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Grassley says it should be legal to buy prescription drugs from Canada

Senator sponsors bill to ensure safety of and timely access to lower-priced pharmaceuticals

WASHINGTON — Sen. Chuck Grassley today introduced a bill that would make it legal for U.S. consumers to buy safe prescription drugs from Canada.

Grassley said his legislation reflects consumer demand for the lower-priced pharmaceuticals available in Canada and responds to the fact that the U.S. Food and Drug Administration (FDA) has declined to take action that could lead to certification of prescription drugs from Canada.

"Free trade principles argue for allowing importation of drugs from Canada and other countries as long as those drugs are safe," Grassley said. "The FDA has been unresponsive for years, and U.S. consumers have been going around the FDA. Congress needs to take action to make sure that prescription drug imports are both safe and available to U.S. consumers."

The new proposal, which Grassley named the *Reliable Entry for Medicines at Everyday Discounts through Importation with Effective Safeguards Act of 2004*, or the REMEDIES Act, would immediately open the door for U.S. consumers to buy prescription drugs from Canadian pharmacies while the FDA gets a new drug importation system up and running. The bill shuts down rogue operators and requires the FDA to establish a new system within 90 days. The new system would allow individuals, pharmacies and drug wholesalers to buy qualified drugs for import to the United States from foreign exporters who register with the FDA.

To register, a foreign exporter must demonstrate compliance with safety measures, submit to the jurisdiction of U.S. courts and take other steps to verify the safety of its drugs. This bill is the first reimportation proposal to contain such a major safety certification component. A user fee charged to registered foreign exporters would provide the financing needed for the FDA to register and oversee foreign drug exporters and ensure the safety of imported drugs.

"Imports create competition and keep domestic industry more responsive to consumers," Grassley said. "Americans are tired of waiting for the federal government to address this issue. My bill lights a fire under the FDA and gives it the directive and resources it needs to fulfill its obligations to U.S. consumers."

The REMEDIES Act includes both a carrot and a stick to keep U.S. drug manufacturers from preventing legal importation. In order to claim either the existing advertising expense deduction or be eligible for a new 20 percent increase in the research and development tax credit, a company must certify that it has not taken any action during the taxable year to prevent or condition the authorized importation of a qualified drug into the United States from a registered exporter in accordance with the legislation.

Grassley has been a consistent supporter of importing prescription drugs from Canada. The first reimportation vote in the U.S. Senate occurred in July 2000, on an amendment offered by Sen. Jim Jeffords of Vermont. Grassley supported the Jeffords amendment. Grassley voted a second time for reimportation of prescription drugs from Canada in July 2002, on an amendment offered by Sen. Byron Dorgan of North Dakota. Grassley voted for another Dorgan amendment when it was offered in June 2003. This legislation became part of the Senate bill to add a prescription drug benefit to Medicare, but it was eliminated in the final conference report on the bill.

"This reimportation initiative would provide yet another option for senior citizens who will enjoy the prescription drug benefits of the new Medicare program," Grassley said. "Reimportation will benefit other consumers, as well."

Grassley is chairman of the Senate Finance Committee. The bulk of his legislative proposal falls within the jurisdiction of the Health, Education, Labor, and Pensions Committee. Grassley said he hopes to have his bill considered as part of the HELP Committee's action this year on prescription drug reimportation.

The text of three documents follows here, including 1) FAQs about the REMEDIES Act of 2004, 2) an overview of key elements of the REMEDIES Act of 2004, and 3) Grassley's floor statement marking introduction of the REMEDIES Act of 2004. A pdf file containing the legislative language of the bill is available at http://finance.senate.gov.

FAQs about the REMEDIES Act of 2004

Q: What are the goals of the legislation?
A: The legislation has two objectives. First, it would put an immediate end to the unregulated and unsafe situation with drug imports that exists today. Second, the legislation would provide the Food and Drug Administration (FDA) with the resources and authority to ensure the safety of imported drugs.

Q: How does the bill work?
A: Current law prohibits the importation of prescription drugs until the Secretary of Health and Human Services (HHS) certifies that importation can be done safely. Using current resources and authority, the FDA has not been able to provide an assurance of safety of imported drugs.

The bill immediately halts unsafe importation but permits individuals to obtain prescriptions from Canadian pharmacies on an interim basis while FDA gets the new drug importation system up and running.

Under the bill, the FDA is required to issue final regulations for the new system within 90 days of enactment. Under the new importation system, individuals, pharmacies, and drug wholesalers could purchase qualified drugs for import into the U.S. from foreign exporters that register with the FDA. To obtain a registration, a foreign exporter must demonstrate compliance with safety

measures, must submit to jurisdiction of U.S. courts, and take other steps to assure safety of imported drugs. A user fee charged to registered exporters would provide the financing needed for FDA to register and oversee foreign drug exporters and ensure the safety of imported drugs.

Q: How will patients get their prescriptions filled at an overseas drug exporter?
A: First of all, consumers that want to have their prescriptions filled at an overseas prescription drug exporter will be able to go to the FDA website and find a list of companies that have passed FDA's requirements to become a registered exporter. Just as for filling a prescription in the U.S. today, the patient must have a valid prescription written by a health care professional licensed in a state to prescribe drugs. The patient will then compare drug prices at the different registered exporters to find the best price available. To get the prescription filled, the patient will have to contact that exporter and either mail or fax the prescription to them.

Alternatively, the registered exporter could call the patient's prescriber and get the prescription over the phone. This is the same process as mail order pharmacies in the U.S. use today.

A pharmacist at the registered exporter would fill the prescription according to the prescriber's instructions. The registered exporter may only fill the prescription with brand-name drugs, meaning these are the same drugs as those approved by the FDA and manufactured by the same company as approved by the FDA for sale in the U.S.

Individuals can also have a prescription filled that is technically not an FDA-approved drug, but the drug must have the same active ingredients, dosage form, strength, and route of administration as the FDA-approved drug and is made by the same manufacturer as the FDA-approved drug. These drugs are manufactured by the same brand-name manufacturer and are made for sale in the market of the approved country.

The registered exporter is required to verify that the drug can be traced back to the original manufacturer and the drug must have been stored and handled properly. The FDA, through its on-site inspectors, will also be verifying that the prescription drugs being dispensed to patients meet FDA's criteria.

Once the prescription is filled, the registered exporter will place a label or other markings on the package for shipping that identify the shipment as being in compliance with FDA's safety requirements and all registration conditions. These markings will be designed by FDA and may include track-and-trace technologies and anti-counterfeiting measures. When the package enters the U.S., that marking will signify to Customs officials that the product was dispensed from a registered exporter and can therefore be permitted to enter the country. Packages with drugs that lack this marking will be seized by Customs and destroyed.

Q: Can the importation of prescription drugs from other countries be expanded?
A: Yes. In the second year of the importation program, HHS would be required to submit a report to Congress on the safety of the program and its impact on trade. Unless Congress acted, the program would be expanded in year three to include importation from the European Union, the European Free Trade Association, Japan, Australia and New Zealand. Other countries that

meet specific statutory criteria may also be added to the list.

Q: What is the complete list of countries that would be permitted in the third year of the program?
A: There are currently 15 members of the European Union: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Portugal, Spain, Sweden, The Netherlands, and the United Kingdom. Beginning on May 1, 2004, there will be 10 new member states in the European Union: Cyprus, Czech Republic, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Slovakia, and Slovenia. There are 4 member countries in the European Free Trade Association: Iceland, Liechtenstein, Norway, and Switzerland.

Q: How much does this program cost?
A: The infrastructure needed to guarantee the safety of the imported prescriptions would be financed through user fees. User fees would be paid by registered exporters, which could be the overseas pharmacies or prescription drug wholesalers, for example. The Congressional Budget Office has not yet officially scored the bill.

Q: Now that the bill is introduced, what comes next?
A: Because the bill contains tax provisions, it has been referred to the Finance Committee. Senate leadership has expressed an interest in developing legislation this year to allow the importation of prescription drugs. Because the bulk of the legislation falls within the jurisdiction of the Health, Education, Labor & Pensions (HELP) Committee, it is expected that HELP will take the lead in reporting any legislation.

Q: How is this bill different than other legislation on importation?
A: While the idea of importation of prescription drugs from foreign countries enjoys broad bipartisan support, the issue of safety continues to remain a major barrier to allowing importation to move forward. Secretaries of HHS from both the Clinton and Bush Administrations have determined that safe importation of prescription drugs cannot be guaranteed with the authority and resources the FDA has today. Many bills presume that importation is safe and that FDA and the public should not be overly alarmed. However, there is a legitimate concern about unsafe pharmaceuticals entering the U.S. every day. Hundreds of thousands of packages enter our country on a daily basis, with little or no ability for the U.S. Customs Service or the FDA to guarantee these drugs are safe and effective. Rather than ignore the safety issue, this bill responds to the concerns raised by FDA and others and creates a way to ensure safe access to lower cost prescriptions.

Q: How does this bill lower the costs of prescription drugs Americans have to pay?
A: United States consumers pay 30 to 300 percent more for their prescriptions drugs than those in other countries. Drug manufacturers are forced to sell their products at lower prices in other countries and try to re-coup their profits by making Americans pay higher prices for the same products. This bill recognizes that competition in the global marketplace can work to lower prescription drug costs. If lower cost pharmaceuticals are made available to Americans, drug companies will be forced to re-think their pricing strategy and won't be able to gouge consumers in the United States.

Q: What mechanisms does the bill propose to guarantee safety?
A: The bill would allow importation of qualified drugs only from registered exporters, whose actions will be held accountable in U.S. federal courts.

Registered exporters must have an FDA-approved compliance plan that demonstrates they are meeting the safety requirements established in the bill or by FDA. Exporters must permit FDA inspectors to be present onsite on a continuous day-to-day basis and FDA is required to have assigned inspectors to that exporter. FDA will conduct day-to-day onsite monitoring of the exporter at the place of business for the exporter including any warehouses owned or operated by the exporter and FDA will have access to inspect the exporters records to ensure compliance. Only where an exporter has demonstrated a track record of compliance will FDA be permitted to perform periodic inspections. The FDA must verify the chain of custody for each qualifying drug from the manufacturer of the drug to the exporter.

Only licensed pharmacists at the registered exporter will be allowed to dispense prescriptions with a valid U.S. prescription from a U.S. physician. Commercial shipments can only be received and resold by licensed pharmacists. Unauthorized imports would be treated as contraband and would be seized and destroyed upon entry without notice. Under the bill, an exporter's registration would automatically be suspended for any attempted entry of non-qualified or unsafe drugs and these exporters can be barred from seeking reinstatement in the future. The bill would allow for importation first from Canada in order to test the safety of the system and determine whether additional controls are needed before expansion to additional counties.

Q: How does the bill prevent drug manufacturers from gaming the system?
A: Drug manufacturers that take any action, directly or indirectly, to prevent authorized importation will see a loss of their tax deduction for advertising expenses. Drug manufacturers that do not take action, directly or indirectly, to prevent importation will see a 20 percent increase in their research and development tax credit for that year.

Overview of Key Elements of the REMEDIES Act of 2004

Legalizes reimportation (or importation) of prescription drugs from FDA approved exporters. To be approved, registered exporters must agree to meet safety requirements and to permit FDA inspectors on their premises full time to ensure compliance.

Creates a "fast-track" regulatory process for FDA to implement the importation system quickly.

Importation of qualified prescription drugs from Canada is immediately legalized while the new importation system is developed and implemented by FDA.

Under the new system, individuals, pharmacies, and drug wholesalers are permitted to legally import prescription drugs from registered foreign exporters:

- Individuals may order drugs from a registered exporter pursuant to a valid prescription

issued by a U.S. doctor and filled by a pharmacist whose licensing requirements are equivalent to those required in the U.S. or by a dispensing pharmacist duly licensed by a state.
o Commercial shipments are permitted only to licensed pharmacists for resale directly to consumers and by drug wholesalers who can sell to pharmacies as they do today.

Drugs imported to U.S. pharmacies and drug wholesalers must be FDA approved drugs produced in the United States or in FDA inspected manufacturing facilities in other counties. FDA is required to provide the proper labeling for drugs for importation.

The FDA through its inspectors is responsible for tracing all drugs exported to the US back to their original manufacturing plant and ensuring that they have been stored and transported safely from that plant.

Individuals may also purchase drugs that are bioequivalent to FDA-approved brand name drugs that are produced by the same brand-name manufacturer.
o These drugs are drugs not technically approved by the FDA but the foreign government has approved the drug and that drug has the same active ingredient or ingredients as the FDA-approved drug and the same route of administration, dosage form, and strength.
o If a drug manufacturer believes, however, that the non-FDA approved drug is not bioequivalent to the FDA approved drug, then it must submit a petition to the FDA to show that (a) the differences result in a product that is not bioequivalent to the drug approved in the U.S., and (b) that such differences are due to scientifically and legally valid differences in the regulatory requirements of the U.S. and the country(ies) in which the apparently similar drug is marketed. The manufacturer is required to pay a user fee sufficient to cover the cost of the FDA's review of the petition and supporting documentation.

A User Fee charged to registered exporters provides the financing to provide the resources to FDA to ensure the safety of imported drugs.
o User fees charged to registered exporters would be sufficient to cover all costs including those incurred for inspection and verification within the United States, at the exporter's premises and any other location where the drugs have been stored prior to entry into the U.S.
o The FDA would be required to verify the source and inspect the intermediate handlers of all drugs intended for export into the United States.
o FDA would also be required to determine by a statistically significant sample that the recipients held valid prescriptions (individuals ordering 90-day supply or less) or verify that recipient was a licensed pharmacy that only dispensed drugs to individuals.

The FDA would also be required to supply valid U.S. labeling upon request of the registered exporter and affix or supervise the affixing of seals, markings or tracking technology that would inform border personnel that such imports were lawful to be entered as labeled.

Drugs not permitted for importation include controlled substances and certain other drugs not appropriate for importation because of storage, significant safety concerns, or drugs that are more likely to be counterfeited.

Provisions to Protect Safety of the Public:

Unauthorized imports would be treated as contraband and would be seized and destroyed upon entry without notice.

For the first two years, importation would be limited to Canada. The Department of Health and Human Services would submit a report to Congress in the second year, and unless Congress changed the law, countries from which importation is permitted would be expanded to include, the European Union, the European Free Trade Association, Japan, Australia, and New Zealand. Other countries meeting statutory criteria could also be added to the list by the Secretary.

The legislation continues to prohibit the import or reimport of drugs supplied free or at nominal cost to charitable or humanitarian organizations including the United Nations or a government of a foreign country.

Requires pedigrees from the manufacturer to the dispensing pharmacist for all prescription drugs sold within the U.S. or to an exporter authorized to export drugs into the U.S.

Requires the automatic suspension of an exporter's registration for any attempted entry of non-qualified or unsafe drugs with restricted ability to seek re-instatement in the future.

Requires that registered exporters submit to the jurisdiction of the U.S. federal court system and provides a mechanism for civil actions against the property of persons that import non-qualified drugs.

Repeals the provision in the Controlled Substances Act that permits the personal import of scheduled drugs, which is a significant source of illegal drug trade in the U.S.
Tax Incentives for Manufacturers to Facilitate Reimportation

Incentive To Not Prevent Reimportation: Manufacturers that do not take any action, directly or indirectly, to prevent reimportation receive a 20% increase in R&D tax credit for that year.

Penalty For Preventing Reimportation: Manufacturers that take any action, directly or indirectly, to prevent authorized reimportation lose the business expense deduction for advertising expenses.

April 8th Floor Statement of Sen. Grassley on the REMEDIES Act of 2004

Mr. President, I would like to pose a question to the chamber today. What would you call it if Americans were paying up to 300 percent more for the same product as consumers from other countries were paying?

In Iowa, we would call that "highway robbery." Yet, highway robbery is what is happening every day in this country, and it's happening over prescription drugs. Yes, prescription drugs are being

sold at prices that are 30 to 300 percent higher in the United States than in places like Canada or Europe. Here are some examples. The price in Canada of Nexium, which is for heart burn and ulcers, is about 40 percent of the price in the U.S. Nexium would cost about $120 for 28 20-milligram capsules if you bought it here in the States. If you order the same Nexium from Canada, you'd pay about $51. Here's another example. The price in Canada for Vioxx, which is for arthritis pain, is also about 40 percent of the price in the U.S. If you purchased 30 12.5-milligram tablets in Canada, you would pay about $36 and in here in a U.S. pharmacy, you would pay about $86.

And why is that, Mr. President? The reason is the importation of prescription drugs, those very same drugs that patients are using in Canada, is illegal in this country. So consumers in other countries get price breaks from the drug manufacturers and the American public doesn't. One way to look at this is that by paying those higher prices, the American public is paying more than its fair share for the cost of research and development for future new drugs. That is not fair. This means when a new drug comes on the market, the American consumer has paid for the research but consumers in other countries benefit from the new therapy.

Now I have supported amendments to permit Canadian drug purchases before. We have had numerous votes in this chamber on legalizing importation. We had a vote most recently during the Medicare debate. Last year, the House overwhelming passed a drug reimportation bill by a vote of 243 to 186. But, in the end, the conference report for the Medicare bill watered down the possibility of legal importation such that it was meaningless. I was very disappointed about that. I think it was victory by subterfuge for the pharmaceutical industry.

So, I decided, Mr. President, to roll up my sleeves and go to work on drafting my own bill that would address the problems surrounding importation. In fact, I was working very closely since the beginning of the year with my friend and colleague from Massachusetts, Senator Kennedy. We were working together until three weeks ago to create a bipartisan piece of legislation. We had made a lot of progress. We still had some issues to work out but we were very close to having a final agreement.

With my leadership on the Finance Committee, and Sen. Kennedy's leadership on the HELP Committee, let alone his expertise on the Food, Drug, and Cosmetics Act, I figured we had a good shot at getting something done. But those discussions have since evaporated.

Apparently, the Democratic Caucus was concerned that things were moving too quickly or that too much momentum was building behind a bipartisan effort. What I do know is that our bipartisan product was no longer the priority. So I was disappointed about that too. Sen. Kennedy and I work well together. In fact, we're joining forces even now to get the Family Opportunity Act to the floor and passed out of the Senate.

So you can understand why I was discouraged that Senator Daschle had determined lowering the costs of prescription drugs through importation was going to be a partisan issue.

This reminded me of what happened in 2002 with the Medicare prescription drug debate. There

too, Senator Daschle became concerned that the Finance Committee, then chaired by my friend Senator Baucus, would report a bipartisan prescription drug benefit for seniors. So, Senator Daschle bypassed the Finance Committee and took a bill straight to the floor. That is not how you get legislation passed in the U.S. Senate and everyone around here knows it. And in 2002, it resulted in a very partisan debate on the floor of the Senate over competing Medicare drug benefit proposals. There were multiple partisan proposals by the Senator from Florida, Senator Graham, and I had a proposal supported by both Republicans and Democrats. The Democratic caucus fought our bill, which was dubbed the Tripartisan Bill because one of the key authors was Senator Jeffords from Vermont, who is an Independent.

And what happened? Well, the Senate did not pass a Medicare drug benefit proposal that year. The debate fell apart in partisan bickering on the floor. That happened because partisan politics had intervened to prevent a bipartisan compromise. Well, it looks to me that this is what is happening here. It's funny, when you go to the pharmacist to pick up a prescription, I don't ever remember them asking if you are a Republican or Democrat. And when you pay your health insurance premiums, I don't think the insurance company looks for an "R" or a "D" by your name before they accept your payment.

No, I don't see the importation of prescription drugs as a partisan issue. Being forced to pay higher prescription prices because there is a lack of competition in the global pharmaceutical industry is not a partisan issue. That's why I decided to move ahead and introduce a bill. Now this bill I am introducing today is, in large degree, the bill that I was working on with Senator Kennedy. I have made a few changes, but this bill is basically what Senator Kennedy and I were working on together. I thought what we had was a good proposal and we were so close to having all the details worked out, I wanted to go ahead and introduce it.

Let me explain what the bill does. Quite simply, it would legalize immediately the importation of prescription drugs from Canada. After two years, consumers would be able to order their drugs from other countries too. And it creates practical and safe system to do it. Today, the law prohibits the importation of prescription drugs until the Secretary of Health and Human Services (HHS) certifies that importation can be done safely. Using current resources and authority, the FDA has not been able to provide an assurance of safety of imported drugs.

So the HHS Secretaries in the Clinton and Bush Administrations have not provided that certification of safety so drug importation was not legally permitted. But we all know more and more people have been getting the prescriptions filled in Canada, which is technically illegal today. The FDA and Customs have been looking the other way. The FDA has said that there are serious safety issues with drug importation from other countries. They say this because no public health authority is oversee many of the prescriptions coming in from other countries. In fact, the Canadian government has said that is will not take responsibility for assuring the safety of drugs being shipped to the U.S. from Canada. They have basically told the U.S. consumer that you are on your own.

Today, importation is not longer limited to organized bus trips across the border to pharmacies in Canada. Instead, it has becoming a booming mail order pharmacy operation with customers all

across the U.S. We see news accounts on a regular basis describing Americans who log on to the Internet to purchase drugs from Canada and elsewhere. The Permanent Subcommittee on Investigations for the Senate Government Affairs Committee conducted an investigation into drug importation. They found that about 40,000 parcels containing prescription drugs come through the JFK airport every day. The JFK airport houses the largest International Mail Branch in the U.S. From Miami, 30,000 packages of drugs come into the U.S. and 20,000 in Chicago each day of the year. About 28 percent of the drugs coming in are controlled substances. These are addictive drugs that require close physician supervision. Where are most of these drugs coming from? I was surprised to hear that it was not only Canada, but also from Brazil, India, Pakistan, the Netherlands, Spain, Portugal, Mexico and Romania.

My bill immediately halts unsafe importation from rogue operators but permits individuals to obtain prescriptions from licensed Canadian pharmacies on an interim basis while FDA gets a new drug importation system up and running. The American public is tired of waiting for the federal government to take action to legalize importation and to assure the safety of imported drugs. So, under my bill, the FDA is required to issue final regulations for the new drug importation system within 90 days of enactment. Under the new importation system, individuals and pharmacies could purchase qualified drugs for import into the U.S. from foreign exporters that register with the FDA. To be registered, a foreign exporter must demonstrate compliance with safety measures, must submit to jurisdiction of U.S. courts, and take others steps to assure safety of imported drugs. A user fee charged to registered exporters would provide the financing needed for FDA to register and oversee foreign drug exporters and ensure the safety of imported drugs.

Now the drug makers do not want to see their lower priced products from other countries coming into the U.S. It undermines their profits here and they will want to do everything they can to stop drug importation. So under my bill, drug makers that take steps to prevent importation of their products from these registered drug importers will lose their tax deduction for their advertising costs. Many people are pretty fed up with all those drug ads you see on TV and how they are probably adding to the cost of prescription drugs. Now I am fully in favor of free speech and I do not in any way want to prohibit companies from running the ads they want to run. But if the drug companies are not going to allow U.S. consumers to have access to these lower prices in other countries then they will lose the tax deduction for the cost of those advertisements.

On the other hand, the drug makers complain that these lower prices take money from research and development. So, my bill also creates an incentive for the drug companies to allow importation. Companies that do not prevent importation from the registered exporters will get a 20 percent increase in their R&D tax credit. I think that is fair. I have a more detailed summary of the bill and I ask unanimous consent that this summary and a question and answer document be inserted into the record immediately following my statement.

I believe that free-trade principles argue in favor of permitting importation from Canada and perhaps from other developed countries as long as we can implement a system for safe importation. Today, there is no assurance of safety-no one is watching the store-and products are coming in from all over the world.

My legislation has two objectives. First, it will put an immediate end to the unregulated and unsafe situation with drug imports that we have today by default. This is key, because the situation today threatens the safety of our nation's prescription drug supply and puts patients who obtain these drugs at risk of harm. Second, the legislation will provide FDA with the resources and authority to ensure the safety of imported drugs, and importation will only be permitted by registered exporters who submit to FDA authority.

Now, this bill will get referred to the Finance Committee because it has tax provisions in it. But the bulk of the bill falls under the jurisdiction of the HELP Committee and my friend Senator Gregg has announced that he will hold a markup this year on a drug importation bill. I do not intend to assert jurisdiction over this proposal and I believe we should rely upon that regular committee process to work. That is how we get legislation passed in the U.S. Senate. Mr. President, I hope my colleagues will look at this bill. I wanted to get these ideas out here for discussion. And, I hope some of them will want to cosponsor this bill.

It is time that we got this done and this is the year to get it done. We must not let partisan politics get in the way. If we do, there will be a penalty paid at the ballot box in November. The American consumer is waiting. Let's get the job done. I yield the floor.