

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

Results in 15 U.S. Pharmacies

- McKesson/Parata RDS
 - ScriptPro SP 200
 - Manual Dispensing

Executive Summary

October 15, 2008

AlburtyLab Project No. SC-2007-01

INVESTIGATION INTO THE IMPACT OF AIR PRESSURE DRIVEN DRUG DISPENSING MACHINES ON THE ENVIRONMENT OF PHARMACY WORKERS

Executive Summary

This research study was designed to determine if air pressure driven drug dispensing machines expose pharmacy workers to unsafe levels of airborne drug agents.

In 2004, the U.S. Centers for Disease Control and Prevention (CDC) recognized the potential for injury to pharmacists and pharmacy technicians from exposure to drugs in retail pharmacies www.cdc.gov/niosh/docs/2004-165/#b. CDC issued a warning that hazardous drugs in the air or on work surfaces may cause skin rashes, infertility, miscarriage, birth defects, and possibly leukemia or other cancers. CDC estimated that the number of workers who may be exposed to hazardous drugs in all settings exceeds 5.5 million.

A core objective of this study was to evaluate another potential source of exposure for pharmacy workers beyond those identified in the CDC report. This study evaluated exposure caused by airborne drugs in the workplace, specifically, those generated during pill dispensing activities. Certain types of robotic dispensing systems used in thousands of retail pharmacies employ air pressure to dispense pills into prescription bottles, and pill dust is readily observed in the vicinity of these machines. This indicates that pharmacy workers are exposed to airborne drug particles when they use air pressure driven dispensers.

AlburtyLab, Inc., working with Inovatia www.inovatia.com and the University of Missouri Mass Spectrometry Facility, conducted a study in five retail pharmacies over 24-hour periods to determine concentration levels, size characteristics, and chemical properties of pill dust generated by McKesson/Parata RDS Robotic Dispensing Systems. McKesson/Parata RDS systems use air pressure to eject pills into prescription bottles www.mckesson.com. Elevated concentrations of airborne pill dust (see Table 1) were observed in McKesson/Parata pharmacies during periods when the machine was operating.

Beyond testing McKesson/Parata RDS, two additional methods of dispensing were studied using the same test protocols. The second technology, ScriptPro SP 200 Robotic Prescription Dispensing System www.scriptpro.com was studied in five pharmacies. ScriptPro SP 200 does not use air pressure to dispense pills. The third method evaluated was manual dispensing, also tested in five pharmacies. ScriptPro SP 200 technology and manual dispensing did not exhibit elevated levels of pill dust. This study was conducted over a period of ten months and was completed in September 2008.

It was determined that the air in McKesson/Parata pharmacies during periods when the machine was operating contained pharmaceutical compounds attributable to the dispensing machines. The study focused on airborne particles less than 2.5 microns in size (PM-2.5). PM-2.5 particle levels are subject to U.S. Environmental Protection Agency (USEPA) National Ambient Air Quality Standards (NAAQS), which regulate outdoor air. These particles penetrate the lungs deeply and rapidly enter the bloodstream. PM-2.5 particles are believed to cause increased heart rate variability and myocardial infarction (heart attacks). Maximum PM-2.5 particle concentrations in

McKesson/Parata pharmacies increased while the machine was operating to levels that were over 500% of concentrations observed in ScriptPro and manual dispensing pharmacies. Maximum PM-2.5 aerosol mass concentrations (which are referenced in the NAAQS) in McKesson/Parata pharmacies increased while the machine was operating to levels that were over 1300% of concentrations observed in ScriptPro and manual dispensing pharmacies. These parameters did not show appreciable increase in ScriptPro or manual pharmacies during periods of dispensing.

Additionally, particle mass concentrations in McKesson/Parata pharmacies frequently exceeded NAAQS. While USEPA has not established general indoor air quality standards, studies performed by Professor William W. Nazaroff of U.C. Berkeley and others indicate that the likelihood of inhaling particles generated from an indoor source while working indoors is increased by a factor of 100 to 1,000 as compared with inhalation of particles while outdoors. For example, the quantity of PM-2.5 inhaled by exposed humans from a gram of such particles released indoors is likely to be 100 to 1,000 times as large as what would be inhaled from a gram of particles outdoors. These studies indicate that workers in pharmacies operating in close proximity to machines generating airborne particles may be subject to an increased risk of health effects as compared with NAAQS. The NAAQS regulate general particulate matter and do not establish safe limits for exposure to airborne drug agents.

Table 1 - PM-2.5 Particles in Pharmacy Air Samples

Dispensing Method	Aerosol Particle Concentration		Aerosol Mass Concentration	
	PPL _{Avg}	PPL _{Max}	µg/m ³ _{Avg}	µg/m ³ _{Max}
Manual	11,601	114,648	1.708	64
ScriptPro SP 200	8,797	105,178	1.705	16
McKesson/Parata RDS	22,903	607,272	2.510	854

PPL = Particles per liter of air, used to measure the number of particles in a volume of air.

µg/m³ = Micrograms per cubic meter of air, used to measure the weight (mass) of the particles in a volume of air.

Dust collected from the surface of another McKesson/Parata RDS was analyzed. For particles in the respirable size range (less than 10 microns), 94.4% of the particle count and 61% of the particle mass were found to be PM-2.5. The log-normalized particle size distribution had a mass median diameter of 2.82 microns and a geometric standard deviation of 1.65 microns. The most common particle size (modal particle size) found was 0.626 microns. This indicates that the dust that had settled from the air onto the machine would be potentially dangerous to breathe.

Additionally, the dust from the same McKesson/Parata RDS contained a substantial population of nanoparticles (less than 0.1 micron in diameter). Nanoparticles do not generally occur in nature – they are man made. These very small particles are used in many pharmaceutical formulations. It has been shown that nanoparticles can enter the bloodstream through the lungs or penetrate directly through the skin, and then affect individual cells of the body. Nanoparticles are implicated in blood clotting and are suspected of causing carotid artery thrombosis. The effect of nanoparticles on human health is a rapidly emerging research topic.

There was a strong association between particle concentrations and dispensing activities for many drugs dispensed by the McKesson/Parata RDS. Aerosolized dust present in the McKesson/Parata

pharmacies was collected on sampling filters and chemically analyzed using high-performance liquid chromatography/diode array detection/mass spectroscopy (HPLC/DAD/MS). The samples contained active pharmaceutical compounds including Acetaminophen (analgesic), Ibuprofen (anti-inflammatory drug), Trazodone (psychoactive compound with sedative and anti-depressant properties), and Isosorbide mononitrate (arterial dilator). The chemical analyses were limited in scope and there were indications that many other drug agents were present.

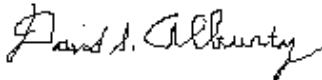
This study finds clear evidence that robotic machines that dispense pills using air pressure, such as the McKesson/Parata RDS, expose pharmacy workers to airborne pharmaceutical agents. Furthermore, the concentrations and particle size ranges observed frequently exceed the levels that are considered harmful under USEPA Standards.

Recommendation

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 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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