







F. Michael Ball Chief Executive Officer Hospira, Inc. 275 North Field Drive Lake Forest, Illinois 60045

Dear Mr. Ball,

We are contacting you on a matter of extreme importance to children diagnosed with acute lymphoblastic leukemia (ALL). We serve in leadership roles for organizations represent physicians and researchers who care for children with cancer.

As you know, since December we have seen a significant decline in the country's production of <u>preservative-free Methotrexate (MTX)</u>. This drug is critical to the treatment of children with ALL. Approximately 3,500 children and teenagers are diagnosed with ALL each year, with cure rates approaching 90%. Without this drug, patients are at dramatically heightened risk of dying.

<u>Institutions will run out of drug in a matter of days to weeks.</u> Doctors and pharmacists are scrounging for supply with very little luck and are beginning to ration the remaining supply. It is not an understatement to say that this is creating a panic in the childhood cancer community.

We understand from our discussions with the Food and Drug Administration (FDA) that your company has been working to address the situation. We implore you to take all necessary steps to rapidly increase access to preservative-free Methotrexate. We appreciate that drug shortages have many causes and that solutions may require difficult decisions. We are hoping that your responsiveness at this critical time will help mitigate the crisis and avoid the tragedy of not being able to deliver curative therapy to children and families facing this horrible disease.

Thank you for your efforts. We are committed to working with you, the FDA, and other key stakeholders to help in any way that we can. Please contact Suanna Bruinooge in ASCO's Cancer Policy and Clinical Affairs Department at 571-483-1613 or <a href="mailto:suanna.bruinooge@asco.org">suanna.bruinooge@asco.org</a> if you can provide additional information.

Sincerely,

Michael P. Link, MD ASCO President

COG Chair

Peter C. Adamson, MD

Jeffrey Lipton, MD, PhD









Heather Bresch Chief Executive Officer Mylan Inc. 1500 Corporate Drive Canonsburg, PA 15317

Dear Ms. Bresch,

We are contacting you on a matter of extreme importance to children diagnosed with acute lymphoblastic leukemia (ALL). We serve in leadership roles for organizations represent physicians and researchers who care for children with cancer.

As you know, since December we have seen a significant decline in the country's production of preservative-free Methotrexate (MTX). This drug is critical to the treatment of children with ALL. Approximately 3,500 children and teenagers are diagnosed with ALL each year, with cure rates approaching 90%. Without this drug, patients are at dramatically heightened risk of dying.

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Sincerely,

Michael P. Link, MD ASCO President Peter C. Adamson, MD

COG Chair

Jeffrey Lipton, MD, PhD









Donald DeGolyer President, Sandoz US Head, Commercial Operations, NA Sandoz, Inc. 506 Carnegie Center, Suite 400 Princeton, NJ 08540

Dear Mr. DeGoyler,

We are contacting you on a matter of extreme importance to children diagnosed with acute lymphoblastic leukemia (ALL). We serve in leadership roles for organizations represent physicians and researchers who care for children with cancer.

As you know, since December we have seen a significant decline in the country's production of preservative-free Methotrexate (MTX). This drug is critical to the treatment of children with ALL. Approximately 3,500 children and teenagers are diagnosed with ALL each year, with cure rates approaching 90%. Without this drug, patients are at dramatically heightened risk of dying.

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We understand from our discussions with the Food and Drug Administration (FDA) that your company has been working to address the situation. We implore you to take all necessary steps to rapidly increase access to preservative-free Methotrexate. We appreciate that drug shortages have many causes and that solutions may require difficult decisions. We are hoping that your responsiveness at this critical time will help mitigate the crisis and avoid the tragedy of not being able to deliver curative therapy to children and families facing this horrible disease.

Thank you for your efforts. We are committed to working with you, the FDA, and other key stakeholders to help in any way that we can. Please contact Suanna Bruinooge in ASCO's Cancer Policy and Clinical Affairs Department at 571-483-1613 or <a href="mailto:suanna.bruinooge@asco.org">suanna.bruinooge@asco.org</a> if you can provide additional information.

Sincerely,

Michael P. Link, MD ASCO President

COG Chair

Peter C. Adamson, MD

Jeffrey Lipton, MD, PhD









John Ducker President and Chief Executive Officer APP Pharmaceuticals, LLC 1501 East Woodfield Road, Suite 300 East Schaumburg, IL 60173-5837

Dear Mr. Ducker,

We are contacting you on a matter of extreme importance to children diagnosed with acute lymphoblastic leukemia (ALL). We serve in leadership roles for organizations represent physicians and researchers who care for children with cancer.

As you know, since December we have seen a significant decline in the country's production of preservative-free Methotrexate (MTX). This drug is critical to the treatment of children with ALL. Approximately 3,500 children and teenagers are diagnosed with ALL each year, with cure rates approaching 90%. Without this drug, patients are at dramatically heightened risk of dying.

Institutions will run out of drug in a matter of days to weeks. Doctors and pharmacists are scrounging for supply with very little luck and are beginning to ration the remaining supply. It is not an understatement to say that this is creating a panic in the childhood cancer community.

We know that your company currently produces Methotrexate with preservative. The preservative-free version is crucial to children with ALL because of the need for intrathecal administration. We urge your company to promptly consider whether it is possible to switch to production of preservative-free Methotrexate or any other means to increase availability of preservative-free Methotrexate, given this critical situation. We appreciate that drug shortages have many causes and that solutions may require difficult decisions. We are hoping that your responsiveness at this critical time will help mitigate the crisis and avoid the tragedy of not being able to deliver curative therapy to children and families facing this horrible disease.

Thank you for your efforts. We are committed to working with you, the FDA, and other key stakeholders to help in any way that we can. Please contact Suanna Bruinooge in ASCO's Cancer Policy and Clinical Affairs Department at 571-483-1613 or suanna.bruinooge@asco.org if you can provide additional information.

Sincerely,

Michael P. Link, MD **ASCO President** 

COG Chair

Jeffrey Lipton, MD, PhD