Australian Broadcasting Corporation
FOUR CORNERS
Investigative TV journalism at its best.
TRANSCRIPT

A Bitter Pill?

Jonathan Holmes investigates the true cost to Australia's subsidised pharmaceutical scheme, under the Free Trade Agreement.

Date: 02/08/2004
JONATHAN HOLMES, REPORTER: When President George W. Bush came to Canberra last October, he had a point to make to his good friend John Howard - Australia is paying too little for American medicine.

JOHN HOWARD (RADIO 3AW, 16/07/04): It was the one part of the Free Trade Agreement that George Bush discussed with me when he came to Australia in October last year and I said, "I don't care if the whole thing falls over, we won't change the PBS."

JONATHAN HOLMES: Now the deal's been signed. It's swept through both Houses of Congress. And John Howard's put the ball in Mark Latham's court.

JOHN HOWARD (ARCHIVAL FOOTAGE, 29/07/04) We have secured absolute protection of the Pharmaceutical Benefits Scheme.

JONATHAN HOLMES: But Washington's agenda on drug prices is clear.

JON KYL, US SENATOR FOR ARIZONA: There's no such thing as a free lunch. Somebody has to pay for the research and development of these miracle drugs.

JONATHAN HOLMES: And experienced voices from across the Pacific are warning us to beware.

PROFESSOR KEVIN OUTTERSON, LAW, WEST VIRGINIA UNIVERSITY: Look at who you're dealing with - a multibillion-dollar, very sophisticated, international industry with specific experience in the United States in beating us over this issue. Will they prevail over Australia and effectively raise prices over the next five years? Absolutely.

JONATHAN HOLMES: Tonight on Four Corners, why American drug companies are targeting our Pharmaceutical Benefits Scheme. Buried deep in the Free Trade Agreement, is there a bitter pill?

A summer Saturday in Maine in the north-east corner of the United States. Along the Atlantic coast, the public beaches are crowded. Tucked away in wooded enclaves, the huge holiday homes of America's wealthy are open for the season. The Bush family's been coming here for generations.

In the neat little towns inland, it's a time for fetes and festivals. But Congressman Tom Allen, out gladhanding the voters, knows that for all the apparent wealth and comfort, too many of his constituents, especially the elderly, harbour a gnawing concern - the ever-increasing price of prescription drugs.

TOM ALLEN, US CONGRESSMAN, MAINE: Seniors in my district simply can't do it. They're not able to pay for the drugs that their doctors tell them they have to take, and so we wind up with many people who are trying to balance between, you know, the rent and the food and the medicine and it's very unhealthy.

JONATHAN HOLMES: Like most Americans, Paulette Beaudoin lost her comprehensive health insurance when she retired. The federal Medicare system pays for hospital cover for senior citizens but not for prescription drugs. The prescription for three months supply of sleeping pills costs her more than $300, straight out of her own pocket. Unfortunately for Paulette Beaudoin, insomnia is the least of her complaints.

PAULETTE BEAUDOIN: I have osteoporosis, osteoarthritis, emphysema and I've got a heart problem. I have just a small piece of small intestine, so I have to have pills to digest my food. I've got to have pills to take care of my acids.

PAULETTE BEAUDOIN: Altogether, she takes 15 different medications every day. But in one way, she's far luckier than most Americans. She lives just a few hours drive from the Canadian border, and twice a year she goes to Canada to buy her prescription drugs.

PAULETTE BEAUDOIN: (Holds up prescription inhaler) This is for my lungs, to open up my lungs, and this costs me almost $2,000 here in the United States for six months. In Canada, I pay just $500 for six months. This is just for one of my prescriptions.

JONATHAN HOLMES: Altogether, Paulette reckons she saves US$10,000 a year by buying 13 of the 15 drugs she needs in Canada. But technically, she's breaking US law.

PAULETTE BEAUDOIN: My country doesn't work for me, that's for sure. Other countries, their country works for the people, to help them out. Mine doesn't. Not at all. Far from it.

JONATHAN HOLMES: In a doctor's surgery in Sydney's Bondi Junction, Dr Gillian Deakin is seeing one of her regular patients. Ten years ago, David Nolan had a heart attack. Since then, he's been taking the cholesterol-lowering drug Zocor. Like the vast majority of drugs prescribed in Australia, Zocor is on the Pharmaceutical Benefits Schedule. That means it'll be massively subsidised by the taxpayer, as long as the doctor follows guidelines laid down in the schedule.

DR GILLIAN DEAKIN: Someone who's had a heart attack, for example, is at high risk of having another one. So cholesterol above four would make them eligible to receive the drug. But if someone has simply nothing wrong with them at all and they have cholesterol, it has to be above nine millimoles per litre before they're eligible. So you can see we have a sliding scale and it depends on their risk.

JONATHAN HOLMES: Despite such controls, the cost of the PBS is the fastest-rising element of the federal health budget - it cost taxpayers $5.2 billion last year. And prescriptions are costing patients more too. Most of us pay a maximum of $23.70 per script item, but both major parties now agree the copayment should soon go up to $28.60. That will still be less than half what a month's supply of Zocor actually costs. As a concession card holder, David Nolan has been paying only $3.80 per script.

PHARMACIST: Mr Nolan? OK, so the prescription that you've bought today means now that you've reached your safety net limit. So now you're entitled to one of these cards…

JONATHAN HOLMES: And from today, he'll be paying nothing at all. So David Nolan's Zocor script will cost the taxpayer about $62 a month. But Paulette Beaudoin would pay an American pharmacist at least twice as much money for the same script - out of her own pocket.

The prices the Australian Government negotiates for prescription drugs, including those that cost many times more than Zocor, are substantially lower even than Canada pays. The system it uses to evaluate drugs is admired by public health experts worldwide.

PROFESSOR KEVIN OUTTERSON, LAW, WEST VIRGINIA UNIVERSITY: The most rational, most thoughtful system of procuring, buying prescription drugs in the world is really the Australian system.

JONATHAN HOLMES: In a hotel in Melbourne's Tullamarine Airport, the Pharmaceutical Benefits Advisory Committee is holding a three-day meeting. The PBAC's dozen members are respected experts - physicians and pharmacologists, health economists and pharmacists. Four times a year, they take time out from busy schedules to decide which of some 30 new drugs they'll recommend should be subsidised by the Australian Government and at roughly what price. To reach its decisions, the committee applies a ruthlessly logical test.

PROFESSOR LLOYD SANSOM, CHAIR, PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE: We make recommendation to the Minister on the basis of cost-effectiveness - that is, what is the incremental cost for the incremental benefit? And so drugs which have large benefits would engender a large price. Drugs which do not provide us with any additional benefit over what we've got at the moment, we're prepared to offer the same price.

JONATHAN HOLMES: In America, drug companies spend hundreds of millions of dollars persuading patients to ask for their new miracle cure, and doctors to prescribe it. But many expensive new products are so-called 'me too' drugs, offering only marginal improvements over older, cheaper medications. The Australian Government won't subsidise higher prices unless the drug companies can provide hard evidence of a real improvement in outcomes.

PROFESSOR DAVID HENRY, CLINICAL PHARMACOLOGY, NEWCASTLE UNI: It's a system called 'reference pricing', and this is a system that is very unpopular with the international pharmaceutical industry, and that is that the price of the new drug is referenced to another product, the cheapest product in that therapeutic class that offers the same performance. And if the new drug doesn't offer more, then it gets the same price as the cheapest product in the class.

JONATHAN HOLMES: Back in the early '90s, David Henry, Professor of Clinical Pharmacology at the University of Newcastle, was the principal architect of Australia's cost-efficiency test. The system worked well enough at first, he says. But by the late '90s, relations with the pharmaceutical industry had soured.

PROFESSOR DAVID HENRY: It became clear to the industry that it wasn't always getting the prices or the listings, the access that they wanted to the Australian market, because the test of evidence and performance is a tough test. So after a while, a certain amount of resistance developed and the industry started to lobby to undermine the operations of the PBS. They basically, through political lobbying, had key members of the older committees removed from their positions.

JONATHAN HOLMES: Including yourself?

PROFESSOR DAVID HENRY: Uh, yeah, sure. I was part of that process.

JONATHAN HOLMES: That's not mere paranoia. In January 2001, all but two of the Pharmaceutical Benefits Advisory Committee were either dismissed or resigned in protest. A few weeks earlier, the Prime Minister had met with major pharmaceutical companies. A background briefing paper for that meeting was leaked to Four Corners reporter Liz Jackson.

LIZ JACKSON, REPORTER: It specifically lists the membership of the PBAC as an issue, and reveals that "industry is greatly concerned about membership of the PBAC, particularly the public hostile attitude of some members and staff to industry."

JONATHAN HOLMES: The new committee, headed by Professor Lloyd Sansom, is perhaps less abrasive than the old one. But in practice, says David Henry, it has proved to be just as tough.

PROFESSOR DAVID HENRY: I don't think that new committee has provided what the industry wants either, which is freer listings and the sort of higher prices they want. So, really, the final avenue that was left for them was through trade agreements, and they're using the Australian-US Free Trade…bilateral Free Trade Agreement, I believe, to get accommodation, to get provisions, to get concessions from Australia that they've not been able to get by lobbying, through committee reviews and through the courts.

MARK VAILE, MINISTER FOR TRADE (ARCHIVAL FOOTAGE, PARLIAMENT, 23/06/04): Let there be no misunderstanding on this point. The agreement I signed in Washington on 18 May this year and the legislation I am now introducing today does not, and will not, have any detrimental effect on the PBS.

JONATHAN HOLMES: That's been the constant refrain of the Australian Government before and after the signing of the Free Trade Agreement. And yet, for the first time in any free trade agreement negotiated by the United States, an annex and a side letter are specifically devoted to how Australia determines what pharmaceuticals to subsidise and at what price. There are many in the US Congress who believe that by paying so little for patented medicines, Australia and most other OECD nations are freeloading at the expense of American consumers. Senator Jon Kyl of Arizona has been one of the most persistent critics of Australia's PBS.

JON KYL: There is no such thing as a free lunch. Somebody has to pay for the research and development of these miracle drugs, and if we're all paying only the marginal cost - the cost of producing the one millionth pill - then there isn't going to be sufficient return for the companies to do the investment, do the research and development to produce the new drugs.

JONATHAN HOLMES: Making medicines, the argument goes, is not like making cars. Once you have the formula, churning out the pills is cheap. It's the research and the clinical trials that take years of effort and chew through hundreds of millions of dollars. And for every Viagra or Lipitor, there are dozens of false starts. Unless they're rewarded by high prices for their successes, there's no incentive for drug companies to invest in new research.

KEVIN HASSETT, AMERICAN ENTERPRISE INSTITUTE: The problem from the point of view of the United States is that we're the only country, really, that's developing large numbers of significant new molecules. The other countries have killed their pharmaceutical industries with these price controls. We're the beacon of hope for people with diseases that aren't cured right now and we're that because we've allowed the marketplace to work.

JONATHAN HOLMES: But others say the American marketplace works all too well - for drug companies, not for consumers. Protected by patents, the companies have little incentive to lower prices. They spend more on advertising and schmoozing doctors and lobbying politicians than they do on R&D. And year after year, the US pharmaceutical sector makes profits matched only by the Wall Street bankers.

PROFESSOR GERARD ANDERSON, HEALTH POLICY, JOHNS HOPKINS UNIVERSITY: These are companies which are exceedingly profitable compared to any other industry, compared to the oil industry. The oil industry has a lot of risk associated with it. They're having to go out there and find oil in Kazakhstan and all sorts of countries that are unstable, in Iraq and all sorts of places like that. They're taking a lot of risk. Their profit margins aren't nearly as much as the pharmaceutical industry.

JONATHAN HOLMES: Besides, says Anderson, most cutting-edge research is done not in the drug companies' labs, but in academic centres like his own Johns Hopkins University in Baltimore. The work of these biochemists hunting for an AIDS vaccine at Johns

Hopkins Medical School is funded mainly by the National Institutes of Health - that is, by the American taxpayer. If they make a breakthrough, the university's patent can be picked up for a comparative song by a big drug company.

PROFESSOR GERARD ANDERSON: It's where the best scientists are. It's where the NIH has put money into research and development and other things which is attracting the pharmaceutical companies to the United States. It's not necessarily that we pay higher prices for our drugs.

JONATHAN HOLMES: Is Australia freeloading?

KEVIN HASSETT, AMERICAN ENTERPRISE INSTITUTE: Yeah. Australia's freeloading.

PROFESSOR GERARD ANDERSON: I think it is pulling its weight. I don't think it's pulling more or less than its fair share.

JONATHAN HOLMES: Anderson has said as much to a Senate subcommittee chaired by Jon Kyl. But his evidence made little impression. He has a simple, if cynical explanation.

PROFESSOR GERARD ANDERSON: Well, because there's a lot of money coming in from the pharmaceutical industry into Congress and they are, um, very interested in making sure that those contributions continue.

JON KYL: I couldn't care less about the pharmaceutical companies. I don't know how much they contribute to me and they don't influence me on this. Their wellbeing is important to me for only one reason and that is I know they're the people who may make the difference between me living and dying some day. That's why it's important to me that they be able to do well and that they have the incentive to do the research to invent these drugs.

JONATHAN HOLMES: So in an ideal world, you'd like to see the Australians paying more, at least for their innovative medicines?

JON KYL: In an ideal world, yes. But having gone to Australia and understood the program, I know that certainly the leaders of Australia are not going to be participating in any such program.

JONATHAN HOLMES: Jon Kyl, together with six other Republican Senators, visited Australia last January. As Chairman of the Republican Policy Committee in the Senate, Kyl's is an influential voice on Capitol Hill.

Did you see Tony Abbott, the Minister of Health?

JON KYL: We did indeed, and had a good meeting with him. That had to do more with the pharmaceutical issues…

JONATHAN HOLMES: Before that meeting, the Australian Embassy in Washington sent Abbott's staff a briefing on Kyl which has been released to Four Corners under the Freedom of Information Act: "Kyl has become the prime champion of the pharmaceutical industry's interests in using the FTA as a vehicle to change the PBS's price-setting procedures." But Tony Abbott insists he gave nothing away.

TONY ABBOTT, MINISTER FOR HEALTH (ARCHIVAL FOOTAGE, 'LATELINE' 22/06/04): The architecture of the PBS remains completely unchanged. Um, prices to consumers won't change. The legislation won't change. The Pharmaceutical Benefits Advisory Committee remains the gatekeeper to the system and cost-effectiveness remains the criteria under which drugs will be listed on the PBS. So none of that will change.

JONATHAN HOLMES: It's true that there's nothing in the Free Trade Agreement that will dramatically change the PBS tomorrow. But Senator Jon Kyl, for one, clearly feels the

agreement is a step in what he considers the right direction. In the US Senate two weeks ago, Senator Kyl said this: "The FTA makes suitable progress of addressing Australia's drug price controls; the US did not have to make any concessions in exchange."

I had interviewed Senator Kyl just three days earlier. For an Australian audience, he'd been careful to emphasise that our pricing system, the heart of the PBS, wouldn't be affected.

JON KYL: Two things - first of all, I was very impressed with the representatives of the Australian Government with whom we met. They were, uh, very willing to look at the process by which drugs would be qualified for distribution through the pharmacy benefits scheme. And, uh, things like the appeals process and transparency and so on, they were willing to look at and actually found their way into the agreement itself. And I think that helps everybody. The one thing, of course, that they were very insistent on was that we not suggest any tampering with the pharmacy benefits scheme. And I think I knew better than to suggest that.

MARK VAILE, MINISTER FOR TRADE: There's this isolated view in some parts of America that the rest of the world is freeloading on their system, on their innovation. We were able to prove through this process that we are not, in Australia - that Australian taxpayers invest hundreds of millions of dollars into the private sector's research and development of new technology and new innovation in pharmaceuticals. And so, um, that...that came to the surface. We've...we've added a layer of transparency with the review mechanism.

JONATHAN HOLMES: The biggest single change to the PBS process will arise from just six words in the massive Free Trade Agreement. Annex 2-C relates to pharmaceuticals. Clause 2 of that annex is headed 'Transparency'. And subclause (f) commits Australia to "make available an independent review process" of the PBAC's decisions.

MARK VAILE: If a pharmaceutical company comes back to the PBAC and says, "I want to instigate a review," we will have appointed a convener who will then select an individual expert from a panel of experts with specific capabilities in the areas of medical science, um, pharmaceuticals and the like to review the process of the decision-making.

JONATHAN HOLMES: But that's not an appeal mechanism? He cannot overrule the PBAC?

MARK VAILE: No. Under the law, in the legislation, it is only the PBAC that can make a decision or recommend to the Minister either the listing of a new drug or not to list a new drug.

JONATHAN HOLMES: But will that Australian interpretation stand? In the legal world, the word 'review' applies to the process by which senior judges in courts of appeal re-examine the decisions of their juniors and frequently overturn them. Critics of the trade agreement on both sides of the Pacific warn that the Americans might well challenge Australia's review process if it doesn't produce the changes they want to the PBAC's decisions.

PROFESSOR KEVIN OUTTERSON, LAW, WEST VIRGINIA UNIVERSITY: I can tell you, from an American trade lawyer reading this agreement, 'review' doesn't mean somebody looks at it, makes a recommendation and it goes right back to the same committee. 'Review' means somebody who has the opportunity to give it a thumbs up or thumbs down, you know?

JONATHAN HOLMES: Like an appeal process?

PROFESSOR KEVIN OUTTERSON: Like an appellate court.

MARK VAILE: What they initially wanted was an appeal mechanism, not a review mechanism. And we were not prepared to do that because we were not prepared to subject ministerial decisions to an appeals mechanism. And so that's what they wanted. We've agreed on a review mechanism, and there's a lot of difference.

JONATHAN HOLMES: Is that going to be enough to satisfy the American side, do you think?

JON KYL, US SENATOR FOR ARIZONA: Well, perhaps in the long run additional changes will be considered by both sides.

JONATHAN HOLMES: Any changes the US wanted to the review process would first be considered by a medicines working group already set up under the agreement.

PROFESSOR PETER DRAHOS, LAW FACULTY, ANU: If the Australian Government resisted, then there would be the threat of litigation, and if the threat of litigation was not enough, the US would ultimately bring an action because it would be pressured to do so by US industry, which would be presumably disappointed by the outcome of the independent review.

JONATHAN HOLMES: According to the agreement's dispute settlement proceedings, that action would be heard by a three-person panel of trade lawyers. They might not be sympathetic to Australia's interpretation.

PROFESSOR PETER DRAHOS: They're hard-headed commercial people that have experience in trade matters. I mean, they're not human rights workers.

PROFESSOR KEVIN OUTTERSON: There's nothing in the agreement that protects Australia's position that this is merely an advisory review or just a, you know, a conciliatory process and then it goes back to the PBAC. No language that supports that.

JONATHAN HOLMES: But even as it stands, says David Henry, the review process will make it even harder than it is now for the PBAC to say no to a drug. Negative decisions cost the companies millions of dollars. They never surrender without a fight, and the review process will add to their armoury.

PROFESSOR DAVID HENRY, CLINICAL PHARMACOLOGY, NEWCASTLE UNI: They just come back time and time again. They have many staff, they have a lot of money. They have quite a lot of time. The committee members don't. They have a big PR machine and lots of lobbyists in various forms. It's the court of public opinion, which is managed by the companies, by the PR companies, by the politics of it. And now you have, perhaps, a dissenting view of an expert, a single expert, which they'll be able to use very powerfully to lobby to overturn the committee's original recommendation.

JONATHAN HOLMES: But the current chairman of the PBAC is more sanguine. For weeks, the committee has been locked in secret negotiations with the umbrella body that represents the pharmaceutical industry, Medicines Australia, over just how the review process will work. And Professor Sansom says he's happy with the result.

PROFESSOR LLOYD SANSOM, CHAIR, PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE: I think the debate we've been having with Medicines Australia has been open and frank. There's been goodwill on both sides to move this thing forward and I'm confident that the outcomes of this free trade agreement will provide the Australian people with more information and with a greater clarity of the reasons why PBAC makes its decisions.

JONATHAN HOLMES: Up to now, the PBAC's been unable to tell doctors and their patients why it lists some drugs for subsidy and turns down others. That's because most of the

information supplied to the committee by the drug companies has been classified "commercial in confidence".

PROFESSOR LLOYD SANSOM: What this agreement does do is enable a greater degree of transparency. I'm delighted in our discussions with Medicines Australia. They've also acknowledged the need to increase the amount of information being provided to consumers, to patients, to prescribers.

JONATHAN HOLMES: But the text of the agreement specifically says that the PBAC should publish reasons for its decisions "while protecting information considered to be confidential".

PROFESSOR DAVID HENRY: The question is "What will actually happen? What will the industry provide once they've got the agreement, once it's passed? Will they actually deliver?" I'll believe it when I see it.

JONATHAN HOLMES: So how will Washington's political and commercial powerbrokers use the agreement down the track? Might the US Government dispute Australia's review process? Will multinational pharmaceutical companies agree to more transparency? Will they use the review process to wage public campaigns against the PBAC? Unfortunately, I can't tell you the answer to any of those crucial questions. Despite all the grand talk about transparency, the Office of the US Trade Representative has declined to take part in this program. So has the US pharmaceutical industry's umbrella group, PhRMA, and its opposite number in Australia, Medicines Australia. Of course, the fears of the critics may be hysterical or overblown, but in that case, one wonders why they can't just come out and tell us that. On this issue, transparency, it seems, is a one-way mirror. What can be said with certainty is that the US drug companies care much more about Australia's PBS than our 1% share of the global drug market would warrant.

Since he left the PBAC, David Henry has been in demand as a consultant, from South Africa to Latvia to Iran.

PROFESSOR DAVID HENRY: Australia's a benchmark country. Other countries are copying the methods that are used. If you go to the World Health Organisation and ask, "How do we do this?" they'll say, "Well, go look at what Australia does." This may look like a small battleground but it's actually part of a much bigger war that's being waged globally. And I think the industry - the US industry - has a strong interest in pushing this as hard as they can.

JONATHAN HOLMES: Some of the fiercest battles in that war are being fought in the United States itself. The state of West Virginia nestles in the Appalachian mountains, a few hours drive west of Washington. If he's ever to get to the White House, John Kerry needs West Virginia, which George Bush took from the Democrats four years ago. The cost of health care is a crucial issue.

JOHN KERRY (ADDRESSING POLITICAL RALLY): Senators and Congressmen give themselves the best health care in the world and they give you the bill. My values say we're going to put in place the principle that every family's health care in America is as important as any politician's in Washington, DC.

JONATHAN HOLMES: The Democrat faithful, rallying in the Charleston University campus just across the river from the state capital, look young and healthy enough. But West Virgina's population is the oldest and poorest in the Union. And out in the small towns, there's a growing mutiny against the cost of prescription drugs.

CHARLIE BALL, PATIENT: You want to know exactly what I think about it? I think it's a rip-off.

JONATHAN HOLMES: The drug companies are attempting to placate the likes of Charlie Ball by providing him with free prescription drugs. He's done 20 different jobs in his time, he says. Now he's too old and sick to do any. Dr Ron Stollings of the Madison Medical Center has him on a cocktail of medicines for high blood pressure and cholesterol. At the chemist, his drugs would cost Charlie Ball well over $1,000 a month. Instead, he steps down the corridor to Nurse Debbie Hopkins's office. Nurse Hopkins spends most of her time helping Madison's poorer citizens apply for free medicines under the drug companies' patients' assistance programs. But the paperwork for each separate prescription is daunting.

NURSE DEBBIE HOPKINS, MADISON MEDICAL CENTER: We have to establish proof of income from the patient, that they meet a certain guideline. And each company is different. And we have to prove that they do not have any other type of prescription coverage and prove that they do not pay income taxes.

JONATHAN HOLMES: Four to six weeks later, if all goes well, Charlie Ball gets his medicine.

NURSE DEBBIE HOPKINS: These are a few of the applications that I have to have filled out by Friday so the patients can get their medications.

JONATHAN HOLMES: Debbie Hopkins's salary is paid by Dr Stollings and his three colleagues out of their own pockets.

NURSE DEBBIE HOPKINS: And a lot of our people are elderly and a lot of them are uneducated, illiterate. And if it wasn't for the doctor's office, I don't think they would have any idea how to get their medications. They would do without. And a lot of people have died because they've done without their medicine - they can't afford it. And it's wonderful to come up with the new ideas and the new health care - it's wonderful. But they have to find a way for the poor people of this nation to get health care and to get prescription drugs.

JONATHAN HOLMES: Up in the State Capitol Building in Charleston, that's just what they're trying to do. The Governor of West Virginia has appointed a pharmaceutical cost-management council to scour the world for strategies.

PROFESSOR KEVIN OUTTERSON (ADDRESSING MEETING): Everyone talks about how the Canadian prices are a good deal. The Australian prices are 40% below the Canadian prices, if you can imagine it.

JONATHAN HOLMES: Kevin Outterson is a law professor at the local university who's made himself into an international expert on pharmaceutical cost-management. And he's a fan of Australia's PBS.

PROFESSOR KEVIN OUTTERSON: And that government agency will look at data that the company submits and say "Is this new drug any better than the existing drugs?" So it's a pay-for-value system, as opposed to leaving that decision up to the companies to set the price.

PROFESSOR KEVIN OUTTERSON: The Australian system of economic evaluation, for paying more for valuable, important drugs and for paying less, frankly, for 'me too' drugs that don't add much therapeutic value, that's a model that many people in the United States are interested in and so we were drawn to it.

JONATHAN HOLMES: No US federal agency measures the cost-efficiency of drugs like the PBAC in Australia. To strengthen its bargaining power with Big Pharma, West Virginia wants access to the PBAC's information.

PROFESSOR KEVIN OUTTERSON: The companies believe in transparency. Then we're asking in West Virginia "Release the data that you give to the PBAC," because I suspect the reason they want to keep that secret is because you have forced them - Australia has forced them - to give you information that says really a lot of these drugs aren't very effective and they want to keep that hidden from the rest of the world. I think that's a shame.

JONATHAN HOLMES: At least 14 other state governments are considering some kind of subsidy program roughly along Australian lines. It's a development the drug companies and their supporters find alarming.

KEVIN HASSETT, AMERICAN ENTERPRISE INSTITUTE: Foreign governments, with their socialised medicine, are destroying innovation. And right now in the United States, the pharmaceutical companies are so impotent that it looks like the policies that destroyed innovation are going to be imported into the United States.

JONATHAN HOLMES: On the contrary, say the Free Trade Agreement's critics, Washington is exporting its intellectual property laws and endangering our health system in the process. Generic medicines, they say, are the first targets. As soon as the patent on an expensive brand-name drug expires, the generics come onto the market. Their makers haven't had to spend hundreds of millions on research and clinical testing and brand-name marketing so their prices are much lower. The longer it takes for generic drugs to arrive on the market, the more the PBS will cost.

PROFESSOR DAVID HENRY, CLINICAL PHARMACOLOGY, NEWCASTLE UNIVERSITY: The entry of a generic is important because it doesn't just affect the price of that cheap generic product. If its reference-priced, it affects the price of every single product in the entire class on the PBS, so generics are vitally important in Australia for that reason.

PROFESSOR PETER DRAHOS, LAW FACULTY, ANU: Ultimately it's the rules of the game that we're talking about here, and if Big Pharma sets the rules of the game, the generic industry will suffer.

JONATHAN HOLMES: Professor Peter Drahos is one of a trio of legal academics from the Australian National University who believe that the Free Trade Agreement will inevitably delay the entry of generics onto the Australian market. Drahos's colleagues, Buddhi Lokuge and Tom Faunce, recently gave evidence to the Australian Senate Committee investigating the agreement.

DR BUDDHI LOKUGE (ARCHIVAL FOOTAGE, 21/06/04): I look at five drugs that are soon to come off patent that account for 16 per cent of PBS expenditures, and if the expected delays arise, the cost to Australia will be $1.1 billion over four years.

JONATHAN HOLMES: The problems, they say, lie in the fine print of Chapter 17, the longest in the Free Trade Agreement, which covers intellectual property rights.

PROFESSOR PETER DRAHOS: There are almost 30 pages of rules, so there is a lot of detail and a lot of devil in that detail.

JONATHAN HOLMES: The most significant devil, according to Drahos, is a clause in which Australia agrees to prevent generic manufacturers from "marketing a product, where that product is claimed in a patent." That little clause could involve a very significant change. Up to now, all a manufacturer has had to do to get government approval to sell a drug in Australia is to prove, first, that it's safe - that it doesn't do any harm - second, that it's efficacious - that it does do at least some good. But now the Government's agreed to get involved in whether there's already a patent claimed over that product. In other words, it's agreed to help police the pharmaceutical companies' patents for them.

PROFESSOR PETER DRAHOS: Before, it was simply a matter of private enforcement between the patent company and the generic company. That's where it should have stayed. It should never have gotten into the area of public health where we are now involving, indirectly, our public health officials and making the whole system more burdensome and complex. Why are we, as it were, making a good system more complicated? Who is going to gain here?

MARK VAILE, MINISTER FOR TRADE: This particular issue is also about the recognition of the value of intellectual property and a patent. Now, all it says is that when a generic drug company comes to the TGA - the Therapeutic Goods Administration in Australia - to list or get recognised by that organisation a drug that they have developed, they'll need to do one of two things - either certify that there is no patent in existence that they believe that they're contravening, or if there is, certify that they have notified the patent holder. That is just a process of transparency. It recognises the value of intellectual property in terms of the investment that's taken place in the patent drug. It does not extend any extra rights to patent drug holders.

JONATHAN HOLMES: But it mightn't be so simple. In Australia's patent office and around the world, pharmaceutical companies routinely file dozens of patents to protect their medicines. Yet if a generic company declared that none of them applied to its product and got it wrong, it would be committing a criminal offence.

PROFESSOR PETER DRAHOS: Essentially, the whole point here is not the certificate itself but it's the effect of the certificate on the mind of the generic company. It's the fear in the mind of the generic company that it creates. It's the deterrent value of the certificate. That's the real problem with the certification system.

JONATHAN HOLMES: In America, Big Pharma has been able to use these so-called 'evergreening' patents, combined with similar certification laws, to delay the entry of generics for years.

PROFESSOR KEVIN OUTTERSON, LAW, WEST VIRGINIA UNIVERSITY: Australia's being told, "Oh, don't worry about it." You know, "Oh, we're just making this one little change." You need to see the context of what's happened in our country over the last decade, how our companies have used it to block generics and slow them down.

JOHN HOWARD (ARCHIVAL FOOTAGE, 29/07/04): We have secured absolute protection of the Pharmaceutical Benefits Scheme. Yes, some of the American drug companies DID try and get in under the radar on that subject, but we didn't agree. I cannot for the life of me understand how any political leader, caring about the national interest, could possibly hesitate about endorsing the Free Trade Agreement.

PROTESTER: And we are here for one specific purpose - to tell Latham, Mr Latham, and the Labor Party to stop shillyshallying. Oppose this thing.

JONATHAN HOLMES: Taunted by the Prime Minister on the one hand, and assailed by the left of his own party on the other, Mark Latham has so far kept his own counsel.

MARK LATHAM (ARCHIVAL FOOTAGE, 29/07/04): We'll take the time and consideration - consideration of the Australian people and the high stakes in this agreement - to get it right.

JONATHAN HOLMES: Mark Latham will have to make a decision soon, and the betting is he will say yes to the FTA. The threat of higher drug prices lies well beyond the next election. But Big Pharma and its allies in Washington are powerful and patient and there will surely be battles to come.

Given that, as you've said, in the long run, you would like to see prices going up, do you see the changes that have occurred as a result of the FTA leading to that in the long term?

JON KYL, US SENATOR FOR ARIZONA: What I would hope that would happen is that there would be a recognition that it's going to cost money to invent these miracle drugs, that somebody has to pay for that.

PROFESSOR PETER DRAHOS, LAW FACULTY, ANU: This is the beginning of a process towards an American future and that American future holds higher drug prices. When that future will arrive, no-one can tell you, but we can be confident that if this agreement goes ahead, that will be our future.

MARK VAILE, MINISTER FOR TRADE: We are not going to be importing the American system into Australia. We're going to keep and maintain the Australian system as we know it.

JONATHAN HOLMES: And you haven't been rolled?

MARK VAILE: And I have not been rolled. I can assure you of that.