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Pfizer Completes Settlement Agreements with State Attorneys General Regarding its NSAID Pain Medications

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(BUSINESS WIRE)--Pfizer Inc announced today that it has finalized agreements with 33 states and the District of Columbia to resolve claims primarily related to alleged promotional practices for Bextra, a medication Pfizer voluntarily withdrew from the United States market in 2005. Last week Pfizer announced agreements in principle to resolve these state claims, indicating that it would pay $60 million and adopt compliance measures as part of the settlement that complement policies and procedures previously established by the Company.

“As we announced last week, these settlements avoid the disruption and expense of litigation and put these matters behind us,” said Amy W. Schulman, senior vice president and general counsel of Pfizer. “Bextra brought effective pain relief to millions of arthritis patients who did not find relief with other treatment therapies. This medicine was rigorously studied and tested by the Company and independent medical experts, and information about its benefits and risks was fully disclosed to the FDA.”

Under the settlements agreed to by the States, Pfizer denies the allegations in the complaints that its promotional practices violated state laws. In response to allegations contained in documents filed by the States, the Company said:

- It shared with the FDA in a timely manner all of the data in its possession regarding the safety and efficacy of Bextra, as well as the Company's approved materials describing such data.
- In addition, the Bextra label, which set forth the approved indications and contained all of the scientific data deemed to be relevant by the FDA, was widely available to physicians.
- All of the studies discussed in the complaints and provided to physicians were principally authored by doctors who did not work at the Company, and were subjected to rigorous peer review before they were published in respected journals.
- The CABG studies referenced in the complaints involved the investigational use of an intravenous form of Bextra, and are not applicable to settings outside of CABG. Specifically, the CABG study safety findings were not replicated in other studies in general or other surgical settings. Indeed, in 2005, the FDA acknowledged that it could not determine the significance of the CABG data for patients in other contexts. The FDA also stated that the totality of the Bextra data did not demonstrate that Bextra posed a different level of cardiovascular risk than other prescription NSAIDs.

- Pfizer provided physicians with truthful and material information about the safety and efficacy of Bextra. When responding to doctors’ questions about Bextra with a medical information letter, the Company included a copy of the Bextra label.

- Pfizer's support of Continuing Medical Education programs complies with the national standards adopted by the ACCME. Pfizer has also adopted strict guidelines regarding its promotional programs for prescribers that require compliance with all applicable laws. Pfizer's relationships with doctors, moreover,

are also governed by industry-adopted standards.

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