independent not for profit citizen groups that do not receive funding or any incentives from Pharmaceutical companies.

We offer our perspectives on these issues as seniors with decades of knowledge and experience of the benefits of, and the gaps in, our public health care system and also of the vagaries of the political process as a contribution to making universal, single-payer Pharmacare a reality for everyone living in Canada.

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1. Introduction

The National Pensioners' Federation (NPF) welcomes this opportunity to comment on the significant changes to the regulations in the 1985 Patent Act that will come into effect on July 1, 2020 and that will be implemented by the Patented Medicine Prices Review Board (PMPRB). Our comments and recommendations to PMPRB are submitted on behalf of the almost one million members of 350 seniors' groups, organizations, and individual members that NPF represents across Canada.

When the imminent changes to the Patent Act regulations were announced in the *Canada Gazette* on August 21, 2019 then federal Minister of Health, Ginette Petitpas-Taylor, said: "Today we take the biggest step to lower drug prices in a generation … these bold reforms will both make prescription drugs more affordable and accessible for all Canadians --- saving them an estimated $13 billion dollars in the next decade --- and lay the foundation for National Pharmacare." At the same time the Minister noted that "Canadians pay among the highest patented drug prices in the world after only the United States and Switzerland …[and] pay close to 25% more than people in other developed countries pay for the same drugs."[1]

The mandate of the PMPRB is to implement these "bold reforms" primarily through setting ceiling prices for new patented medicines. More specifically, it will employ three new measures: 1) Take an approach that looks at price in relation to its value and impact on the Canadian health care system; 2) Update the list of countries that Canada compares drug prices with to include only countries with similar social and economic systems; 3) Change current reporting requirements.

The agency is described by Health Canada as a quasi-judicial body that protects consumers and contributes to health care by ensuring that the manufacturers' prices of

[1] https://www.canad/en-canada/health/news/2019/08/government-of-c...wer-drug-prices-and-lay-the-foundation-for-national-pharmacare.html

patented medicines are not excessive. PMPRB is part of the “arms-length” portfolio of the Minister of Health.

The PPMRB does not have jurisdiction over prices charged by wholesalers or pharmacies. Its overall purpose is “to protect and inform Canadians by ensuring that the prices of patented medicines sold in Canada are not excessive and by reporting on Pharmaceutical trends.”[2] PMPRB is moving forward with the reforms by, among other things, changing the Canadian list of comparator countries by eliminating the US and Switzerland from Canada’s list and using 11 OECD countries for price comparison.

Although PMPRB is seen as pivotal to the implementation of universal Pharmacare, it is one component in a number of federal/ provincial and territorial government decision-making entities that have some changing involvement in the pricing of, and Canadians’ access to, patented drugs.

The Canadian Agency for Drugs and Technology in Health (CADTH) conducts a technical review of the efficacy of new drugs and informs the pricing decisions made by the PMPRB.[3] The Quebec-based Institut national d’excellence en santé et en services sociaux (INESSS) which has a similar function in Quebec may also be consulted. In addition, provincial and territorial governments created their own Pan-Canadian Pharmaceutical Alliance in 2010 to “conduct joint provincial/territorial/federal negotiations for brand name and generic drugs in Canada to achieve greater value for publicly funded drug programs and patients through the use of the combined negotiating power of participating jurisdictions.”[4]

A new Canadian Drug Agency that is intended to provide oversight and possibly amalgamate all these disparate agencies was announced in the February 4, 2019 federal Budget which states that the Canadian Drug Agency will work with provinces, territories and stakeholders to create the Canadian Drug Agency that will:

- “Assess the effectiveness of new prescription drugs.
- Negotiate drug prices on behalf of Canada’s drug plans.
- Recommend which drugs represent the best value-for-money for Canadians. “[5]

In June 2019 the federally-appointed Advisory Council Report on the Implementation of National Pharmacare also recommended the creation of a Canadian drug agency and outlined its possible scope.[6]

NPF supports all efforts to ensure a strong humanitarian and economic basis for implementing national, single payer universal Pharmacare and commends PMPRB for

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[2] pmprb-cepmb.gc.ca

[3] https://www.canada.ca/en/patented-medicine-prices-review/services/consultations/draft-guidelines.html#10

[4] https://canadaspremiers.ca/pan-canadian-pharmaceutical-alliance/

[5] https://budget.gc.ca/2019/docs/themes/pharmacare-assurance-medicaments-en.html

[6] https://www.canada.ca/en/health-canada/corporate/about-health-canad..dvisory-bodies/implementation-national-pharmacare/final-report.html

its initiative in consulting with and receiving submissions from NPF and other major citizen and labour groups on the proposed regulatory changes. It sees this approach as a step to more ongoing citizen involvement in deliberations by the varied government agencies involved in ensuring equitable access to new medicines.

2. Seniors as Equity-Seeking Stakeholders in Access to Patented Prescription Drugs

We seniors have a vested interest in promoting equitable access to prescription drugs whether they are patented or generic. But we are not all the same. Seniors can range in age from 60 to 100 years or more. Canadian seniors are also diverse in health status, culture, education, and income and these factors can affect their quality of life and life-span differently. Seniors with higher levels of education and higher incomes, for example, will have longer years in good health.[7] However, sooner or later we will all become frail and so all seniors become major stakeholders in this endeavour

Seniors are major users of prescription drugs --- connoisseurs you might say. According to CIHI, one in four Canadian seniors is prescribed ten or more drug classes per year and on average 5.9 different drug classes per year.[8] Seniors may have, or develop, age-related chronic illnesses and be dependent on patented medicines to maintain their quality of life, even to stay alive. Seniors with an age-related incurable or rare disease, such as multiple system atrophy, or Alzheimer's, for example, live in the hope that the remarkable advances in medical research now being made will lead to more effective symptom control or cures. Some seniors may ultimately choose programs to assist them in dying when medicine fails them.

Decisions made by PMPRB on timely and equitable access to new and effective drugs are experienced as being very personal and are critically important for all, old or young, with otherwise limited life spans or money.

3. PMPRB Decision-Making Tools

We appreciate federal efforts to ensure access to needed prescription drugs for all but we remain concerned about the extent to which decisions on managing drug funding levels and access appear to be based almost entirely on traditional economic measures and considerations such as GDP (Gross Domestic Product) and QALY (Quality-adjusted life year) that are not balanced by measures of social or environmental well-being.

QALY has been used for decades by health economists as a measure that combines in a single index number quality of life and the quantity of life lived or life expectancy. In essence, it's a convenient measure for allocating scarce resources.

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[7] Statistics Canada, Health Report January 15, 2020. *Socioeconomic disparities in life and health expectancy among the household population in Canada.* Tracey Bushnik et al. www150.statcan.gc.ca

[8] Canadian Institute for Health Information. *Drug use among seniors in Canada, 2016*.

However, as some scholars have noticed this index is reductionist. They note it does not capture all the benefits of a health care intervention or account for inequities or ethical concerns such as the role and values of the allocator of the resources. [9]

It seems possible that QUALY could be used to discriminate against some seniors who need a new medication but have fewer years of life left. It might also be used to discriminate against people from lower socio-economic groups and others who have shorter life expectancies. NPF believes that QALY and its underlying assumptions need to be examined and expanded to ensure that they support core Canadian values of fairness and equity in access to new patented medicines.

Gross Domestic Product (GDP) is an aggregate measure of economic performance and was never meant to measure societal well-being or the environment when it was developed by Nobel prize winning economist Simon Kuznets in the 1930s but it is often assumed to be able to do so today. Ninety years ago, Simon Kuznets, warned in a report to the US Congress: "The valuable capacity of the human mind to simplify a complex situation in compact characterization becomes dangerous when not controlled in terms of definitely stated criteria. With quantitative measurements especially, the definiteness of the result suggests, often misleadingly, a precision and simplicity in the outlines of the object measured."[10]

More recently, Nobel-prizewinning economist, Joseph Stiglitz, noted "GDP is not a good measure of economic performance, and it's not a good measure of well-being." Together with Christine Lagarde, Head of the International Monetary Fund (IMF), and Erik Brynjolfsson of the Massachusetts Institute of Technology (MIT), Stiglitz argued at the 2016 World Economic Forum for a change in the way we measure both economic and social development. [11]

The National Pensioners' Federation believes that PPMRB has made a corporate choice to reify these two measures (QUALY and GDP) and that it may help to look more deeply into other measures that offer more balance such as the Human Development Index (HDI) or the 2013 OECD Better Life index.

That being said, NPF recognizes, that an important step to achieving our long-term goal of seeing public, single-payer, universal Pharmacare operating in our lifetimes is to control expenditures on patented drugs. And NPF also recognizes that in the face of the spiralling and unsustainable costs of new drugs to our public health care system and the efforts of large pharmaceutical companies to block any restrictions that can impact on profits to their shareholders, the work of PPMRB and its federal partners is absolutely essential.

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[9] Health Expectations, Vol.5, Issue 3, September 2002. *Resource allocation: social values and the QALY: a review of the debate and empirical evidence.* David L.P. Schwappach

[10] National Incomes 1929-1932. Senate Report no. 124, 73rd Congress, 2nd session.

[11] Social Europe 7 January 2019. *Beyond GDP.* Joseph Stiglitz

4. Opponents of the amended PMPMB regulations and Universal Pharmacare

Two days after the federal government announced the amended PMPRB regulations in 2019, five large pharmaceutical companies filed a challenge to the amendments in federal court alleging that the changes were contrary to provisions of the Canadian constitution which they argue makes the provision of health care a provincial responsibility. [12]

Shortly after that, a separate lawsuit was launched in federal court by Innovative Medicines Canada (IMC), a drug industry lobby group, on behalf of 16 of its member companies, arguing that Canada cannot "fundamentally alter" the role of the PMPRB.[13]

An IMC industry spokesperson is quoted in their August 2019 media release as saying that they had been trying to work with Health Canada to find policy alternatives to the amendments for 2 years.

These court cases and the apparent long-term ability of IMC and big pharmaceutical companies to lobby Health Canada on policy matters provide a chilling insight into the reach and power that the Pharmaceutical industry has in Canada.

Clearly these companies are taking steps to protect their profits; they also threaten dire consequences for Canadians if Canada does not toe their line. In so doing so they seem to believe they can nullify the will of the majority of the people of Canada who want and need universal single payer Pharmacare and who understand that bringing current drug spending under control in Canada is a necessary pre-condition for universal Pharmacare to become a reality.

The pharmaceutical industry does not stop at lobbying governments to protect their interests; it has increasingly involved patient groups and seniors' organizations in financial relationships that are influenced by commercial objectives. A *Globe and Mail* investigative report of December 2018 found that there was an extensive "web of influence between patient-advocates and Big Pharma" in Canada and that pharmaceutical companies' funding to patient advocacy groups, small or large, tends to coincide with the drugs up for technical review by the Canadian Agency for Drugs and Technology in Health (CADTH).[14]

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[12] The five Pharmaceutical companies are Merck Canada Inc, Janssen Inc, Boehringer Ingelheim Sevier Canada and Bayer Inc.

[13] Reuters

[14] Globe and Mail, December 13, 2018. How a little-known agency reveals the web of influence between patient advocates and Big Pharma.
https://www.theglobeandmail.com/canada/investigations/article-how-a-little known-agency-reveals the-web- of influence between-patient- advocates-and-Big-Pharma

Such influencing of patient groups is not confined to Canada. The British Medical Association Journal reported in May 2019 that £57 million had been donated by the drug industry to patient organizations in the UK between 2012 and 2016 and that "priority for funding is given to those groups supporting commercially high-profile conditions." [15]

In the US, a long-delayed Bill to limit the high costs of drugs was passed by Congress on December 12, 2019 but is not expected to pass in the Senate. Extensive lobbying by big Pharmaceutical companies has been identified as one reason.

5. Conclusion

NPF sees the role of the PMPRB as complex, challenging, and currently, at least, very powerful. It is one that requires it to balance many different factors that contribute to Canadians health and quality of life as well as control the prices of new patented drugs. We believe it is an essential step in the journey to the implementation of a universal single payer Pharmacare plan.

In making its decisions, the PMPRB does not lack for support and advice from experts in advisory committee and working groups in economic and pharmaceutical fields of knowledge. This pharma-economic reasoning, we believe, needs to be balanced by applications from fields that consider social and individual well-being. An independent ethics committee also needs to be appointed and included in decisions-making. A specific recommendation and measure of fairness is that Canada should not lag behind other comparable countries in approving new patented drugs.

We support the PMPRB in carrying out all its responsibilities in an equitable way. However, we would like to remind all the agencies involved in making decisions on the allocation of health resources that seemingly impartial judgements or measures adopted by any public agency inevitably involve some present-day ethical and moral assumptions or state-of-knowledge judgements about the value to society of any person or group of persons. The use of QUALYs and the GDP in key decision-making on matters that are not solely economic are prime examples.

Implementing current federal policy objectives related to the federal PMPRB mandate and its role in moving Pharmacare forward while dealing with the intensive lobbying and the legal challenges of many large pharmaceutical companies and their allies may seem daunting. We believe, however, that Canada, unlike the US, is still not in thrall to the pharmaceutical industry and that the extensive public support that exists for a Universal Pharmacare plan will ensure that it becomes a reality very soon. It just has to be done right.

We, therefore, recommend that the ongoing work of PMPRB in making these critical decisions be transparent, and monitored and have an appeal board. The appeal board

[15] British Medical Journal, May22, 2019

should be composed not only of academics and politicians but also of representatives of independent not for profit citizen groups that do not receive funding or any incentives from Pharmaceutical companies.

We offer our perspectives on these issues as seniors with decades of knowledge and experience of the benefits of, and the gaps in, our public health care system and also of the vagaries of the political process as a contribution to making universal, single-payer Pharmacare a reality for everyone living in Canada.