

Investigation into the Impact
Of Air Pressure Driven
Drug Dispensing Machines
On the Environment of
Pharmacy Workers

Results in Two U.S. Pharmacies
Personal Exposure Monitoring

- McKesson/Parata RDS
- McKesson/Parata Max

Executive Summary

July 27, 2009

AlburtyLab Project No. SP 2009-01

EXECUTIVE SUMMARY

This study evaluates the potential risk for workers in a pharmacy environment in which an air pressure-driven drug dispensing machine is in operation. The study evaluated the two leading types of technology utilizing air pressure dispensing machines – the McKesson/Parata Max and the McKesson/Parata RDS.

In accordance with best practice, this study utilized personal exposure monitors (PEMs), small, self-contained sampling systems that were worn in the breathing zone of staff working in the pharmacies during the study.

The study found that the PEMs worn by workers in the pharmacies collected significant samples of particles that were in the PM-2.5 range and that these particles contained active pharmaceutical agents. This study outlines the range of pharmaceuticals in the air concentrations observed in pharmacies, and the current standards for which particles in this size range raise serious concerns regarding human health.

Additionally, this study lays out the need for further study and the process by which it should be conducted to predict health risks from exposure to aerosolized active pharmaceutical compounds in the particle size ranges and concentrations observed.

Previous extensive air quality studies have been performed with respect to personnel safety in coal mines, cotton mills, etc., leading to workplace standards. This study is the first to unveil the risks to workers and customers in pharmacies arising from pill dust.

In part, this study was developed in conjunction with and as adjunct to previous reviews and recommendations presented in peer review.

This study raises serious issues relative to exposure risks for workers in pharmacies using air pressure driven dispensing machines. It is important that further studies be conducted by federal regulatory agencies. It is recommended that these studies assess human health risks, set guidelines for these types of machines, and establish procedures to monitor the health impact on pharmacy workers. Such studies should include temporary total enclosures to enable determination of mass rate emissions from the machines during operation; use of PEMs, as were employed during this phase of testing, on pharmacy workers; health monitoring of exposed workers; and ongoing blood and urinalysis monitoring of exposed workers.

Please note: all previous studies, their findings and corresponding independent peer reviews can be found online at www.alburtylab.com/downloads.

INVESTIGATION INTO THE IMPACT OF AIR PRESSURE DRIVEN DRUG DISPENSING MACHINES ON THE ENVIRONMENT OF PHARMACY WORKERS: MCKESSON/PARATA MAX AND MCKESSON/PARATA RDS, PERSONAL EXPOSURE MONITORING

Preface

This report is an extension of two previous studies of the potential negative impact of air pressure driven drug dispensing machines on the environment of pharmacy workers. This study extension addresses the exposure of personnel to aerosolized pharmaceutical compounds while working in the vicinity of a McKesson/Parata Max and a McKesson/Parata RDS robotic dispensing system using a direct sampling method.

The original study (“Investigation into the Impact of Air Pressure Driven Drug Dispensing Machines on the Environment of Pharmacy Workers, Results in 15 U.S. Pharmacies” published October 15, 2008, www.alburtylab.com) included detailed observation, study, and analysis of the McKesson/Parata Robotic Dispensing System (RDS), the ScriptPro Robotic Prescription Dispensing System (SP 200), and the manual counting method, in fifteen pharmacies. The McKesson/Parata RDS is an air pressure driven dispensing machine, while the ScriptPro SP 200 uses a gravity driven process. Manual counting is performed using counting trays and spatulas. The original study determined that the McKesson/Parata RDS was a substantial source of respirable particles, raising concerns of potential exposure of thousands of pharmacy workers. The study further concluded that manual counting was a source of very limited particle emissions and that the SP 200 did not cause any particle emissions.

The core objective of the first extension of the original study (“Investigation into the Impact of Air Pressure Driven Drug Dispensing Machines on the Environment of Pharmacy Workers, Results in Two U.S. Pharmacies, McKesson/Parata Max” published January 6, 2009, www.alburtylab.com), was to evaluate the McKesson/Parata Max to see if it, like the McKesson/Parata RDS, is a source of significant respirable particle emissions. Highly elevated aerosol concentrations of PM-2.5 particles were observed in the vicinity of the operating McKesson/Parata Max machines.

The results of the initial studies, which were peer reviewed by Dennis D. Lane, PhD, N.T. Veatch Distinguished Professor of Environmental Engineering, University of Kansas, and by Ralph Keller, PhD, CIH, PE, suggested that there should be a further evaluation of the exposure of personnel working in the vicinity of the McKesson/Parata Max and the McKesson/Parata RDS machines. This was accomplished using a direct sampling method. Personal exposure monitoring (PEM) devices were worn by four individuals working in the pharmacy area during one work shift. Analysis of the samples showed that all personnel were exposed to airborne respirable particles containing active drug agents dispensed by the machines.

As in the original studies, this investigation focused on airborne particles less than 2.5 microns in diameter (PM-2.5). These particles penetrate the lungs deeply and rapidly enter the bloodstream. PM-2.5 particles are believed to cause a number of health problems, including increased heart rate variability and myocardial infarction (heart attacks). Table 1 summarizes the results.

According to Dr. Lane's peer review of the original studies, "It is clear that pill dispensing methods have the potential to drastically increase the risk of exposure by pharmacists to potentially unhealthy pharmaceuticals through respiration." Data from the PEM devices employed in the current study provide strong evidence that personnel working in the area of the McKesson/Parata Max and McKesson/Parata RDS machines are exposed to airborne drug agents.

Table 1. Compounds Identified Using Personal Exposure Monitoring Devices in Pharmacies using McKesson/Parata Dispensing Machines

Compounds	
Acetaminophen	Diclofenac
Amitriptyline	Hydrochlorothiazide
Amoxicillin	Metformin
Atenolol	Paroxetine
Carisoprodol	Prednisone
Citalopram	Sulfamethoxazole
Clonidine	Tamsulosin
Cyclobenzaprine	Warfarin

Recommendation

This study once again points out the need for federal review of serious issues relative to exposure risks for workers in pharmacies using air pressure driven dispensing machines. Specifically, further studies should be conducted by federal regulatory agencies to assess risk, set guidelines for these types of machines, and establish procedures to monitor the health impact on pharmacy workers.

Mr. David S. Alburty and Mrs. Pam Murowchick of AlburtyLab, Inc. were the principal investigators and authors of this report.

Approved for:
ALBURTYLAB, INC.



David S. Alburty
President
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About AlburtyLab, Inc.

AlburtyLab is an independent laboratory located in Drexel, Missouri that serves the aerosol research, development, and instrumentation communities. AlburtyLab has conducted independent studies for a range of agencies and companies, including Boeing/US Navy, Boston Scientific, Northrop Grumman, US Postal Service, US Department of Homeland Security, and the US Army Research Laboratory.

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