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July 13, 2009

Judge Brian J. Corrigan
Cuyahoga County
Court of Common Pleas
1200 Ontario Street
Cleveland, Ohio 44113-1678

Dear Judge Corrigan:

I am writing on behalf of Eric Cropp, a pharmacist who will appear before you for sentencing this week. Mr. Cropp was involved in a tragic event in which a pharmacy technician he was supervising incorrectly prepared a chemotherapy drug for Emily Jerry, a 2-year-old with cancer. Mr. Cropp missed the fact that the technician used too much concentrated sodium chloride injection (23.4%) when compounding the chemotherapy drug. The high amount of sodium in the drug led o the child's death. I am so deeply saddened by the tragic loss of a child's life due to a medication error—indeed, the prevention of medication errors has long been a professional and personal goal in my life. Yet, I sincerely hope you will not impose incarceration on Mr. Cropp, who made a human error with no intent to cause harm, and as a healthcare professional, has personally suffered and will continue to suffer greatly from knowing that his failure to detect the technician's error contributed to the death of a child.

Our organization, the Institute for Safe Medication Practices (ISMP), is a federally certified patient safety organization (PSO) that operates the ISMP Medication Errors Reporting Program (MERP), the nation's voluntary practitioner medication error reporting program. Reports sent to us are confidential, and the information attains privileged status when submitted to our PSO as patient safety work product. We are a public charity registered in Pennsylvania since 1994. On behalf of the Commonwealth of Pennsylvania Patient Safety Authority, we receive and analyze all medication related events submitted by Pennsylvania hospitals. These reports are also protected from disclosure by a state statute.

ISMP uses information we learn from error reports to publish four newsletters (*ISMP Medication Safety Alert!* – community, acute care, nursing, and consumer editions) and operate two websites devoted to medication safety (www.ismp.org and www.consumermedsafety.org). Virtually all hospitals and over 2 million health professionals receive our publications, which advise on reported medication errors, related medical device issues, and error-prevention measures. We work directly with the US Food and Drug Administration (FDA) to improve medication safety, and we submit reports sent to our program to the FDA MedWatch program. Our work is also pivotal to many other US safety organizations as well as state health departments, professional licensing boards, accrediting agencies, and national professional associations.

Mr. Cropp recently pleaded *no contest* in response to an indictment for involuntary manslaughter in Emily Jerry's death. The reason for this letter is to share our experiences in investigating the root causes and

underlying system vulnerabilities of thousands of medication incidents like this one. These system vulnerabilities have a major impact on the ability for errors like this to happen. We hope that you will recognize that these system vulnerabilities are not under the direct control of those who make errors.

For example, to prepare drugs like chemotherapy, some pharmacy staff remove fluid from a bag of diluent when they have to add a large volume of medication to the bag. They then add more diluent and 23.4% sodium chloride injection to the bag to bring the final concentration of the infusion to the prescribed value. Or they start with an empty bag and follow a similar process to make the chemotherapy solution. Compounding the solution from scratch, using either method described above, is error-prone. Such exactness of the diluent is most often unnecessary from a clinical standpoint; thus pharmacies that require such methods—as in Mr. Cropp's case—make the compounding system unnecessarily vulnerable to errors.

Communication failures between technicians and pharmacists, IV compounder-related failures, inaccurate documentation of the exact amounts of products in a compounded medication, and other system vulnerabilities have contributed to numerous fatal errors. In pharmacy settings, reliance on manual double-check systems to capture compounding errors is especially error-prone. Acknowledging this risk, many pharmacies have automated the process and use more sophisticated checking systems to detect compounding errors.

In Mr. Cropp's case, the double-check system was manual and thus prone to adverse performance shaping factors such as lack of space, time pressures, poor lighting, clutter, noise, and interruptions. In fact, news reports suggest that Mr. Cropp felt rushed, causing him to miss information that might have signaled an error. As we understand it, Mr. Cropp was told that Emily's solution was needed right away. In truth, the solution was not needed for several hours. Thus, undue pressure placed upon Mr. Cropp and the technician to prepare the drug immediately also contributed to less than ideal conditions under which to prepare and check the solution. Factors such as these, which set people up to make errors, are not under the direct control of the individual practitioner. Rather, most performance shaping factors that contribute to human error are under the direct control of those who design and manage the workplace, as well as external organizations, such as licensing and regulatory agencies, which influence the design of the workplace and the policies and procedures under which individuals carry out the work.

Without minimizing the loss of life in this case, we are deeply concerned about the criminalization and punishment of human errors in healthcare. Safety experts including ISMP, advocate for a fair and just path for individuals involved in adverse events, arguing that punishment simply because the patient was harmed does not serve the public interest. Its potential impact on patient safety is enormous, sending the wrong message to healthcare professionals about the importance of reporting and analyzing errors.

Most healthcare professionals unwittingly put themselves at risk for criminal indictments when they enter the profession. They are fallible human beings destined to make mistakes along the way, as well as to drift away from safe behaviors as perceptions of risk fade when trying to do more in resource strapped professions. Many healthcare professionals already fear making that one error that could result in the harm or death of a patient. Escalating application of criminal error laws also serves as a reminder that a harmful error—often similar in form to minor mistakes we all make on a daily basis—could also strip away a hard-earned and cherished livelihood, the ability to help others, and personal freedoms perhaps once taken for granted, as may happen with Mr. Cropp.

While the law clearly allows for the criminal indictment of healthcare professionals who make harmful errors, despite no intent to cause harm, it will long be debated whether this course of action is fair, required, or even beneficial. The fact remains that the greater good is served by focusing on system issues that allow tragedies like this to happen. By focusing instead on those involved—the easy targets—one can easily avoid addressing the systems issues. Focus on the easy target in this case makes us wonder whether any regulatory or accreditation agency is assuring that all hospitals learn from this event and adjust their systems to prevent the same type of error. If not, the death of this little girl is a heartbreaking commentary on healthcare's inability to truly learn from mistakes so they are not destined to repeat.

Sincerely,

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