The Cincinnati
# Law Library Association

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Tom Enneking, Editor

## Inside This Issue



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## FDA Prescription Drug Labeling: Preemption and Effect on State Product Liability Lawsuits

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**Overview & Background of FDA's January 2006 Preemptive Policy Statement**

On January 18, 2006, the Food and Drug Administration (FDA) released its final rule revising the content and format requirements of prescription drug package labeling and inserts (which final rule will take effect on June 30). The final rule requires labeling that should provide health care professionals, and ultimately patients, with more clear and concise information about prescriptions by, among other things, including a new

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## The Law Library as Gateway: Remote Access to Premium Databases

Tom Enneking, Assistant Law Librarian

A webpage is a powerful tool. It advertises the goods and services you offer, but it can function as a gateway to other resources laden with useful information.

From the Cincinnati Law Library's webpage (http://www.hamilton-co.org/cinlawlib/), you may access three premium databases from the comfort of your home or office: HeinOnline, FastCase, and CCH Newsletters. From a single webpage, you can research law journals; case law for the 50 states and the federal courts; and newsletters on business, human resources and tax.

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and abbreviated "Highlights" section on a drug's labeling that provides a brief summary of key safety and effectiveness information.

In the preamble to the final rule, and as a response to comments that the new labeling requirements may be used by plaintiffs as evidence that labeling in the prior format did not provide adequate warning to patients, the FDA also provides clear guidance on the preemptive effect of the FDA's drug labeling determinations: Except in very limited circumstances, the FDA's approval of a drug's labeling will preempt "conflicting or contrary" state law affecting such labeling, whether arising by statute, administrative rule or through state law in product liability/personal injury actions. The FDA's preemption stance would presumably result in state product liability claims based on alleged inadequate warnings ("failure to warn" claims) in FDA-approved labels being preempted by federal law. Such federal preemption would affect state claims against drug manufacturers, as well as claims against health care professionals for claims related to dissemination of risk information to patients beyond what is included in a drug's label. The FDA's preemption position also applies to print drug advertising that reprints warning information from drug labels.

The FDA bases its preemption position primarily on the fact that it employs experts to perform lengthy and comprehensive scientific evaluations before it determines to approve a drug's labeling, and that state product liability claims conflict with such federal efforts and objectives by permitting judges and juries to apply conflicting state law that is at odds with the FDA's institutional expertise.

The FDA's position on preemption as stated in the preamble to its final rule is not new. In response to what the FDA had perceived as the increasing trend of state product liability lawsuits encroaching upon the FDA's regulatory authority, the FDA has submitted many amicus briefs in recent years stating and reiterating its strong and consistent position on federal preemption.
The scope of the FDA's preemption position is broad. First, the preamble provides that federal preemption will apply to drug labeling approved by the FDA under either the "old or new format," indicating the FDA's intent that its position on preemption as stated in the preamble should also apply to drug labeling that the FDA approved prior to the final rule. Second, the preamble states that "at least" the following specific types of claims would be preempted by the FDA's regulation of drug labeling:
Claims that a drug sponsor breached an obligation to warn by failing to include a statement in labeling or advertising the substance of which the FDA has prohibited in labeling or advertising.

Claims that a drug sponsor breached an obligation to warn by failing to include a statement in labeling or advertising the substance of which had been proposed by the FDA for inclusion in the labeling or advertising, if such statement was not required by the FDA at the time the plaintiff claims the sponsor had an obligation to warn (absent an FDA finding of fraud on the sponsor's part).

Claims that a drug sponsor breached an obligation to warn by failing to put in the "Highlights" section of a drug label or otherwise emphasize any information the substance of which is included anywhere in the label.

Claims that a drug sponsor breached an obligation to warn by failing to include in an advertisement any information the substance of which is included anywhere in a drug's labeling (in cases where the sponsor otherwise followed relevant FDA guidance).

Claims that a drug sponsor breached an obligation to warn by failing to include contraindications or warnings that are not supported by evidence satisfying FDA standards.

Claims that a drug sponsor breached an obligation to a plaintiff by making statements that the FDA approved for inclusion in a drug's labeling (absent an FDA finding of fraud on the sponsor's part).

The preamble specifies only a single set of circumstances where federal preemption would not apply: where obligations imposed under state common law are parallel to FDA requirements (and, even in these cases, the FDA would have the first cut at determining whether an FDA regulation had been violated).

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Third, the FDA specifically rejects one of the arguments frequently made against federal preemption in product liability lawsuits: that FDA labeling determinations impose only "minimum standards" and therefore leave states free to impose greater and/or more stringent disclosure requirements on drug sponsors. To the contrary, in the preamble the FDA makes clear that it interprets its final rule to provide both a "floor" and a "ceiling," and that labeling disclosure beyond that required by the FDA may in fact expose drug manufacturers to liability under the final rule if such statements are "unsubstantiated or otherwise false or misleading." Lastly, in the preamble the FDA explicitly rejects any suggestion that drug manufacturers may add to or revise risk information disclosed in a drug's labeling without first obtaining FDA approval.

**Anticipated Effect of FDA's January 2006 Preemption Policy Statement**

It is important to recognize that the FDA's preemption statement does not itself have the force of law. It represents only the agency's position on the issue. The preemptive effect of the FDA's regulatory actions will continue to be a question for the courts, but the agency's decision to formalize its position in an official policy statement may strengthen the argument for preemption by drug manufacturers and sponsors in product liability litigation.

**Weight of Official Agency Rulemaking**

**Why did the FDA feel compelled to address the topic of preemption in the preamble to its final drug labeling rule?**

Even though the codified version of the final rule (that is, the actual FDA regulation) does not address the topic of preemption (only the preamble to the rule does so), courts have traditionally given much deference to formal agency rulemaking, especially policies that are issued in formal agency action as opposed to informal policy statements in the context of individual litigation actions (such as amicus briefs). In fact, there is a strong argument to be made that the FDA included its preemption policy in the preamble of its final rule on drug labeling in order to finally hand down its preemption policy in the form of a formal agency rule. The preamble is a culmination of years of briefs submitted by the FDA in product liability cases to defend the preemptive effect of its drug approval and labeling regulations. Moreover, the final rule and the preamble were issued following five years of public scrutiny and comment in response to the proposed rule that was published by the FDA in December 2000, comments that were particularly related to the rule's anticipated effect on state product liability litigation. Finally, the FDA's consideration of its preemption policy in the preamble is arguably extensive and grounded in sound legal and policy rationale.

**Existing v. Future Product Liability Claims**

**Will the FDA's preemption policy be applied to existing state law claims or only to future claims?**

By stating in the preamble that the "FDA believes that[,] under existing preemption principles," the FDA's approval of drug labeling, "whether it be in the old or new format," preempts "conflicting or contrary state law," the FDA makes clear that its preemption policy is an existing (not new) policy and that it expects the policy to be applied to pending, as well as future, state law product liability claims.

**Anticipated Breadth and Most Likely Applications**

**How broad is the potential application of the FDA's preemption policy and in what contexts will the policy be most likely invoked?**

It is impossible to predict with certainty, but it is likely that the FDA's preemption policy will first and most readily be applied in cases where a plaintiff claims that a drug manufacturer was required under state law to provide risk information that the FDA specifically considered and rejected, or where the FDA's regulations clearly prohibit the dissemination of risk information that a plaintiff claims is required under state law. When the FDA listed the six types of state law claims that would undoubtedly be preempted pursuant to the preamble of the final rule, it made a point to indicate that the list was not exhaustive by using the phrase "at least." And, it is equally as significant that the FDA specified only

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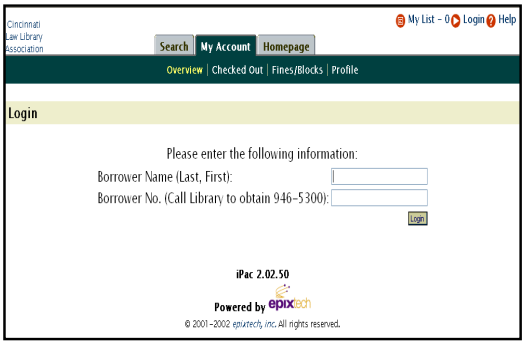
# Manage Your Law Library Account Online

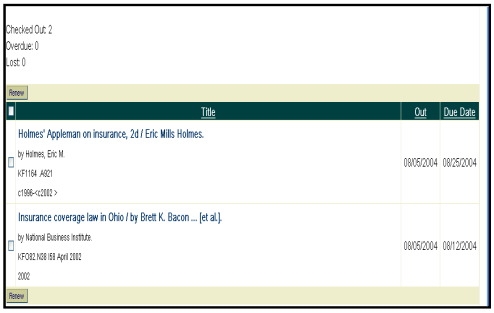
Julie Koehne

You may use the Law Library's online catalog to manage your library account online, enabling you to see what you have checked out and renew books online, 24 hours a day.

To start, go to the online catalog and click the My Account tab.
http://lawlib.hamilton-co.org/ipac20/ipac.jsp?profile=clla#focus




Enter your last name, first name, and borrower number in the spaces provided. If you need your borrower number, check your newsletter label or call us at 946-5300 and we will give it you.

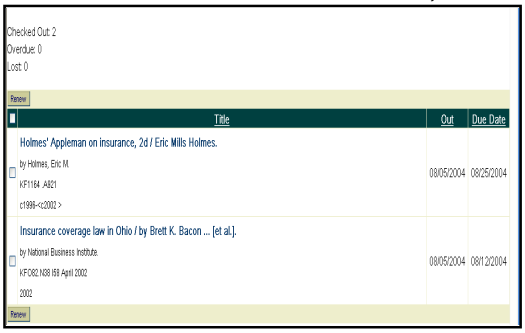



## Review Your Account

Once logged in, you may observe an overview of you account, the items you have checked out, fines, and other account information.

## Renew Books

By clicking the **Checked Out** tab, you can see the items you have checked out and their due dates. Click the box next to the title, or select the box at the top of the column to renew ALL titles, and then click the **RENEW** button.




## Did You Know Our Members Receive:

- ❖ Free Lexis Access in the Library
- ❖ Free Internet Access in the Library
- ❖ Free Remote Access to HeinOnline, FastCase, Aspen/Loislaw Treatises, and CCH Newsletters
- ❖ Free Reference Assistance, in person, by phone, or via e-mail
- ❖ Extensive Ohio and Federal primary law collection in print and electronic formats
- ❖ Practice materials, including:
  - handbooks
  - rules
  - treatises
  - jury verdicts
- ❖ Borrowing privileges to nearly all materials in the Library's collection, including CLE materials.

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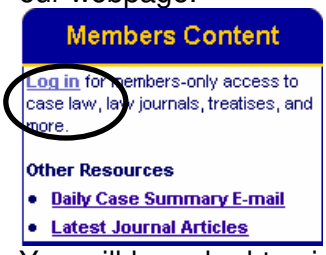
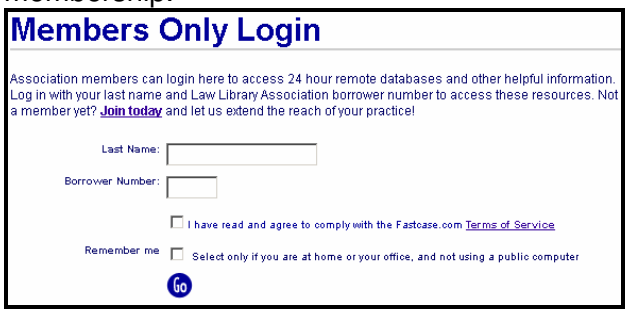
### Signing On

From our homepage, click the "Log in" link located in the Members Content box in the upper right corner of our webpage.




You will be asked to sign in using your last name and borrower number. Your borrower number is printed on your address label of the paper newsletter, but you can also contact the Law Library at 946-5300 to get it. The login page for our remote access services is http://www.hamilton-co.org/cinlawlib/intra/login.asp. These services are available to all solo attorney members and lawyers at firms with a firm membership.



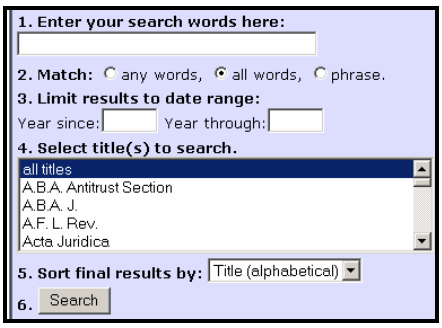

Once inside, select from the following: HeinOnline, FastCase, and CCH Newsletters.

### HeinOnline

You may access the content of HeinOnline, the law journal research service, in several different ways:

- you may select Law Journal Library, then select the title, volume, and page number, if you have that information;
- you can enter the citation at the Citation Navigator, in the upper right corner of the page;
- you may search HeinOnline's holdings in two different ways:

1. Author/Title Search – enter the title and author in the search bars and click Search Articles;
2. Full Text Word and Phrase Search – enter your words or phrases in the search bars; set date, journal and sorting parameters, click Search.

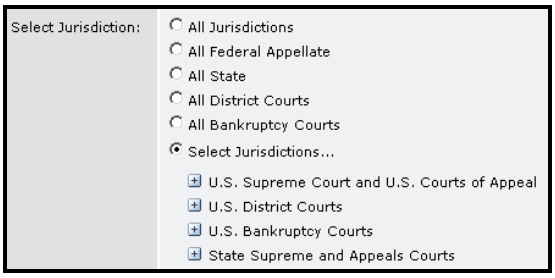



### FastCase

FastCase allows you to search statutes, regulations, constitutions and court rules from a variety of jurisdictions, but it is best used for researching case law.

To search, you must run either a Boolean search using terms and connectors or you must search via natural language, in which the system tries to match results to your words and phrases. You may also enter a citation to find a case.


If you want to search specific jurisdictions, you should select them from the following menu:




Selecting State Supreme and Appeals Court, you may access cases from Ohio, Kentucky, Indiana, and other individual states. You also have several sorting options, a navigation guide, and a comprehensive help page.

### CCH Newsletters

The CCH newsletters represent electronic versions of some of that publisher's print titles.

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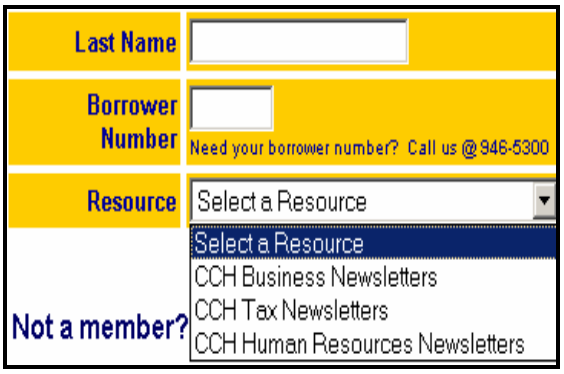
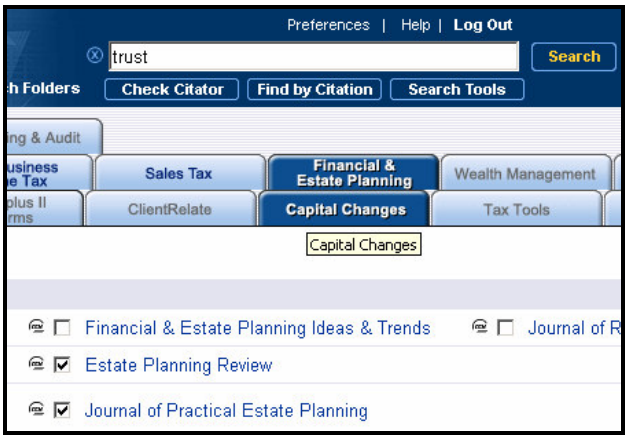



The database is organized like a file cabinet: major topics have their own folders, the contents of which are listed as subtopics. For example, once in the State Tax folder, simply click one of the subtopic links (State Tax Day → Ohio → Gasoline Taxes) and you can view the contents.


To begin a term search, you must first enter the folder that contains the titles you want to search. Next, click the box next to the title of the item. Finally, enter terms or a citation in the search box, select additional options for your search from Search Tools, and then click the Search button on the navigation bar.

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one limited circumstance in which federal preemption would not apply and then qualified that circumstance. Drug manufacturers and other respondents in product liability lawsuits will therefore have the opportunity to put forth additional theories as to why FDA regulations should have a preemptive effect on types of state law claims not specifically listed in the preamble.

## Conclusion

A certain outcome of the FDA's January 2006 statement will be that drug manufacturers and sponsors will now be required to comply with the new prescription drug labeling requirements specified in the regulation portion of the FDA's final rule. It is too early to predict what other outcomes and changes, if any, will result from the statement, particularly in relation to the FDA's preemption policy statement in the preamble to the final rule. Only time will tell whether the preemption statement will in practice actually strengthen preemption claims made by drug manufacturers and sponsors in product liability actions . . . or whether preemption claims will continue to be dealt with on a case-by-case basis in state courts in virtually the same manner as prior to the issuance of the January 2006 statement. What at least seems likely, if not certain, is that law firms representing drug manufacturers and sponsors and other respondents in product liability claims will now have the opportunity to point to the FDA's January 2006 statement as "formal" support for their preemption claims. What weight judges and juries ultimately assign to the FDA's formal preemption statement remains to be seen.

**Editor's note:** This article is intended to inform about legal matters of interest. It is not intended as legal advice. Readers should not act upon this information without professional legal counsel.

# Elder Law CLE Opportunity

*Location:* Cincinnati Law Library Association, 1000 Main Street, Room 601
*Date:* Friday, July 21
*Time:* 12:30 pm - 2pm (Lunch from 12:30 to 1pm)
*Speaker:* Miriam Sheline, Pro Seniors

Members: $15 **
Non-Members: $50 **
** Box lunch included

Ms. Sheline, Pro Seniors' Staff Attorney & Medicaid Specialist, will provide an update on recent Medicaid changes including:

- Ohio's New Medicaid Assisted Living Waiver
- Ohio's New Crime of Medicaid Eligibility Fraud
- Medicaid Changes Included in the Federal Deficit Reduction Act of 2005
- Changes to Ohio's Medicaid Estate Recovery Law & Medicaid Estate Recovery Liens.

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