

Community/Ambulatory Care

ISMP Medication Safety Alert!®

Educating the Healthcare Community About Safe Medication Practices

Drug diversion—A direct and indirect threat to patient safety

PROBLEM: Drug diversion impacts more than just those who divert. The true cost of drug diversion includes considerable risk to patients. Many may suffer from suboptimal therapy if their medications are diverted, receive substandard care from impaired healthcare workers, or be at risk for adverse drug reactions if they are provided with medications that they should not receive, or bloodstream infections from adulterated products. One in ten healthcare workers misuse drugs (or alcohol) during their career, which is similar to the percentage seen in the general population; however, the trend is slightly different as healthcare workers are more likely to misuse prescription drugs instead of illicit drugs. Healthcare workers have greater access to prescription drugs, they see the positive effects these medications have on patients, and they may have a false belief, thinking they are in control of the situation and are less likely to become addicted.¹

Pharmacies face regulatory and legal risks with the mishandling of drugs, which include increased costs or fines for having inadequate safeguards.^{1,2} Individual diverters face professional and legal implications, on top of the obvious risks for overdose or death associated with drug misuse. Some indirect and overlooked ramifications of diversion include emotional and moral conflict between friends, families, and coworkers who feel guilty for not identifying the signs or speaking up; and within the organization that may believe they failed because they did not implement adequate safeguards to identify and prevent diversion. Patients' families may also feel betrayed, worry about their family member who received suboptimal care, and ultimately lose trust in healthcare systems, which can result in future avoidance of care.¹


A common barrier seen in identifying and preventing diversion may include a lack of recognition and action by organizational leadership. Studies have shown that while 89% of healthcare executives acknowledge that substance abuse is a problem, only 53% felt it was an issue in healthcare, and only 17% believed it was a problem in their facility. This disjointed view may lead to lower allocations of time and other resources to provide education, supportive services, and other prevention efforts.³

Signs of diversion. Signs of diversion often manifest in the person's physical appearance, personal behavior, or their work habits and performance, which may be identifiable in some electronic health systems.^{1,4,5} Behaviors of an employee who may be abusing medications include increased isolation and social avoidance at work, frequent illness or absences from work, poorly explained errors, frequent trips to the bathroom or locker room and other unexplained absences, increased accidents or injuries, refusing drug testing, being unreliable, taking greater effort or more time to complete ordinary tasks, or providing elaborate excuses.⁵

Physical signs may include wearing long-sleeved clothing even in warm environments, shakiness, tremors, slurred speech, sweating, bloodshot eyes, appearing visibly intoxicated, or deterioration in their personal appearance.⁵ Other suspicious behaviors of an employee who may be diverting controlled substances include

continued on page 2 — **Diversion** >

SAFETY briefs

 **Look-alike medication bottles from Zydus.** The look-alike medication packaging (Figure 1) employed by Zydus Pharmaceuticals was recently shared with us. The containers for atorvastatin 40 mg, allopurinol 100 mg, amitriptyline 10 mg, and labetalol 100 mg look nearly identical with each sharing the same

continued on page 2 — **SAFETY briefs** >



Figure 1. Look-alike medication bottles from Zydus Pharmaceuticals.

Please take our survey on tall man letters!

ISMP is updating our list of **Look-Alike Drug Names with Recommended Tall Man Letters** (www.ismp.org/node/136). We are asking for your input by taking a short survey (see page 6). Please submit your responses by **December 2, 2022**, online at www.ismp.org/ext/1014. Our list of drug name pairs with tall man letters was first compiled in 2008 to help healthcare organizations employ a standard set of tall man letters to differentiate look-alike drug names. We are considering adding a few name pairs that have been involved in errors, and we truly value your opinion! Meanwhile, ISMP is participating in a 4-year Northwestern University (Chicago) research project, led by Bruce L. Lambert, PhD, and funded by the US Food and Drug Administration (FDA), to assess the comparative effectiveness of various methods of drug name text enhancements and the ability of tall man (mixed case) lettering to reduce errors during drug selection.

> **Diversion** — continued from page 1

consistently arriving early, staying late, volunteering for overtime, “wasting” controlled substances more often than peers, or carrying controlled substances in their pockets.^{1,5}

Patterns or trends that may be identified within the organization’s medication-use system include frequent incorrect controlled substance counts and discrepancies; increases in usage of controlled substances outside of normal levels; missing medications or prescription pads; signs of tampering with a medication or medication packaging; improper storage of controlled substances; frequent overrides in drug dispensing technologies; waste not being appropriately witnessed or large and inconsistent amounts of waste; controlled substances being removed from an unsecured waste container; or expired controlled substances being removed from their holding area.^{4,5} Another sign includes poor documentation of controlled substances, which could include late documentation, coworkers helping each other in completing documentation, or inappropriate documentation “batching.”^{2,4} In addition, pharmacy staff may notice potential for external diversion if a prescriber is self-prescribing controlled substances or if written prescriptions appear to be altered by patients.⁴

Some diversion may be less obvious and may be identified by patients if they find they were dispensed fewer tablets than prescribed, or if other incorrect tablets are mixed in with their correct tablets. These may be interpreted as system process errors but may also be signs of diversion.

SAFE PRACTICE RECOMMENDATIONS: Consider the following recommendations, in accordance with state and federal laws, to implement a proactive approach to prevent, identify, report, and respond to drug diversion:

Promote a culture of safety. Engage senior leadership to support a “trust but verify” approach to shift towards a culture of safety related to controlled substance handling. Leaders should recognize that no news is not good news as many diverters are never caught.¹ As Just Culture focuses on fixing systems and helping healthcare workers make the right decisions, the culture and actions taken toward individuals diverting as a result of drug addiction should have a focus on counseling and recovery instead of punitive action. Remember, to err is human, and this goes beyond medical errors. Provide resources, like access to employee assistance programs, for staff who may be in crisis. Create safe work environments with appropriate staffing ratios to reduce physical injury and undue mental stress.

Educate staff. A culture shift starts with appropriate education for all staff who handle or may be in proximity to controlled substances.^{1,6} Initial and annual staff education is recommended and should include information about controlled substance handling to prevent drug diversion, how to recognize the signs of drug diversion, how to report and respond to drug diversion, and what resources are available to those who need help.^{1,2}

Safeguard controlled substance handling. Follow the *ISMP Hierarchy of Error-Reduction Strategies* when considering processes and safeguards to prevent drug diversion, using high leverage strategies such as barriers and fail-safes whenever possible instead of relying on low leverage strategies such as rules and policies.^{1,6} Consider the recommendations listed below for community and specialty pharmacies. Implementing these strategies can help you safeguard your pharmacy’s handling of controlled substances.

Procurement

- Implement purchasing safeguards that prohibit the purchase of controlled substances by unauthorized personnel.²
- Use tamper-evident closures for packaged controlled substances, when possible.^{1,2}

continued on page 3 — **Diversion** >

> **SAFETY briefs** cont’d from page 1

design elements, color bars at the top of the labels, and color backgrounds for the dosage strengths. Additionally, three of the four medications start with the letter “A.” This level of similarity increases the risk of medication error. This risk is further increased if drugs like atorvastatin, allopurinol, and amitriptyline are stored near one another in a fast-movers section within the pharmacy.

In order to prevent errors and protect patients, ISMP suggests purchasing some of these medications from different manufacturers, if possible. If you have these products in stock, consider physically separating them in stock locations. Avoid keeping look-alike products in a fast movers section. Always use barcode scanning to verify each manufacturer bottle used to fill a prescription. ISMP has communicated with the US Food and Drug Administration (FDA) and the manufacturer regarding these look-alike container labels. The manufacturer informed us that they will investigate the issue as well as potential labeling improvements.



Confused drug names: Ilaris and Ilumya.

A specialty pharmacy recently reported look- and sound-alike concerns with **ILARIS** (canakinumab), an interleukin-1 beta inhibitor used for Still’s disease, periodic fever syndromes, and systemic juvenile idiopathic arthritis; and **ILUMYA** (tildrakizumab), an interleukin-23 inhibitor used for plaque psoriasis. Product similarities increase the risk of mix-ups. Both brand names start with the letters “I-L,” and both products are used for inflammatory conditions, are injectable drugs administered subcutaneously, and are stored in the refrigerator. However, the packaging and concentrations are different. Ilaris is available as an 150 mg/mL vial for injection while Ilumya is available as an 100 mg/mL prefilled syringe for injection. Alert pharmacy staff and prescribers about the potential to mix up these products. Prescribers should include the purpose of the drug on prescriptions to help prevent errors. Use barcode scanning to prevent dispensing of the incorrect product. Consider affixing auxiliary labels to these products in the refrigerator to raise awareness for the risk of mix-ups.

continued on page 3 — **SAFETY briefs** >

> **Diversion**— continued from page 2

- Use an electronic controlled substance ordering system (CSOS) instead of paper forms (i.e., Drug Enforcement Agency [DEA] Form 222), whenever possible.²
 - Archive and back up CSOS files.²
 - Record DEA Form 222 paper forms on a perpetual inventory log, filed and locked in a secure location accessible only to authorized personnel.²
- Separate the duties of ordering and receiving controlled substances. Have two authorized staff members count and log in controlled substances when shipments are received.²
- Employ a process to investigate and respond to any discrepancies.^{1,2}
- Consider having an external third party reconcile and audit orders, shipments, and invoices.

Storage and Security

- Use facility controls such as camera surveillance in areas where there is risk for diversion.²
- Use physical access controls for the following:
 - Store Schedule II controlled substances in a secure location such as a safe or a locked cabinet.²
 - Limit access to authorized staff by using biometric identification, passwords/codes, or badge readers.^{1,2}
 - Access should be recorded and retrievable for surveillance.²
 - If physical keys are used, there must be a method to track them to ensure all keys are accounted for, and only authorized employees have keys.²
 - Store Schedule II refrigerated medications in a locked compartment, if possible.²
 - Store Schedule III through V controlled substances (including bulk containers) dispersed (e.g., not in their own section) with non-controlled medication inventory to help prevent theft.²
 - Do not store controlled substances in transportable lock boxes or allow staff to store them in their pockets.
 - Review and audit staff access to ensure authorized staff have appropriate access and unauthorized staff (e.g., transferred staff, terminated staff) do not have access.
 - Establish a process to track who accessed the controlled substance inventory, when it was accessed, and what changes were made.²
- Monitor other controlled substance storage areas such as those where filled prescriptions await delivery or pick up, for example in the pharmacy’s will call area.²
- Use automated dispensing technology with a witness or another verification process when restocking.²
- Consider safety controls (e.g., barcode scanning, weight checks, drug photo identification) when using automated dispensing technology.²
- Secure and monitor the use of documents used to procure or prescribe controlled substances such as DEA form 222 and blank prescription pads.²

Inventory Management

- Implement an electronic system, rather than relying on human effort, to maintain a perpetual inventory, if possible.¹ All transactions should be documented through the pharmacy software or automated dispensing equipment, when possible. Use barcode scanning, whenever possible.²
- Maintain a perpetual inventory of Schedule II controlled substances.
 - Use labels from the prescription software to record the quantity filled in the perpetual inventory log.²
 - Have two staff members sign off on the perpetual inventory log.²
- Audit Schedule II controlled substances daily for any medication used that day and weekly for all Schedule II products to ensure the counts are correct and that the perpetual inventory log has been signed by two employees, when possible.²

continued on page 4 — **Diversion** >

> **SAFETY briefs** cont’d from page 2



Specialty refill reminder breakdowns.

A specialty pharmacy reported a unique challenge that may result in patients receiving a late refill of their medication. Some specialty pharmacies have a proactive refill reminder process where staff set a refill reminder date in their clinical management software (not their dispensing software). This date is typically set a week before the patient is actually due for their refill, which allows the pharmacy time to set up delivery of the medication and ship it to the patient before it runs out. When completing delivery set up, the clinical management software may provide standardized options based on the delivery schedule (**Figure 1**). For example, the refill reminder date will be set for 21 days after the delivery if the patient receives a 28-day supply. Or the refill reminder date may be set manually using free text or a calendar feature (**Figure 2**).

- 2 weeks (14 days)
- 3 weeks (21 days)
- 1 month (28 days)
- 6 weeks (42 days)
- 2 months (56 days)
- 3 months (84 days)
- Specific date
- No follow-up required

Figure 1. Specialty pharmacy clinical management software may present multiple time periods from which to pick a refill reminder date.

The pharmacy reported that sometimes staff have selected the wrong timeframe or date resulting in the refill reminder date being set incorrectly. When this happens, the patient may not receive their medication on time or the pharmacy may have to ship the medication as a STAT order to prevent a lapse in therapy, increasing the risk of errors when preparing the prescription and increasing the cost of shipping.

continued on page 4 — **SAFETY briefs** >

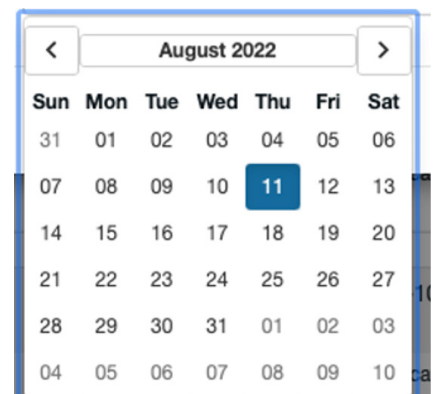


Figure 2. Specialty pharmacy clinical management software may allow the user to manually enter or select the refill reminder date from a calendar.

> **Diversion** — continued from page 3

- Inspect drug products and packaging (including returns and expired medications) for signs of alterations or tampering.²
- Although the DEA only requires controlled substance inventory to be completed every two years, it is recommended that pharmacies perform inventory and/or surveillance checks more frequently to discover discrepancies as soon as possible.^{2,7}
 - Use multiple, rotating, licensed staff (at least one pharmacist) to complete inventories.²
 - Inventories should include expired or unusable controlled substances awaiting disposal or return.²
 - Use a “blind count” process, meaning that staff does not know the quantity of the medications in the inventory system when performing the counts.²
- Audit controlled substances regularly to ensure purchases are reconciled with quantity dispensed and on-hand quantities.²
- Consider auditing inventory adjustments.²
- Consider tamper-evident packaging when dispensing or delivering controlled substances to patients to ensure chain of custody.

Returns, Waste, and Disposal

- Establish a process to waste damaged or expiring controlled substances.²
 - Use an independent witness.
 - Define who can waste them, how they are wasted, and how to document the medication, dosage form, and quantity that is wasted.
 - Pharmacy staff involved with wasting medications should verify the product label, volume and quantity being wasted, and the physical drug to ensure the documentation matches what is being wasted.
 - Wasted drug should not be retrievable (e.g., use a secure sharps container).
 - Minimize controlled substance waste, whenever possible.
- Establish a process to return to the wholesaler overstock or otherwise unused controlled substances.³
 - Use an independent witness.
 - Before the transfer, store returnable controlled substances in a separate, secure location. Schedule returns regularly to avoid accumulation of controlled substance products marked for return.
 - Audit DEA Form 222 to confirm the correct quantities are transferred.
- Establish a process for will-call or canceled prescriptions.
 - Run reports to identify controlled substances that have not been picked up within a specified period of time.²
 - Integrate point-of-sale with the prescription software and develop a report to reconcile processed prescriptions with prescriptions that are sold or in the will-call area.²
 - Require two employees to count the medication before returning it to stock.

Controlled Substance Prescriptions

- Pharmacists should check the Prescription Drug Monitoring Program (PDMP) for each controlled substance prescription to have a full understanding of the controlled substances and dosages a patient is taking.
- Pharmacy staff should review controlled substance prescriptions for possible fraudulent activity.² Consider red flags such as concomitant prescribed opioids/benzodiazepines, high daily doses, cash-only claims, and when multiple prescribers are prescribing controlled substances for one patient.²
 - Document investigation and resolution of red flags.
 - Monitor red flags within patient and prescriber profiles for possible trends.
- Encourage prescribers to maximize the use of electronic prescribing when ordering controlled substances for a patient.²
- If the pharmacy receives a hard copy prescription, document the pharmacy staff person(s) who received and processed the prescription.²

continued on page 5 — **Diversion** >> **SAFETY briefs** cont'd from page 3

The pharmacy stated that this error is more likely to happen for medications that have an odd day supply, for example a 21-day cycle medication, or when sending a two- or three-month supply (most specialty medications are dispensed as a one-month supply). If the day supply is different, the refill reminder date is more likely to be set incorrectly.

Explore integrating dispensing software with clinical management software to automatically set the refill reminder date based on the last fill date and number of days supply dispensed. If manually setting up refill reminder dates, double check the refill reminder date by comparing it with the number of days supply dispensed. Educate staff about the risk and consequences of errors in this process. Consider providing staff with a “cheat sheet” or list of odd day supply (i.e., not a 28-day supply) medications to help guide refill reminder selections.

Worth repeating...**Mix-ups between COVID-19 and influenza (flu) vaccines**

Here we go again. It is that time when the flu season and the need for coronavirus disease 2019 (COVID-19) bivalent boosters are converging. We previously noted mix-ups between the COVID-19 and the flu vaccines in our newsletter. Just like the previous flu season, we are now seeing a lot of similar mix-ups between these vaccines. Case in point: recently, a patient went to the pharmacy to receive both the flu vaccine and the bivalent Moderna COVID-19 booster. After a pharmacist administered the two vaccines, the pharmacy notified the patient that the pharmacist had inadvertently administered two doses of the bivalent COVID-19 booster. The patient later reported nausea, vomiting, headache, and joint pain. We anticipate more mix-ups to occur now that both the COVID-19 and flu vaccines are often given simultaneously.

To prevent mix-ups, handle one vaccine at a time, and provide separate areas for vaccine preparation and administration, away from distractions and interruptions.

continued on page 5 — **Worth repeating** >

> **Diversion** — continued from page 4

- File controlled substance prescriptions sequentially.²
- Establish a process for partial fills of Schedule II controlled substances (if allowed), as these are at significant risk for diversion.²
- Monitor reports of controlled substance medications processed by staff members and look for potential outliers.²

Report and respond to potential diversion. Pharmacies should establish an anonymous reporting platform for staff to report concerns for drug diversion.² Treat all reports confidentially. Educate staff about how and when to report drug diversion, as well as the importance of reporting for both the health and safety of the diverter and other associated professional and criminal implications.³ Ensure that staff will be protected from retaliation if they report a concern about drug diversion.³

Leaders should establish a standard process for drug diversion investigations.¹ Define what staff members and leadership roles are involved (e.g., human resources, leadership, occupational health, compliance).¹ Include a clinician on this team to assess if patient safety has been impacted.¹ The American Society of Health-System Pharmacists provides tools that pharmacies can use when developing this process.^{8,9} Also consider using a third party to help investigate and resolve discrepancies.³

Pharmacies are required to notify the DEA (via DEA Form 106) and the local police within one business day of discovering a theft or significant loss of any controlled substances. Pharmacies should take a standardized approach to identify what constitutes a “significant loss.” This definition may depend on the business of the pharmacy and whether there is a rational explanation for a particular situation. Pharmacies should also report repeated losses of small quantities of controlled substances, as this may be considered a significant loss over time.^{2,7} In addition, pharmacies should review and adhere to any state-specific reporting requirements.^{1,2}

Patient Involvement. Consider providing patients receiving controlled substances with educational information on the signs and risks of addiction and available resources if help is needed. Also discuss the importance of safeguarding medications at home, verifying the medication and the quantity when picking up prescriptions, and if they suspect diversion in their home. Transparency and involvement with patients can go a long way to enhancing trust and safety. Provide resources for the safe disposal of the medications.

Conclusion. Pharmacies should take a proactive approach to prevent and identify drug diversion issues, which can affect patients, staff, and the organization. High-leverage system-based strategies should be used to discourage and prevent drug diversion when possible. Leaders must take an active role to ensure that system processes are in place and that staff are prepared to report and respond to drug diversion.

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> **Worth repeating** cont’d from page 4

Using manufacturer prefilled flu vaccine syringes may help distinguish them from the COVID-19 vaccines and boosters, which must be withdrawn from a vial into a syringe. Before vaccine administration, check the patient’s vaccine card/medical record and the state/local immunization information system. Ask the patient which vaccine(s) they have requested and verify the vaccine(s) with a signed consent form(s). Only bring the intended vaccine(s) for one patient at a time into the vaccination area and include the parent/patient in verifying the prepared vaccine(s). Clearly label all syringes. During preparation and administration, use barcode scanning to confirm the correct vaccine. Document the lot number and expiration date prior to administration, and document administration afterward. Ensure adequate staffing and do not expect staff to accomplish both vaccine administration and other responsibilities simultaneously.

If a mix-up occurs, notify the patient and provide the intended vaccine before they leave the vaccination area (or ask the patient to return to the vaccination site). Report any vaccination errors to the US Food and Drug Administration (FDA) Vaccine Adverse Event Reporting System (www.vaers.hhs.gov)—reporting is mandatory for vaccines authorized for emergency use. Also report the error to the **ISMP Vaccine Errors Reporting Program** (ISMP VERP) (www.ismp.org/verp).

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ISMP survey on tall man (mixed case) lettering to reduce drug name confusion

In 2008, ISMP compiled a list of look-alike drug name pairs with suggested tall man (mixed case) letters to be used in ambulatory and inpatient healthcare organizations to differentiate these products on pharmacy-generated labels, documents, and computer screens. It has been 6 years since we last updated the list, so we are seeking your input regarding a few more drug name pairs we are considering for addition to the list. Also, we are interested in learning how useful you find tall man (mixed case) letters as an effective differentiating strategy and any other name pairs you believe we should consider for the list. Please submit your survey responses by **December 2, 2022**, online at: www.ismp.org/ext/1014.

KEY DK = Don't Know/Uncertain

Question and Confused Drug Name Pairs or Groups	Aware of Confusion?		Add to List?			Proposed Tall Man (Mixed Case) Lettering?					Alternate Lettering?	
	Yes	No	Yes	No	DK	Strongly Agree	Agree	Neutral/DK	Disagree	Strongly Disagree		
1 Please tell us whether you are aware of any confusion or mix-ups with the drug name pairs/groups below, whether you believe the name pairs/groups should be added to our list, and whether you agree or disagree with the tall man (mixed case) letters selected to help differentiate the drug names. ¹ You can also provide alternative suggestions regarding how to use tall man (mixed case) letters with each name pair.												
hydroxyUREA (and hydroXYzine, already on list)												
cycloPHOSphamide (and cycloSPORINE and cycloSERINE, already on list)												
droPERidol and droNABinol												
dexAMETHasone and dexmedeTOMIDine												
NIZatidine and nitaZOxanide (and tiZANidine, already on list)												
methoTRESate (and metOLazone, already on list)												
linaGLIPtin and linaCLOtide												
pyRIDostigmine and PHYSostigmine												
DESMOpressin and VASOpressin												
leNALIDomide and leFLUNomide												

¹To determine which letters to capitalize, we attempted to apply the CD3 rule. This methodology suggests working from the left of the drug name first by capitalizing all the characters to the right once two or more dissimilar letters are encountered, and then working from the right of the name back, returning two or more letters common to both words to lowercase letters. When the rule cannot be applied because there are no common letters on the right side of the drug name, the methodology suggests capitalizing the central part of the name only.

2 Please review the name pairs listed in Question 1 AND those found on our current list at: www.ismp.org/node/136, and then let us know if there are any **additional** name pairs that you feel should be included (please specify): _____

3 Do you believe the use of tall man (mixed case) letters by the pharmaceutical industry on product and carton labels helps to reduce drug selection errors?
 Yes No Don't know

4 Please select the category that best describes your profession (select one):
 Nurse Pharmacist Pharmacy technician Physician Other prescriber Other (please specify): _____

Answer questions 5, 6, and 7 only if you use tall man (mixed case) letters in your facility.

5 Are tall man (mixed case) letters for organization-defined drug names used consistently in all required contexts (e.g., computer drug screens for pharmacy and prescribers, smart infusion pump drug libraries, labels) and in all required settings (e.g., pharmacy, surgical suites, multihospital or multi-clinic settings)?
Across all required contexts? Yes No Don't Know
Across all required settings? Yes No Don't Know
Across multihospital and/or multi-clinic settings? Not Applicable Yes No Don't Know

6 Do you use tall man (mixed case) letters for drug names that do **NOT** comply with the configurations on the FDA and ISMP lists (www.ismp.org/node/136)?
 No Don't Know Yes **If Yes**, please list the drug names with tall man (mixed case) letters used in your organization that differ from the configurations on the FDA or ISMP lists: _____

7 Do you believe tall man (mixed case) lettering has prevented you from prescribing, transcribing, dispensing, or administering the wrong medication?
 No Don't Know Yes **If Yes**, please describe: _____

Walk the Red Carpet with Safety Stars

ISMP 25th Annual Cheers Awards

Join Us on Tuesday, December 6, 2022

ISMP is recognizing medication safety leaders at the 2022 Cheers Awards dinner and we would love to see you there.

This is not only the **25th anniversary of the Cheers Awards**, but we are also honoring a true medication safety star, **Michael R. Cohen**, who is this year's Keynote Speaker and Lifetime Achievement Award winner.

Support Cheers During Our Blockbuster Year!

Keynote Speaker and Lifetime Achievement Award Winner:

Michael R. Cohen, RPh, MS, ScD (hon.), DPS (hon.), FASHP

Michael R. Cohen, President Emeritus and co-founder of the Institute for Safe Medication Practices (ISMP), has dedicated his career to advocating for medication error prevention. His passion for medication safety began in 1974 when he saw the value in sharing the story of a serious adverse event that occurred at a local hospital to help prevent the same error from happening again. He founded ISMP in 1994 and launched the first of its newsletters in 1997. ISMP's publications now reach over a million health professionals in the US and over 30 foreign countries. Dr. Cohen also has helped bring about countless changes in clinical practice, public policy, and drug labeling and packaging that have impacted millions of patients and healthcare professionals. He has received numerous awards for his leadership and advocacy in medication safety.



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