Statement of the Commission
Cephalon, Inc./Cima Labs Inc., File No. 041-0025

Today, the Commission released a proposed complaint and accepted for public comment a proposed consent order that obtains significant relief regarding Cephalon, Inc.'s proposed acquisition of Cima Labs Inc. The complaint alleges that the acquisition may substantially lessen competition in the market for the manufacture and sale of prescription drug products to treat breakthrough cancer pain (BTCP). These medications bring many cancer patients significant improvement in the quality of their lives. Cephalon's product Actiq is the only treatment on the market indicated for BTCP. Cima Labs is developing oravescent fentanyl (OVF), which is in Phase III clinical trials and is the product best positioned to enter the market.

To address potential anticompetitive effects that may arise from the transaction as originally contemplated, the Commission has required the merging parties to grant a license and transfer all of the technological know-how for Actiq to Barr Laboratories, Inc., a leading generic drug manufacturer. This transfer will significantly expedite the entry of a generic BTCP product. Our experience and the empirical literature[1] demonstrate that the entry of a generic BTCP product will provide a substantially lower-priced alternative to consumers and thereby significantly lower the average price of BTCP medication. The availability of a substantially lower-priced BTCP medication will be particularly important for patients on limited budgets or without insurance.

Normally, creation of a generic competitor would be insufficient to solve the anticompetitive problems raised by a merger of two branded pharmaceutical competitors. In the usual case, such a remedy would not replace the lost promotion and innovation competition between the branded companies regarding the particular illness the companies competed to treat. In this case, however, the facts showed that an important anticompetitive effect of the merger was to defeat generic competition. The facts further showed that there is not likely to be *any* further innovation competition between Cephalon and Cima for BTCP products because, among other things, Actiq is near the end of its patent life and neither Cephalon nor Cima has any other BTCP products in the pipeline. Moreover, Actiq and OVF are both formulations of fentanyl, a readily-available, non-patented active ingredient.

The earlier entry of lower-priced generic Actiq, made possible by the remedy, will more than restore any loss in brand-to-brand price competition that would have occurred between Cephalon and Cima. The average price that consumers will pay for BTCP medication will be lower after the merger and the proposed remedy than it would have been without the merger and remedy. In addition, the consent order ensures that the competition between Actiq and its generic equivalent will be robust. Because the generic product should be on the market no later

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[1]This literature is reviewed at *Generic Drug Entry Prior to Patent Expiration: An FTC Study* 9 (July 2002).

than the launch of OVF,[2] Cephalon will be unable to shift patients preemptively to OVF to undermine generic competition. Thus, the proposed remedy would bring significant benefits to patients and would reverse the anticompetitive effects of the proposed acquisition.

Commissioner Thompson has dissented, arguing that the Commission should have sought a preliminary injunction to block this transaction on the grounds that there is a group of consumers who would purchase a branded BTCP product and would thus face higher prices. However, the evidence is not clear that this will happen. Even if it were to happen, this outcome would be a well-recognized result of the introduction of generic competition.[3] In the past, the Commission has recognized and resolved the particular tradeoff that concerns Commissioner Thompson today. The Commission, including Commissioner Thompson, has recognized the net benefits that arise from the entry of generic pharmaceutical products and consequently has devoted substantial resources to identify and prohibit anticompetitive practices that have made the entry of generic drugs more difficult.[4] As in our earlier cases, the benefits that earlier generic entry will bring to consumers of BTCP treatment in terms of lower average prices greatly exceed

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[2]The license to Barr provided by the order enables Barr to begin marketing the generic versions of Actiq at the earliest of final FDA approval of OVF or various specified dates. If Cephalon delays the introduction of OVF, the license allows Barr to market the generic products at specific dates that approximate the time that the parties' premerger documents predict OVF would have been launched.

[3]In the face of generic entry, branded companies frequently raise the price for branded products that did not previously face such competition. *See* supra note 1. In this case, however, given the particular characteristics regarding the branded formulations, it is unclear whether the branded price actually will increase.

[4]*See, e.g.*, *Schering-Plough Corp.*, Dkt. No. 9297, *available at* <http://www.ftc.gov/os/adjpro/d9297/031218commissionopinion.pdf> (agreement between branded and generic manufacturers to delay entry of generic); *Biovail Corp.*, Dkt. No. C-4060 (consent order); *available at* <http://www.ftc.gov/os/2002/04/biovailcomplaint.htm> (wrongful Orange Book listing for Tiazac); *Biovail Corp. and Elan Corp.*, Dkt. No. C-4057 (consent order), *available at* <http://www.ftc.gov/os/2002/06/biovailelancmp.pdf> (agreement among generic drug companies to divide market for generic Adalat CC); *Abbott Labs.*, Dkt. No. C-3945 (consent order), *complaint available at* <http://www.ftc.gov/os/2000/05/c3945complaint.htm>; *Geneva Pharm., Inc.*, Dkt. No. C-3946 (consent order), *complaint available at* <http://www.ftc.gov/os/2000/05/c3946complaint.htm>; *Hoechst Marion Roussel, Inc.*, Dkt. No. 9293 (consent order), *complaint available at* <http://www.ftc.gov/os/2000/03/hoechstandrxcomplaint.htm>.

any price increases to the less price-sensitive patients who may continue to choose branded products.[5] Contrary to Commission Thompson's claim, the underlying rationale for the relief mandated in this case is supported by unanimous Commission precedent.

[5]In his dissent, Commissioner Thompson relies on a statement in the old case of *United States v. Philadelphia National Bank*, 374 U.S. 321, 371 (1963), that anticompetitive mergers cannot be justified by some "ultimate reckoning of social or economic debits and credits." We support this general principle. The issue here, however, is whether the transaction, as modified by the Order, can be considered anticompetitive in the first place when price increases, if any, are weighed against much larger price decreases to the same group of customers. In any merger case, predictions of procompetitive and anticompetitive effects are inherently uncertain, and – whether we choose to challenge or to pass – there often is a risk that one set of consumers will benefit and another set will lose. We are choosing between *probabilities* rather than sets of consumers.