

BEFORE THE FOOD AND DRUG ADMINISTRATION

Response to the Food and Drug
Administration's Call for Comments
On Prescription Drug Importation
(69 Fed. Reg. 12810 (Mar. 18, 2004))

Docket No. 2004N-0115

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Comments of Hoffmann-La Roche Inc.

2004N - 0115

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**Comments to Docket No. 2004N-0015 Regarding Prescription Drug Importation
(69 Fed. Reg. 12810 (Mar. 18, 2004))**

Hoffmann-La Roche Inc. (hereinafter "Roche") respectfully submits these comments in response to the Food and Drug Administration's ("FDA's") call for comments on prescription drug importation.¹ Roche, which is based in Nutley, New Jersey, is the U.S. prescription drug unit of Roche Group, a research-based health care company that ranks among the world's leading manufacturers of pharmaceutical and diagnostic products. Roche provides innovative products that enhance the public's health and quality of life by preventing and treating diseases and disorders. As such, Roche has a significant interest in securing the safety of the U.S. drug supply.

Last year, Congress enacted, and President Bush signed, the Medicare Prescription Drug, Improvement and Modernization Act of 2003 ("MMA" or "the Act"), with the goal of providing an important new drug benefit for seniors. The MMA also authorized the Secretary of the Department of Health and Human Services ("HHS") to open the U.S.'s closed drug distribution system to the importation of Canadian prescription drugs only if he can certify to Congress that opening the closed system would: (1) "pose no additional risk to the public's health," and (2) "result in a significant reduction in the cost of covered products to the American consumer."² Roche believes that no such certification should occur. We believe that such a move would compromise the current U.S. system and would pose a substantial, direct threat to U.S. patients.

Although prescription drug affordability is a laudable goal, Section 1121 is an inapposite vehicle to attain that goal. Overwhelming evidence indicates that opening the U.S. distribution system to imported drugs would undermine the integrity of the U.S. drug supply and expose Americans to a wide range of additional risks, jeopardizing public health. Moreover, given the restructuring of the U.S. drug distribution system that would occur with importation, and the enormity of the associated costs, it is highly unlikely that importation would significantly reduce drug prices, if they are reduced at all.

Even assuming that the importation scheme would have some impact on drug prices, there would be other substantial costs. For example, a drug importation scheme would negatively impact employment, as jobs would be shifted abroad. The pharmaceutical industry is a key component to the U.S. economy, contributing \$75.4 billion in labor income, and nearly 1.1 million employees to the economy in 1999 alone.³ Therefore, the Secretary of HHS should consider more than the potential health risks and the potential cost-savings posed by a drug importation scheme – the Secretary should consider potential American job losses.

Roche is deeply concerned that certification of the drug importation scheme established under the MMA would jeopardize public health and safety without any countervailing drug price benefits for

¹ 69 Fed. Reg. 12810 (Mar. 18, 2004).

² Pub. L. No. 108-173, § 1121, 117 Stat. 2468-69 (2003) (adding Section 804(l)(1)(A) and (B) to the FFDCA, 21 U.S.C. § 384(l)(1)(A) and (B)) (emphasis added).

³ Arthur D. Little, *Examining the Relationship Between Market-Based Pricing and Bio-Pharmaceutical Innovation* (2002), at 24.

Americans, and that it would lead to the loss of American jobs. Thus, Roche strongly urges the Secretary to refuse to certify importation.

I. **Opening the U.S.'s Closed Drug Distribution System to Imports Would Jeopardize Public Health Without Any Guarantee of Countervailing Drug Price Benefits**

As mentioned, the MMA authorized the Secretary of HHS to permit prescription drug importation from Canada only if he can certify to Congress that opening the closed system would: (1) “pose no additional risk to the public’s health,” and (2) “result in a significant reduction in the cost of covered products to the American consumer.”⁴

This statutory test for certification simply cannot be met. The first prong of the test does not contemplate a risk/benefit analysis. Rather, it requires the Secretary to find that opening the existing closed U.S. distribution system would pose no additional risk to the health and safety of the public. The overwhelming majority of evidence, however, suggests that opening the U.S. distribution system would expose Americans to a wide range of increased risks – e.g., unapproved, sub-potent, counterfeit, diverted, or adulterated drugs that are ineffective, dangerous, or both.

Moreover, the second prong of the test requires the Secretary to find that opening the closed distribution system would result in a significant reduction in the cost of covered products to the American consumer. Even assuming that prescription drugs in Canada are cheaper than their U.S. counterparts, consumers may not significantly profit from importation, if they profit at all, because of the introduction of new middlemen into the distribution system and the additional costs of attempting to safeguard imported prescription drugs, costs which are likely to be passed on to the consumer.

A. **Opening the U.S.'s Closed Distribution System Would Jeopardize Public Health**

Congress, HHS, FDA, and the states have long worked together to keep the existing drug distribution system in the U.S. closed to keep potentially dangerous drugs out of the drug supply. Under our current closed drug distribution system, the development, approval, manufacture, distribution and sale of prescription drugs are subject to federal and state regulation, and the reimportation of prescription drugs is severely restricted.

Section 505 of the Federal Food, Drug and Cosmetic Act (“FFDCA”),⁵ for example, requires FDA to approve the safety and efficacy of new drugs before the drugs can be introduced into interstate commerce. Moreover, Section 501 of the FFDCA and its implementing regulations subject prescription drug manufacturers to current Good Manufacturing Practices (“GMPs”),⁶ and Section 502 of the FFDCA and its implementing regulations set forth detailed requirements for the

⁴ Pub. L. No. 108-173, § 1121, 117 Stat. 2468-69 (2003).

⁵ 21 U.S.C. § 355 (Supp. 2003).

⁶ *Id.* § 351; 21 C.F.R. pts. 210 and 211 (2003).

appropriate labeling of drugs.⁷ Further, Section 503(b)(1) of the FDCA authorizes the FDA to take action against any person or entity that sells a prescription drug without a valid prescription.⁸

In addition, when Congress enacted the Prescription Drug Marketing Act (“PDMA”) in 1987, Congress made an affirmative decision to limit the reimportation of drugs to FDA-approved drugs reimported by the original manufacturer.⁹ The PDMA and its implementing regulations also require the states to subject prescription drug distributors to minimum requirements, including licensure and storage and handling procedures.¹⁰ Indeed, HHS Secretary Tommy Thompson has observed that the distribution and reimportation of drugs in the U.S. is highly regulated:

FDA and the states exercise oversight of every step within the chain of commercial distribution, generating a high degree of product potency, purity, and quality. In order to ensure safety and compliance with current law, only the original drug manufacturer is allowed to reimport FDA-approved drugs.¹¹

Even with the U.S.’s closed drug distribution system, an increasing number of counterfeit, adulterated, and diverted drug products are entering the U.S. market. In fact, in its recently issued report, “Combating Counterfeit Drugs – A Report of the Food and Drug Administration,” FDA recommended stepped up efforts “to create a comprehensive system of modern protections against counterfeit drugs,”¹² including implementation of anti-counterfeiting technologies, implementation of state anti-counterfeiting laws and regulations, increased focus on state licensing of wholesalers, and the adoption of secure business practices by companies in the drug distribution chain.¹³ Notably, FDA would lack the authority to impose these same types of measures on companies abroad.

Importantly, in the past four years, two different Secretaries of HHS have been asked to certify, under the Medicine Equity and Drug Safety (“MEDS”) Act of 2000,¹⁴ the safety of drugs imported outside our existing legal framework. However, based on well-documented safety concerns, both former Secretary Donna Shalala, and current Secretary Tommy Thompson, refused to do so. The safety concerns in the record have not changed, and therefore, any decision to certify a prescription drug importation scheme under Section 1121 of the MMA would be unwarranted.

⁷ 21 U.S.C. § 352 (Supp. 2003).

⁸ See 21 U.S.C. § 353(b)(1) (Supp. 2003).

⁹ *Id.* § 381(d); 21 C.F.R. § 203.10 (2003).

¹⁰ 21 C.F.R. pt. 205 (2003).

¹¹ Letter from Tommy G. Thompson, Secretary, HHS, to Sen. James Jeffords (I-VT), dated July 9, 2001.

¹² *Combating Counterfeit Drugs: A Report of the Food and Drug Administration*, FDA (Feb. 2004), at i.

¹³ *Id.* at i-v.

¹⁴ Pub. L. No. 106-387, 114 Stat. 1549 (2000).

Given the well-documented safety concerns and the increasing number of system breaches, the U.S. distribution system should be strengthened, not weakened. Many, if not most, imported drugs would be beyond the reach of the safeguards contained in the U.S. distribution system. Moreover, importation would only increase the number of middlemen handling each drug, creating more opportunity for counterfeiting, adulterating, or diverting drugs.

The potential risks of imported drugs, whether they be imported from Canada or elsewhere, are wide-ranging – e.g., unapproved, sub-potent, counterfeit, diverted, or adulterated drugs that are ineffective, dangerous, or both. Stop-gap measures, such as anti-counterfeiting technologies, paper or electronic pedigree systems, and border testing are insufficient to prevent the entry of potentially dangerous drug products. Thus, the Secretary simply should not open the U.S. drug system to these hazards.

1. Safety Issues Associated with Imported Drugs Are Well-Documented

As mentioned, even with the current safeguards in the U.S.'s "closed" drug distribution system, an increasing number of counterfeit, adulterated, and diverted drug products are entering the U.S. market. This is not surprising, given that FDA estimates that approximately 2 million packages containing FDA-regulated products for personal use are being imported into the U.S. annually from countries around the world.¹⁵

FDA's inspections have revealed that a significant number of the drugs imported are potentially dangerous and pose wide-ranging safety hazards. Categories of dangerous drugs that have been imported into the U.S. include, among others: (1) unapproved drugs, (2) foreign versions of FDA approved drugs that may have different levels of potency and purity, (3) drugs that have only been approved for animal use, (4) counterfeit drugs, (5) sub-potent drugs, (6) drugs without active ingredients, (7) super-potent drugs, (8) drugs that have been recalled or banned in the U.S., (9) drugs with inaccurate or substandard labeling or packaging, (10) drugs with incorrect ingredients, (11) contaminated drugs, (12) tampered drugs, and (13) drugs shipped from Canada that originate elsewhere.¹⁶

According to FDA, the incidence of injuries and deaths related to drug imports under the existing system is "unknowable" because: (1) there is no system to track import related deaths and injuries, (2) people who obtain products "in surreptitious ways" generally do not want to report associated problems, and (3) injuries caused by sub-potent (or inactive) drugs are difficult to identify because

¹⁵ Statement of William K. Hubbard, *Continuing Concerns Over Imported Pharmaceuticals*, Hearing Before the House Committee on Energy and Commerce, Subcommittee on Health, 107th Cong. 47-48 (2001); see also Rep. James Greenwood (R-PA), *The Tide of Imported Medicines Must be Turned*, THE HILL, July 16, 2003, at 34.

¹⁶ See, e.g., *Combating Counterfeit Drugs, A Report of the Food and Drug Administration*, FDA (Feb. 2004); *Recent FDA/U.S. Customs Import Blitz Exams Continue to Reveal Potentially Dangerous Illegally Imported Drug Shipments*, FDA Press Release, Jan. 27, 2004; *FDA/U.S. Customs Import Blitz Exams Reveal Hundreds of Potentially Dangerous Imported Drug Shipments*, FDA Press Release, Sept. 29, 2003; *What You Should Know... Guttmacht-Ermeron Bill: Counterfeit Drugs on the Rise*, Vol. 1, Issue 7, Pharmaceutical Research Manufacturers of America, July 23, 2003.

doctors may assume that the underlying disease, rather than a substandard drug, is causing a patient's health to deteriorate.¹⁷

If the Secretary were to legalize drug importation, the number of dangerous drug products imported into the U.S. would only increase, as would the incidence of deaths and injuries related to those drug products. In addition, opening the U.S. drug distribution system to imports would increase the risk of tampering and the risk that terrorists would target the U.S. drug supply.

2. Even Drug Imports that Are Specifically From Canada Would Compromise the Integrity of the U.S. Drug Supply

The fact that the MMA contemplates authorizing drug imports from Canada does not minimize safety risks. First, Canada's drug supply contains potentially dangerous drugs that are counterfeit, contaminated, adulterated, misbranded, and unapproved by FDA, among other things. For example, Mark B. McClellan, M.D., Ph.D., while he was the FDA Commissioner, observed that:

[There are] many examples of drugs that appear to be from Canada but pose significant dangers to American consumers. Examples include expired drugs, substitution of the wrong drug, unrefrigerated shipments of drugs that must be kept cool, sale to American women of drugs that are potent causes of birth defects (and so are tightly controlled in the U.S.), failure to include proper instructions and warnings, and other problems that would rarely be seen in purchases from licensed U.S. pharmacies.¹⁸

In addition, on a separate occasion, then-Commissioner McClellan acknowledged that:

[FDA] has concrete examples of drugs purchased from Canada that violate safety provisions established by FDA and by state pharmacy authorities, and we have seen instances of internet sites that offer to sell FDA-approved drugs, but upon further investigation we have determined that the drugs they sell are adulterated, sub-potent, or counterfeit.¹⁹

Indeed, Canada has had particular problems with counterfeiting, leading the Royal Canadian Mounted Police to concede that counterfeiting is "an epidemic" in Canada.²⁰

¹⁷ See Statement of William K. Hubbard, *Examining Prescription Drug Importation: A Review of a Proposal to Allow Third Parties to Reimport Prescription Drugs*, Hearing Before the House Committee on Energy and Commerce, Subcommittee on Health, 107th Cong. 52-53 (2002); Statement of William K. Hubbard, *Continuing Concerns Over Imported Pharmaceuticals*, Hearing Before the House Committee on Energy and Commerce, Subcommittee on Health, 107th Cong. 47-48 (2001).

¹⁸ Letter from Mark B. McClellan, M.D., Ph.D. to Gov. Rod R. Blagojevich (Illinois), dated Sept. 23, 2003.

¹⁹ Letter from Mark B. McClellan, M.D., Ph.D. to Sen. Thad Cochran (R-MS), dated June 19, 2003.

²⁰ Merrill Matthews, Jr., *The Ethical Dilemmas of Prescription Drug Reimportation*, Institute for Policy Innovation Ideas, Issue No. 19 (Apr. 2003).

Second, although Canada regulates drugs intended to be used by Canadians, it does not regulate drugs that are transshipped through Canada, which are intended for use in other countries. Taking this regulatory reality into consideration, Canadian officials have made it clear that they cannot take responsibility for the safety of drugs entering the U.S. if Canadian drug importation becomes legal.²¹ Moreover, while he was the FDA Commissioner, Dr. McClellan stated in no uncertain terms that FDA cannot guarantee the safety of Canadian drug imports.²² According to Dr. McClellan:

[FDA has] seen Internet sites purporting to be Canadian that appear to be in other countries, and Canadian pharmacies that claim to sell only U.S.-made drugs that actually send the consumer drugs from developing countries. While FDA works to protect Americans from such potentially unsafe unapproved drugs, we do not have the ability or the resources to assure the safety of unapproved imported drugs that claim to be “just as good” as FDA-approved drugs.²³

Finally, if the U.S. were to accept Canadian drug imports, it would increase the risk that counterfeit and other potentially dangerous drug products from other countries would compromise the integrity of the U.S. drug supply. FDA has repeatedly expressed concern that if the U.S. opened the door to drug imports from Canada, legitimate and illegitimate drug companies from all over the world would use Canada as a conduit to the lucrative U.S. prescription drug market. According to FDA, Canada would likely become “a transshipment point for legitimate or non-legitimate manufacturing concerns throughout the world, and in many cases we would be unable to determine the country of origin.”²⁴

If Canada becomes a transshipment point, it could facilitate an influx of counterfeit and substandard drug products from other countries into the U.S. Indeed, it is well-documented that counterfeiting in countries other than the U.S. and Canada is exceedingly widespread, with the World Health Organization estimating that approximately 25% of the drugs sold in poor countries are counterfeit or substandard.²⁵ Moreover, many other countries, like Canada, have drug laws that only protect the domestic drug supply, failing to ensure the safety of drug exports. In addition, if Canada operated as a transshipment point, it could become a prime terrorist target.

²¹ Letter from Mark B. McClellan, M.D., Ph.D. to Sen. Thad Cochran (R-MS), dated June 19, 2003.

²² *See id.*

²³ Letter from Mark B. McClellan, M.D., Ph.D. to Gov. Rod R. Blagojevich (Illinois), Sept. 23, 2003.

²⁴ Letter from Lester M. Crawford, Deputy Comm’r of the Food and Drug Administration, to Sen. Thad Cochran (R-MS), dated July 17, 2002.

²⁵ *See Substandard and Counterfeit Medicines*, World Health Organization (“WHO”), Nov. 2003, <http://www.who.int/mediacentre/factsheets/fs275/en>.

3. Stop-Gap Measures Are Insufficient to Ensure the Safety of Canadian Drug Imports

If HHS were to permit the implementation of Canadian prescription drug importation under Section 1121 of the MMA, it could not ensure the safety of the U.S. drug supply with stop-gap measures, such as anti-counterfeiting technologies, paper or electronic pedigrees, and/or border testing. Such stop-gap measures cannot substitute for the safeguards in place under the existing U.S. closed drug distribution system.

Although requiring border testing, unlike requiring anti-counterfeiting technologies or a pedigree system, is within the U.S.'s purview, border testing cannot ensure the safety of Canadian drug imports. Notably, FDA has repeatedly taken the position that end-product testing in general is not a substitute for process validation – *i.e.*, ensuring that a drug product is properly manufactured, handled, stored, and distributed.²⁶ According to FDA, “[q]uality cannot be inspected into a product.”²⁷ Border testing simply cannot guarantee that a drug product is properly manufactured, handled and stored, nor can it catch the infinite number of issues that could potentially render a drug product dangerous. For example, border testing is likely to miss sub-potency and super-potency problems, problems with unapproved ingredients, and even contamination. With regard to contamination, border labs simply cannot test for the infinite number product contaminants.

B. It Is Highly Unlikely that Importation Would Make Prescription Drugs Significantly More Affordable for Americans

The second prong of the test for drug importation certification under Section 1121 of the MMA,²⁸ requires the Secretary of HHS to find that opening the closed U.S. distribution system would result in a significant reduction in the cost of covered products to the American consumer. This is no small task given that: (1) any benefit of a Canadian price differential will likely accrue to the middlemen in the chain of distribution, and (2) many of the costs of attempting to safeguard the drug products are likely to be passed to the consumer.

1. The Benefit of Any Canadian Price Differential Would Likely Accrue to the Middlemen in the Chain of Distribution

Although proponents of drug importation have asserted that importation would lead to lower consumer drug prices in the U.S., studies do not back-up this assertion. Legalizing importation would permit commercial importers/exporters in Canada and the U.S. to purchase products at artificially low prices in price-controlled jurisdictions and resell them at – or just below – market price in the U.S. This practice would be similar to parallel trade in Europe, where a supplier purchases drugs in Southern Europe (where drug prices tend to be lower) and resells them in Northern Europe (where drug prices tend to be higher). Studies in Europe unequivocally show that

²⁶ See, e.g., *Guidelines on General Principles of Process Validation*, FDA's Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research, and Center for Devices and Radiological Health (May 1987, reprinted Feb. 1993).

²⁷ *Id.*

²⁸ Pub. L. No. 108-173, § 1121, 117 Stat. 2468-69 (2003).

parallel trade has had little impact on prescription drug prices in the destination countries. For example, prices in the United Kingdom have dropped by less than two percent since parallel trade began, and in Sweden they fell by only four percent.²⁹

In Europe, the benefit of parallel trade accrues almost entirely to the parallel trader.³⁰ For example, in a survey of parallel trade in five countries – Denmark, the United Kingdom, the Netherlands, Ireland, and Germany – from 1990 to 1997, the National Economic Research Associates found that parallel importers took, on average, a markup of 68% prior to sale in the destination country.³¹ A more recent study from the London School of Economics and Political Science reached the same conclusion: that profits from parallel trade accrue mostly to the benefit of the middlemen or parallel traders.³² This parallel trade problem is further exacerbated by MMA's failure to hold importers responsible for federal and state rebates, charge backs, and other pricing obligations under U.S. federal programs.

2. Many of the Costs of Attempting to Safeguard the Imported Drug Products Are Likely To be Passed on to the Consumer

Section 1121 of the MMA would require importers to engage in extensive testing, tracking, and recordkeeping in an attempt to ensure that the drug products imported are safe.³³ Implementing these types of measures would be exceedingly costly to set up and maintain. Moreover, as mentioned above, although these types of measures may be effective in keeping some potentially dangerous drug products out of the U.S. drug supply, no stop-gap measure is foolproof.

II. The Enormity of Other Costs Associated with Drug Importation Also Warrant Consideration

Other costs associated with implementing a drug importation scheme would burden the American public, as well as American pharmaceutical companies, wholesalers, and retailers. Notably, the Canadian drug importation scheme carries a substantial price tag for taxpayers. FDA officials expect that drug importation under the MMA would cost taxpayers well over \$58 million to set up and well over \$100 million annually to continue. Although Lester Crawford, the Acting FDA Commissioner, has testified before Congress that Canadian drug importation would cost about \$58 million to set up, that number was taken from an old forecast, which also estimated that it would cost approximately \$100 million annually to continue the program. Today, FDA officials estimate that

²⁹ *E.U. Parallel Drug Trade Cited in U.S. Reimportation Debate*, Drug Industry Daily, dated Nov. 12, 2003.

³⁰ Patricia M. Danzon, *The Economics of Parallel Trade*, PharmacoEconomics (1998).

³¹ *Survey of Parallel Trade*, N/E/R/A (1997) (conducted for Interpharma).

³² P. Kanavos et al., *The Economic Impact of Pharmaceutical Parallel Trade in European Union Member States: A Shareholder Analysis*, LSE Health and Social Care, London School of Economics and Political Science (Jan. 2004); see also *New LSE Study Contradicts Accepted Benefits of E U Pharmaceutical Parallel Trade*, Press Release, The London School of Economics and Political Science (Nov. 2003).

³³ Pub. L. No. 108-173, § 1121, 117 Stat. 2464-69 (2003)

due to the increased volume of drugs coming across the border, the actual costs of setting up and running the program would well exceed the out-dated forecast.³⁴

Moreover, a Canadian drug importation scheme would likely have a significant impact on the return on investment of American pharmaceutical companies, drug wholesalers, and drug retailers, as a significant volume of sales are transferred elsewhere. Reduced return on investment for American pharmaceutical companies would adversely impact research and development. Notably, the research and development process for a drug generally takes up to 15 years and costs over \$800 million.³⁵ In recent years, the U.S. has contributed approximately 40% of the worldwide investment in research and development, and it has generally introduced 25-30 new drugs each year. If American pharmaceutical companies were forced to reduce their investment in research and development, the rate of development of new cost-saving pharmaceutical innovations, and new, more efficacious therapies would slow significantly.

American pharmaceutical companies, drug wholesalers, and drug retailers are also important to U.S. workers, and legalizing drug importation could put jobs in jeopardy. For pharmaceutical companies, importation would affect investment and planning, which would reduce employment and lower wages in the industry. Moreover, as the business of American wholesalers and retailers is shifted to wholesalers and retailers abroad, jobs will be shifted as well.

The pharmaceutical industry is a key component of the U.S. economy. The pharmaceutical sector contributed \$75.4 billion in labor income, and nearly 1.1 million employees to the economy in 1999 alone.³⁶ Therefore, in deciding whether to certify drug importation, the Secretary of HHS should be considering more than just the potential health risks and the potential cost-savings posed by a drug importation scheme – the Secretary should be considering potential American job losses.

* * * *

For the foregoing reasons, Roche believes that certification under Section 1121 of the MMA cannot occur because drug importation would compromise the U.S. drug distribution system and pose a substantial, direct threat to U.S. patients. Moreover, Section 1121 is an inapposite vehicle to achieve drug affordability. Drug importation is highly unlikely to significantly reduce drug prices, if they are reduced at all, because any benefit of a Canadian price differential would likely accrue to middlemen in the chain of distribution, and the costs associated with attempting to safeguard drug imports

³⁴ \$58 Million for Canadian Rx Reimportation Program Based on Outdated Estimate, InsideHealthPolicy.com Daily Updates, dated Mar. 24, 2004.

³⁵ J.A. DiMasi, R.W. Hansen and H.G. Grabowski, *The Price of Innovation: New Estimate of Drug Development Costs*, 22 *Journal of Health Economics* 151 (2003).

³⁶ Arthur D. Little, *Examining the Relationship Between Market-Based Pricing and Bio-Pharmaceutical Innovation* (2002), at 24.

would likely be passed on to the consumer. Even assuming that the importation scheme would have some impact on drug prices, there would be other substantial costs, including potential American job losses and issues involving reimbursement fraud. Accordingly, Roche strongly urges the Secretary to refuse to certify importation.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Michael J. Eging". The signature is fluid and cursive, with a large loop at the end.

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March 10, 2004

David Holmstorm
Minnesota Board of Pharmacy
Fax: (612) 617 -2212

Subject: ADV-CARE Response to Minnesota Report

Dear Sir:

Pursuant to MINNESOTA DEPARTMENT OF HUMAN SERVICES RFR, ADV-CARE Pharmacy was visited on December 13, 2003 and it's procedures were evaluated against it's RFR and Minnesota's DHS program requirements. The purpose of this response by ADV-CARE is to clarify, rectify and assure Minnesota that all concerns have been addressed.

Circumstances

In order to accommodate the travel plans of the visiting team, ADV-CARE brought in available personnel on **the weekend** to demonstrate functions not within their regular job assignments. Some staff members were utilized in a capacity they were unfamiliar with. As a result, a **shipping clerk** was used as a **line technician** for demonstration purposes only. A newly hired pharmacist, **in training**, demonstrated the final checkout.

The Minnesota Report states ADV-CARE does not fully utilize their automation as claimed in the RFR response, referring to some large American mail order pharmacies using Baker cells. ADV-CARE does not utilize Baker cell technology due to its policy to ship all medications in the original factory sealed containers showing Product Name, Strength, DIN Number, Expiry Date and Lot Number to guarantee product safety and authenticity. This aids in identifying product recalls, eliminates counterfeit concerns and the possibility of tampering during shipping.

ADV-CARE requests a re-evaluation of all systems during regular production hours.