Production Planning for Medical Devices with an Uncertain Regulatory Approval Date

Arthur V. Hill

Operations & Management Science Department
Curtis L. Carlson School of Management
University of Minnesota
321 19-th Avenue South
Minneapolis, MN 55455-0413 USA

Email: ahill@umn.edu
Voice: 612-624-4015
Fax: 612-624-8804

William J. Sawaya III

Operations & Management Science Department
Curtis L. Carlson School of Management
University of Minnesota
321 19-th Avenue South
Minneapolis, MN 55455-0413 USA

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Authors' Vitae

Arthur V. Hill is a professor in the Curtis L. Carlson School of Management at the University of Minnesota. He earned a B.A. in Mathematics from Indiana University, an M.S. in Industrial Administration and a Ph.D. in Management from the Krannert Graduate School of Management at Purdue University. Professor Hill served as the Editor-in-Chief of the ***Journal of Operations Management*** and on the editorial review boards for a number of academic and practitioner journals, including ***Decision Sciences***, ***Production Operations Management***, and ***Production & Inventory Management Journal***. He has been a member of IIE since 1977. He has worked extensively with medical device manufacturers in the United States, particularly in "medical alley" in Minnesota. His current research interests include service guarantees as a means to accelerate service quality improvement, manufacturing management for medical device manufacturing, demand chain management, and mass customization.

William J. Sawaya III is a doctoral student in the Curtis L. Carlson School of Management at the University of Minnesota. He earned a B.S. in Manufacturing Engineering from Brigham Young University and an M.S. in Industrial Engineering from the Georgia Institute of Technology. He is a member of IIE. His work experience includes consulting on both product transition planning and quality assurance issues.

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Why this paper is important

This paper is important because it …

1. Addresses an important emerging production planning problem

This paper addresses a production planning problem that is increasing in importance in the medical device industry and other industries that offer products subject to government regulatory approval. This important operations/marketing interface problem involves the timing of the phase-in of a new product and the phase-out of an existing product.

2. Develops an innovative, new mathematical model for the problem

The paper develops an innovative, new mathematical model for the problem. The two decision variables include the date to start production of the new product and the date to stop production of the existing product. Both dates need to be planned ahead of time in order to allow for procurement and manufacturing leadtimes. The structure of the problem is essentially two newsvendor problems that share several parameters.

3. Provides helpful intuition to managers

The model provides helpful intuitive insights into the value of improving the forecasts of the government approval date and shows that the cost of planning for the worst-case scenario for both decision variables can be quite high.

4. Reports on the successful implementation of the model

The paper reports on the implementation of the model in a large medical device firm. For competitive reasons, the firm did not give the authors permission to publish any cost savings data; however, the paper does provide an example with data that is representative for the industry. The paper also reports management's qualitative evaluation of the contribution of the model to their decision process and to their intuition.

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ABSTRACT

The demand for medical devices such as pacemakers, defibrillators, catheters, and heart valves is growing rapidly throughout the world. This demand is driven by both the "technology push" of new medical device technologies and by the "demand pull" of an aging population in North America, Western Europe, and Japan. Production planning for these products is increasing in importance as demand increases, global competition intensifies, and product lifecycles shorten.

In all developed countries, medical devices must pass through a government approval process. An uncertain government approval date makes it difficult to create production and inventory plans for both the phase-out of an existing product and the phase-in of a replacement product.

This paper presents a mathematical model for finding the optimal dates to stop production of an existing product and to start production of a new product in the presence of an uncertain approval date. The paper also presents an example and reports on an implementation in a Fortune 500 medical device firm.

Subject Areas: Inventory Theory, Production Planning, Master Production Scheduling, Mathematical Optimization, Marketing-Operations Coordination, Medical Device Manufacturing.

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INTRODUCTION

The demand for medical devices such as pacemakers, defibrillators, cochlear implants, stents, catheters, and heart valves is growing rapidly throughout the world. Industry leaders such as Medtronic, Guidant, St. Jude Medical, and Boston Scientific have experienced impressive growth rates. For example, between 1992 and 2001, Medtronic's sales grew by 18% per year and profits grew by 24% per year (Medtronic 2001 Annual Report). Demand for medical devices is driven by both the "technology push" of new medical device technologies and by the "demand pull" of an aging population in North America, Western Europe, and Japan.

Medical device production planning is complicated by a government approval process that has an uncertain approval date. In all developed countries of the world, medical devices cannot be sold until a government approval body grants permission. For example, the web page for the State Institute for Drug Control for the Slovak Republic (SIDC, 1999) outlines the approval process for medical devices in that country. In the United States, the Food and Drug Administration (FDA) had an average time to approval for Premarket Approval Applications of 12.4 months in 1998 (FDA Report, 1999, page 1). It is common for the forecast interval for the approval date to be more than six months wide.

The uncertainty of the approval date for new devices makes it difficult to create production and inventory plans for both the phase-out of the existing product and the phase-in of the replacement product. Manufacturing and procurement leadtimes of unique parts require the firm to commit to phase-out and phase-in plans before the earliest approval date. If production

of the existing product is stopped too early, the firm will lose profit and customer goodwill; conversely, if production is stopped too late, the firm will experience obsolescence cost for the existing product. If production of the new product is started too early, the firm will experience inventory carrying cost; if the production is started too late, the firm will lose revenue.

To further complicate the planning problem, it is often necessary to scrap much of the inventory of the existing product immediately when the new product is approved. This is due to three market forces. First, patients and their doctors want the latest medical device technology for treatment. Second, higher demand, higher prices, and higher commissions drive sales organizations to shift to the new product. Third, marketing organizations want products that accentuate the "leading edge" nature of the firm's brand, and do not want to lose the opportunity to sell the "latest and greatest" product when approval is announced by the government agency. A recent article about Medtronic emphasized this point with the statement, "Because lives (and careers) require that a doctor use the best technology, a lag in a product introduction can chop a company's market share in half almost overnight" (McLean 1999, page 178). On the other hand, if a medical device firm has clear technological superiority for an existing product, it may be possible to sell off existing inventory before introducing the new product.

Given that medical devices often have high prices and costs, the impact of production planning decisions can be significant. For example, three of the leading medical device manufacturers in the United States reported inventory write-offs of over $12 million (roughly 1% of sales) in their 1998 annual reports. The 1998 Guidant Annual Report stated:

> The second charge was a $28.8 million non-cash charge to cost of products sold resulting from the obsolescence of older-generation cardiac rhythm management products and programmers. The charge resulted from accelerated regulatory approval for market release and customer acceptance of new-generation cardiac rhythm management products.

Boston Scientific's 1998 Annual Report stated:

> During 1998, the Company initiated a full-time global program to focus on supply chain optimization. The program is designed to lower inventory levels and the cost of manufacturing, improve absorption, and minimize inventory write-downs. By addressing the entire supply chain, including application of lean manufacturing techniques, the Company seeks to return gross margins to more acceptable levels and to improve working capital. The decline in gross margins during 1997 is primarily attributable to write-downs for excess and obsolete inventory and a decline in average selling prices as a result of continuing pressure on healthcare costs and increased competition.

The 1999 Medtronic Annual Report stated:

> Fiscal 1999 cost of products sold included $29 million in charges related to inventory obsolescence in the vascular and cardiac surgery product lines …"

These and other medical device firms apparently tend to follow what we call the safe policy for product transition planning. The safe policy plans to build enough of the existing product to carry the firm to the latest approval date and plans to have the new product available by the earliest approval date. Parlar and Weng support the safe policy concept when they point out that, "An unsatisfied customer order not only results in lost potential revenue, but … drives a firm to satisfy all demand, even at a loss" (Parlar & Weng, 1997, page 1343). As we will show later in the paper, the safe policy minimizes stockout costs at the expense of high obsolescence and carrying costs.

Many authors have argued that coordination between the production and marketing functions is critical to business success (Balakrishnan, Chakravarty, & Ghose, 1997; Berry, Hill, Klompmaker, & McLaughlin, 1991; Berry, Hill, & Klompmaker, 1995; Deane, McDougall, and Gargeya, 1991; Karmarkar, 1996; Meredith & McTavish, 1992). For example, Berry, Hill, Klompmaker, and McLaughlin (1991, p. 295) state that:

> There is very little emphasis in operations strategy on how to acquire and apply market information and coordinate marketing and operations strategies ...

> improved competitive performance can be obtained by incorporating market analysis and marketing strategy considerations in the formulation of operations strategy.

Krishnan and Ulrich (2001) provide an excellent review of the product development literature, including discussion of product launch and ramp-up decisions. Hultink, Griffin, Hart, and Robben (1997) argue that product launch strategy is an important success factor. Kalish and Lilien (1986) find that significant penalties may be associated with mistiming the introduction of new products. Billington, Lee, and Tang (1998, page 24) argue that planning for product introduction and product phase-out should be done jointly:

> To manage product rollovers efficiently, it is critical to plan the introduction of new products and the displacement of old products *jointly*. Most of the literature treats the two processes *separately*. Moreover, the execution of an effective plan also calls for coordination among different departments.

They compare solo-product and dual-product strategies. The solo-product strategy offers only one product to the market at a time; the dual-product strategy offers both products. They explore many of the risk and cost factors related to these strategic decisions.

Some research (Kurawarwala & Matsuo, 1996; Jain, 1998) has addressed marketing/operations coordination in the context of planning the transition from one product to another for short lifecycle products such as personal computers. This research is based on the concept that "for many such products, the production and procurement decisions need to be made fairly in advance of the product's introduction stage" (Kurawarwala & Matsuo, 1996, page 131). Their research concludes that it is often desirable to be the first firm to adapt the new product technology. The research presented in this paper considers marketing/operations coordination for production transition planning in the context of medical device manufacturing with an uncertain approval date.

The first section of the paper develops a mathematical model that can be used to plan production for both the existing product and a replacement product. The second section reports on the implementation of the model in a Fortune 500 medical device firm. The third section illustrates the model with a hypothetical example. The fourth section discusses limitations and extensions. The last section concludes with an overview of the contributions of the research.

THE PRODUCTION PLANNING MODEL

The problem context requires a production plan for phasing out an existing product (hereafter called product 1) and phasing in a replacement product (product 2). The t_1 decision variable is the date the firm plans to run-out of product 1. The manufacturing and procurement leadtimes for product 1 are significant, making it necessary to commit to the t_1 planning date before the earliest approval date. The planned stop-date for product 1 in the Master Production Schedule (MPS) is then determined by taking into account the trailing demand and back-scheduling from the run-out date. The MRP system uses this MPS stop-date to phase out all unique components for product 1.

The t_2 decision variable is the date product 2 is planned to be available to sell. Product 2 is not available for sale until the distribution channel is filled with I_2 units. The manufacturing and procurement leadtimes for product 2 are significant, making it necessary to commit to the t_2 planned availability date long before the earliest approval date. The planned start date for manufacturing product 2 in the MPS is then determined by back-scheduling from the t_2 planned availability date while taking into account learning curve and shop calendar issues.

The existing product is sold until the firm runs out of inventory or until an approved new product replaces it. The firm's policy is to scrap all product 1 units immediately when an approved product 2 is available for sale. As mentioned earlier, this is justified by the higher margins for product 2 and by the need to maintain brand equity as a leading-edge provider. We will relax this assumption later in the paper and allow for trailing demand for product 1 after product 2 has been introduced.

The goal is to maximize the expected contribution to profit, which is the sum of the contribution to profit for products 1 and 2 less the scrap loss for product 1, the carrying cost for both products, and lost goodwill during the time the firm cannot sell either product. The planning horizon is fairly short (about a year), so it is not necessary to discount cash flows.

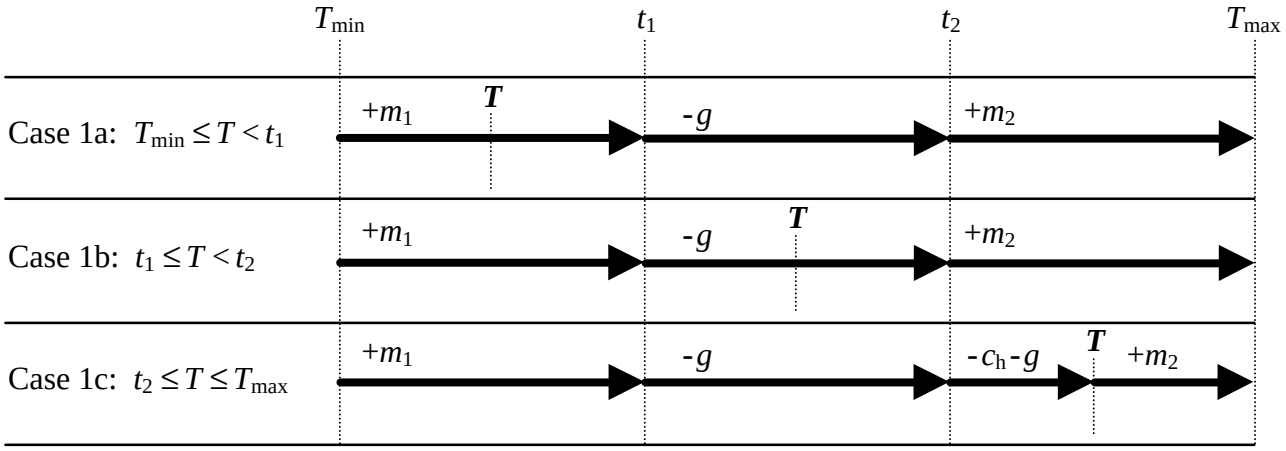
The government approval date is a random variable, *T*, with density function $f(T)$, distribution function $F(T)$, and mean m_T. The demand rates for products 1 and 2 are d_1 and d_2 units per period, respectively.

The solution space can be divided into three cases. For Case 1, the firm plans to run-out of product 1 before product 2 becomes available (e.g., $t_1 < t_2$), which means the firm plans to have neither product available during the time interval (t_1, t_2). For Case 2, the firm plans to have the product 2 available on the same date that product 1 runs out (e.g., $t_1 = t_2$). For Case 3, the firm plans to have the new product available before the date product 1 runs out (e.g., $t_2 < t_1$), which means that the firm plans to carry inventory for product 2 during the time interval (t_2, t_1) and scrap some product 1 units if $T < t_1$. The next three subsections show that Case 1 is never optimal, derive optimal closed-form policies for Cases 2 and 3, and develop a decision rule for determining if the optimal solution can be found in Case 2 or Case 3.

Case 1: Phase-out before phase-in ($t_1 < t_2$)

For Case 1, the firm plans to run-out of product 1 before having product 2 available. Figure 1 shows the problem structure for this case. The random approval date, *T*, falls into one of three cases, $T_{\min} \le T < t_1$, $t_1 \le T < t_2$, and $t_2 \le T \le T_{\max}$. For all three cases, the firm sells product 1 during $(T_{\min}, t_1)$. The contribution to profit per period for product 1 is $m_1 = d_1(p_1 - c_1) - hc_1 I_1$, where $d_1(p_1 - c_1)$ is the demand rate times the gross margin, I_1 is the channel inventory needed to support product 1 in the field, and h is the carrying charge per period. For all three cases, the firm has neither product to sell between t_1 and t_2 and loses goodwill of g per period. The lost goodwill per period is assumed to be independent of T.

Figure 1. Case 1 problem structure ($t_1 < t_2$**)**



For cases 1a and 1b, product 2 is sold from t_2 to $T_{\max}$ with contribution per period of $m_2 = d_2(p_2 - c_2) - hc_2 I_2$. For case 1c, the random approval date is after product 2 becomes available ($T \ge t_2$), which means that product 2 contributes m_2 per period for $T_{\max} - T$ periods.

Between t_2 and T, the firm has neither product to sell with a goodwill loss of g per period and carries I_2 units of product 2 with a carrying cost of $c_h = hc_2 I_2$ per period.

For any realization of the random approval date (T), Case 1 contribution to profit is:

$$CP_1(t_1,t_2,T) = \begin{cases} m_1(t_1 - T_{\min}) - g(t_2 - t_1) + m_2(T_{\max} - t_2) & \text{for } T_{\min} \le T < t_1 \\ m_1(t_1 - T_{\min}) - g(t_2 - t_1) + m_2(T_{\max} - t_2) & \text{for } t_1 \le T < t_2 \\ m_1(t_1 - T_{\min}) - g(t_2 - t_1) - (c_h + g)(T - t_2) + m_2(T_{\max} - T) & \text{for } t_2 \le T \le T_{\max} \end{cases} \quad (1)$$

It is clear from Figure 1 and equation (1) that for any given value of t_2, the firm can always increase the contribution to profit and reduce lost goodwill by increasing t_1. This means that the optimal policy can always be found in either Case 2 or 3. The next two sections develop optimal closed-form solutions for Case 2 and Case 3.

Case 2: Same-date policy ($t_1 = t_2$)

For Case 2, the firm plans to run-out of product 1 on the same-date that product 2 becomes available (e.g., $t_1 = t_2$). From Figure 1, we can see that for any realization of the random approval date (T), the contribution to profit for Case 1 is given by:

$$CP_2(t_1,T) = \begin{cases} m_1(t_1 - T_{\min}) + m_2(T_{\max} - t_1) & \text{for } T_{\min} \le T < t_1 \\ m_1(t_1 - T_{\min}) - (c_h + g)(T - t_1) + m_2(T_{\max} - T) & \text{for } t_1 \le T \le T_{\max} \end{cases} \quad (2)$$

The expected contribution to profit function is given by:

$$\begin{aligned} ECP(t_1) &= \int_{T=T_{\min}}^{T_{\max}} CP(t_1,T)\, f(T)\, dT \\ &= \int_{T=T_{\min}}^{t_1} [m_1(t_1 - T_{\min}) + m_2(T_{\max} - t_1)]\, f(T)\, dT \\ &+ \int_{T=t_1}^{T_{\max}} [m_1(t_1 - T_{\min}) - (c_h + g)(T - t_1) + m_2(T_{\max} - T)]\, f(T)\, dT \end{aligned} \quad (3)$$

where, $f(T)$ is the density function for the random approval date T in the interval $(T_{\min}, T_{\max})$. Defining the partial expectation $G(t) = \int_{T=T_{\min}}^{t} Tf(T)dT$ and recognizing that the mean approval time is $m_T = G(T_{\max})$, the expected contribution to profit for Case 2 simplifies to:

$$ECP_2(t_1) = -m_1 T_{\min} + m_2 T_{\max} + (m_1 + c_h + g)t_1 - (m_2 + c_h + g)[t_1 F(t_1) + m_T - G(t_1)] \quad (4)$$

Setting the first derivative with respect to t_1 to zero and taking advantage of the fact that $\partial G(t)/\partial t = tf(t)$, we find the optimal Case 2 same-date policy is given by:

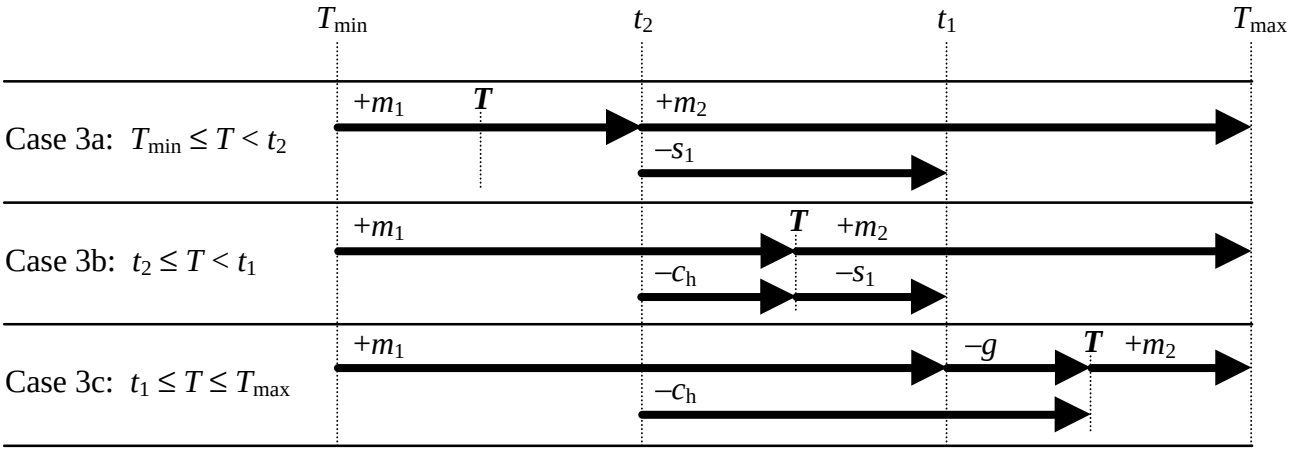
$$\begin{aligned} \partial ECP_2(t_1)/\partial t_1 &= m_1 + c_h + g - (m_2 + c_h + g)F(t_1) = 0 \\ \Rightarrow t_1^* = t_2^* &= F^{-1}\left(\frac{m_1 + c_h + g}{m_2 + c_h + g}\right) \end{aligned} \quad (5)$$

The second derivative is $\partial^2 ECP_2(t_1)/\partial t_1^2 = -(m_2 + c_h + g) f(t_1)$. Given that $f(t) \geq 0$ and that all parameters are non-negative, this is strictly non-positive for all t_1, which proves that equation (5) is the global optimal solution for Case 2. This is a newsvendor-type result with a continuous time decision variable. If the firm plans to have the combined run-out/availability date one period earlier than the random approval date, the underage cost is $m_1 + c_h + g$, one period of the lost contribution for product 1, one period of carrying cost for product 2, and one period of lost goodwill for having neither product to sell. If the firm plans the date one period later than the approval date, the overage cost is $m_2 - m_1$, the difference between the contributions for the two products. The optimal same-date policy increases as the difference between contributions per period decreases. When $m_1 = m_2$, the optimal policy is $t_1^* = t_2^* = T_{\max}$.

Case 3: Phase-in before phase-out ($t_2 < t_1$)

For Case 3 the firm has an availability date for product 2 before the run-out date of product 1. Figure 2 shows the problem structure for Case 3 with the random approval date again falling into one of three time intervals. For case 3a, the approval date is before product 2 becomes available ($T < t_2$), and the firm sells product 1 with contribution m_1 per period from the beginning of the planning horizon ($T_{\min}$) until product 2 becomes available at t_2. If approval is before t_2, the model assumes the firm loses no goodwill in selling only product 1 after product 2 is approved. Product 2 is sold with contribution m_2 per period from t_2 to the end of the planning horizon ($T_{\max}$). At time t_2 all remaining units of product 1 are scrapped with scrap cost of $s_1 = d_1(c_1 - p_s)$ per period, where p_s is the scrap revenue (salvage value) per unit. The firm has planned ahead to have enough inventory of product 1 to last until time t_1, which means that $d_1(t_1 - t_2)$ units will be scrapped. (Later in the paper we will extend the model to allow for trailing demand.)

Figure 2. Case 3 problem structure ($t_2 < t_1$)



For case 3b ($t_2 \le T < t_1$), the firm sells product 1 until the approval date (T) when product 2 is sold for the remainder of the planning horizon ($T, T_{\max}$). The firm incurs a cost for carrying I_2 units of product 2 for $T - t_2$ time periods. At time T, the remaining $d_1(t_1 - T)$ units of product 1 are scrapped at scrap cost s_1 per period.

For case 3c ($t_1 \le T \le T_{\max}$), the firm sells product 1 until it runs out at time t_1. At that time, no units of product 1 are remaining and product 2 is not yet approved for sale. The firm does not have either product to sell during the time interval (T, t_1) and loses goodwill of g per period. At time T product 2 is approved and contributes to profit during the time interval ($T, T_{\max}$). However, the firm incurs an unnecessary carrying cost of c_h per period during (t_2, T).

For any realization of the approval date T, the Case 3 contribution to profit is given by:

$$CP_3(t_1,t_2,T) = \begin{cases} m_1(t_2 - T_{\min}) + m_2(T_{\max} - t_2) - s_1(t_1 - t_2) & \text{for } T_{\min} \le T \le t_2 \\ m_1(T - T_{\min}) + m_2(T_{\max} - T) - s_1(t_1 - T) - c_h(T - t_2) & \text{for } t_2 < T \le t_1 \\ m_1(t_1 - T_{\min}) + m_2(T_{\max} - T) - g(T - t_1) - c_h(T - t_2) & \text{for } t_1 < T \le T_{\max} \end{cases} \quad (6)$$

The expected contribution to profit for Case 3, therefore, is given by:

$$\begin{aligned} ECP_3(t_1,t_2) &= \int_{T=T_{\min}}^{T_{\max}} CP_3(t_1,t_2,T)\, f(T)\, dT \\ &= \int_{T=T_{\min}}^{t_2} [m_1(t_2 - T_{\min}) + m_2(T_{\max} - t_2) - s_1(t_1 - t_2)]\, f(T)\, dT \\ &+ \int_{T=t_2}^{t_1} [m_1(T - T_{\min}) + m_2(T_{\max} - T) - s_1(t_1 - T) - c_h(T - t_2)]\, f(T)\, dT \\ &+ \int_{T=t_1}^{T_{\max}} [m_1(t_1 - T_{\min}) + m_2(T_{\max} - T) - g(T - t_1) - c_h(T - t_2)]\, f(T)\, dT \end{aligned} \quad (7)$$

This simplifies to:

$$\begin{aligned} ECP_3(t_1,t_2) &= -m_1 T_{\min} + m_2 T_{\max} - (m_2 + c_h + g) m_T + (m_1 + g) t_1 + c_h t_2 \\ &+ (m_1 + g + s_1)[G(t_1) - t_1 F(t_1)] + (m_2 - m_1 + c_h - s_1)[G(t_2) - t_2 F(t_2)] \end{aligned} \quad (8)$$

Setting the first derivative with respect to t_1 to zero, we find the optimal Case 3 policy:

$$\frac{\partial ECP_3(t_1,t_2)}{\partial t_1} = m_1 + g - (m_1 + g + s_1)F(t_1) = 0$$
$$\Rightarrow t_1^* = F^{-1}\left(\frac{m_1 + g}{m_1 + g + s_1}\right) \tag{9}$$

The second derivative is $\partial^2 ECP_3(t_1,t_2)/\partial t_1^2 = -(m_1 + g + s_1) f(t_1)$. Given that $f(t) \geq 0$ and that all parameters are non-negative, this is strictly non-positive for all t_1, which proves that equation (9) is the global optimal solution for Case 3. This is a newsvendor-type result with a continuous time decision variable. The underage cost for planning the run-out time one period too early is $m_1 + g$ (product 1 contribution per period plus lost goodwill per period). The overage cost for planning a run-out time for product 1 one period too late is s_1, the product 1 scrap cost per period. The optimal planned run-out time for product 1 increases with product 1 contribution per period and goodwill loss and decreases with product 1 scrap cost.

For the planned availability date for product 2 for Case 3, we find:

$$\frac{\partial ECP_3(t_1,t_2)}{\partial t_2} = c_h - (c_h + m_2 - m_1 - s_1)F(t_2) = 0$$
$$\Rightarrow t_2^* = F^{-1}\left(\frac{c_h}{c_h + m_2 - m_1 - s_1}\right) \tag{10}$$

This is a proven optimal solution when the Case 3 condition ($t_2 < t_1$) is satisfied and when the following condition is satisfied:

$$\partial^2 ECP_3(t_1,t_2)/\partial t_2^2 = -(c_h + m_2 - m_1 - s_1) f(t_2) \leq 0 \tag{11}$$

Given that all parameters are non-negative and that $f(t) \geq 0$, this condition is satisfied when $c_h + m_2 - m_1 - s_1 \geq 0$. The product 2 contribution to profit per period is almost always greater

than the product 1 contribution ($m_2 > m_1$), but the carrying cost per period for I_2 units is not necessarily greater than the scrap cost for one period of demand. Therefore, it is necessary to check condition (11) in order to find the optimal policy for product 2. It is also necessary to confirm that the Case 3 solution does in fact satisfy the Case 3 condition (e.g., $t_2 < t_1$).

When either condition (11) or the Case 3 condition is not satisfied, the optimal solution will be found with the Case 2 equation (5) (e.g., $t_1 = t_2$). When both conditions are satisfied, equation (10) is the optimal policy and the underage cost for planning product 2 availability one period earlier than the approval date is the cost of carrying I_2 units of product 2 for one period. The overage cost for planning product 2 availability one period later than the approval date is $m_2 - m_1 - s_1$, which means the firm loses one period of contribution to profit for product 2, gains one period of contribution to profit for product 1, and has one period less scrap for product 1. The product 2 availability date, therefore, increases with c_h, m_1, and s_1, but decreases with m_2.

In order to graph the entire response surface, we use equation (1) to develop an expression for the expected contribution to profit for Case 1:

$$ECP_1(t_1, t_2) = -m_1 T_{\min} + m_2 T_{\max} + (m_1 + g)t_1 + c_h t_2 + (c_h + g + m_2)[G(t_2) - m_t - t_2 F(t_2)] \quad (12)$$

It is intuitively satisfying to know that the optimal same-date policy (equation (5)) is equivalent for the ECP functions for all three cases (equations (12), (4) and (8)).

In summary, Case 1 is never optimal. This paper has derived closed-form newsvendor-type results for the Case 2 and Case 3 optimal policies. Case 2 is optimal when condition (11) is not satisfied (e.g., when $c_h + m_2 - m_1 - s_1 \le 0$) and when the Case 3 solution does not satisfy the Case 3 condition (e.g., $t_2 < t_1$). When these two conditions are satisfied, Case 3 is optimal.

IMPLEMENTATION EXPERIENCE

The proposed model was implemented at a Fortune 500 medical device firm. The dual risks of very high stockout cost and very high obsolescence cost made the problem important to the senior management of the firm, with marketing, operations, purchasing, finance, and regulatory affairs all bringing different viewpoints to the problem. Before implementation, the practice was to plan to have the new product available at the earliest approval date and plan to produce enough of the existing product to last until the latest approval date. This safe policy is defined as $(t_1, t_2) = (T_{\max}, T_{\min})$.

Insights from the mathematical model

The model was particularly helpful in giving management new insights in many different dimensions. First, the research was judged by management to be surprising and important because it found that the two decision variables could be optimized independently as newsvendor-type problems. This was counter-intuitive to most managers, who believed that the two decisions were intimately related and that one decision affected the other. Management understood correctly that the *ECP* was a function of both decision variables, but incorrectly assumed the function had interaction terms where one decision affected the other.

Second, the two decisions are related only through the common parameters m_1 and s_1 and the parameters of the approval date distribution. A change in any of these parameters results in a change in both t_1 and t_2. Both t_1 and t_2 increase as m_1 increases and/or as s_1 decreases. In other words, if the contribution to profit for product 1 increases and/or the scrap loss associated with product 1 decreases, it makes sense to delay the planned run-out date of product 1 and the planned availability date for product 2. The carrying cost and product 2 contribution parameters

only affect the planned availability date for product 2; they have no impact on the optimal planned run-out date for product 1.

Third, the model showed that the safe policy $(T_{\max}, T_{\min})$ was very costly due to large scrap loss. The model showed that savings on the order of millions of dollars might be available. The product 1 safe policy $(t_1 = T_{\max})$ is only optimal when $(m_1 + g)/(m_1 + g + s_1) = 1$ and only advisable when $s_1 << m_1 + g$. Similarly, the product 2 safe policy $(t_2 = T_{\min})$ is only optimal when $c_h/(c_h + m_2 - m_1 - s_1) = 0$ and only advisable when $m_2 - m_1 - s_1 >> 0$ and/or $c_h \cong 0$. Neither of these conditions was satisfied for the firm.

Fourth, the model made it clear that it was best to plan to have significant obsolescence when introducing new products. This helped senior management set more realistic expectations for the transition planning process.

Fifth, the model results were sensitive to approval date distribution parameters. This motivated more attention to the forecasting process, particularly the frequency of updates and accountability for forecast bias.

Sixth, the model helped management frame the problem more as an economic optimization problem and less as a political one. The model provided a new paradigm and vocabulary that enabled management to have a more intelligent debate of the problem.

The model provided exchange curves that management could use for sensitivity analysis for several important issues. These included decreasing procurement and manufacturing leadtimes (Hill & Khosla, 1992), increasing component part commonality and modularity (Eynan & Rosenblatt, 1996; Billington, Lee, and Tang, 1998), and using common platforms for more products (Lee & Tang, 1997). The model convinced management that the expected benefits of these three programs were much higher than anticipated.

Approval date distribution

The proposed model can be implemented with any approval date distribution. However, the time random variable must be bounded at zero, which suggests the beta, gamma, lognormal, Weibull, or triangular distributions. Law and Kelton (1992) recommend the triangular distribution for subjective forecasting situations such as this. Forecasters only needed to estimate the minimum, most likely, and maximum dates ($T_{\min}, T_{\mathrm{ml}}, T_{\max}$). The triangular distribution is also useful because we have closed-form expressions for the density function, $f(T)$, and distribution function, $F(T)$. From these expressions we derived useful closed-form expressions for the inverse distribution and partial expectation functions for the triangular distribution:

$$F^{-1}(p) = \begin{cases} T_{min} & \text{for } p \le 0 \\ T_{min} + \sqrt{2p/a_1} & \text{for } 0 < p \le (T_{ml} - T_{min})/(T_{max} - T_{min}) \\ T_{max} - \sqrt{2(1-p)/a_2} & \text{for } (T_{ml} - T_{min})/(T_{max} - T_{min}) < p < 1 \\ T_{max} & \text{for } 1 \le p \end{cases} \tag{13}$$

$$G(t) = \begin{cases} 0 & \text{for } t \le T_{\min} \\ a_1[H(t, T_{min}) - H(T_{min}, T_{min})] & \text{for } T_{\min} < t \le T_{\mathrm{ml}} \\ m_T - a_2[H(t, T_{max}) - H(T_{max}, T_{max})] & \text{for } T_{\mathrm{ml}} < t < T_{\max} \\ m_T & \text{for } T_{\max} \le T \end{cases} \tag{14}$$

with $a_1 = 2/(T_{\max} - T_{\min})/T_{\mathrm{ml}} - T_{\min})$, $a_2 = 2/(T_{\max} - T_{\min})/(T_{\max} - T_{\mathrm{ml}})$, $m_T = (T_{\min} + T_{\mathrm{ml}} + T_{\max})/3$, and $H(T_1, T_2) = T_1^3/3 - T_2 T_1^2/2$. Alternative distributions such as the beta, gamma, and Weibull may be more accurate, but do not have closed-form expressions for the distribution, inverse distribution, or partial expectation functions and therefore require numerical integration. A test was conducted to determine the impact of using these distributions instead of the triangular. The optimal policy parameters and the corresponding optimal expected contribution to profit were nearly identical for all four distributions.

The parameters for the approval date distribution were determined from four parameters estimated by the management of the regulatory affairs department -- the earliest, 50-th percentile, 90-th percentile, and latest approval dates. The triangular distribution was fit to these parameters. The firm's regulatory affairs department had a challenging job in estimating and updating these parameters. These forecasts had many "customers" such as the external medical community, marketing, manufacturing, purchasing, and product design. As a result, the forecasts tended to be biased toward late government approval. The firm was explicitly using the safe policy and implicitly using "safe" forecasts, which together resulted in extremely "safe" plans and millions of dollars of obsolete inventory.

Translating the model results into the master production schedule

The above mathematical model assumes that the demand for the old product drops to zero immediately after the new product is approved and available. However, most medical device products experience a trailing demand that is the result of some customers being reluctant to change to the new product and demand in other countries that have longer approval processes. Trailing demand can be modeled as a geometric decay time series (Hill, Giard & Mabert, 1989; Brown, 1982). Assuming that product 2 is available and approved at the beginning of period T, the demand for product 1 in period $t > T$ is $d_{1,t} = r^{t-T+1} d_1$, where $r = d_{1,t} / d_{1,t-1}$ is the common ratio with $r < 1$. Based on the sum of an infinite geometric series, the cumulative product 1 trailing demand from period $T+1$ to infinity is $D_1 = d_1 r /(1-r)$. Regression was applied to estimate r from ten historical time series using the non-linear model $d_{1,t} = r^t d_1 \exp(e_t)$. The fit was very good, with all R^2 values over 90%. The common ratios for all models within a product family were nearly equal. The firm maintained a finished goods and distribution channel inventory of I_1 units of product 1. Therefore, the last net requirement in the Master Production

Schedule for product 1 was planned on $t_1 * -(I_1 - D_1)/r_1$, where r_1 is the production rate for product 1. In other words, even though the model assumes trailing demand is zero, trailing demand can be considered by adjusting the stop-date for product 1 in the MPS. Petruzzi and Dada (1999) recently developed pricing models for clearing residual inventory such as this.

Cost parameter estimation

Parameters such as m_1, m_2, and c_h were fairly easy to estimate. The scrap cost per period parameter, s_1, should reflect the cost of producing product 1 for one period too long. Upon approval, the firm will likely have to scrap all completed units in the system (less trailing demand) plus all unique components purchased (or committed to be purchased) from suppliers. If approval is early, some shorter leadtime components may not need to be purchased. Scrap write-off costs are mitigated by the tax savings associated with the write-off. The lost goodwill per period, g, should not include the lost margin, which is already imbedded in the model, but should include the reduction in future demand due to doctors "defecting" to use another product, bad word-of-mouth, etc.

A HYPOTHETICAL EXAMPLE

A hypothetical example is presented here to illustrate the model. (The data from the actual implementation is not available.) The example data is derived from our experience with several large medical device firms. The medical device firm is selling $d_1 = 10$ units per day of product 1 and has submitted product 2 for FDA approval on January 1, 2003. Product 2 is expected to be approved sometime between October 1, 2003 and June 1, 2004, with a most likely approval date of December 1, 2003 and demand of $d_2 = 10$ per day. A triangular distribution for

the approval date is used to make it easy to solicit the parameters of the distribution and implement the code. Table 1 shows the parameters for the example problem.

Table 1. Example problem parameters.

Product 2 earliest approval date ($T_{\min}$)	October 1, 2003
Product 2 most likely approval date (T_{ml})	December 1, 2003
Product 2 latest approval date ($T_{\max}$)	June 1, 2004
Demand per day ($d_1 = d_2$)	10 units/day
Goodwill lost per day with neither product to sell (g)	\$100,000/day
Product 1 salvage cost per day (s_1)	\$5,000
Carrying charge per dollar per year	36.5%
Product 2 carrying cost per day for I_2 units (c_h)	\$5000
Product price per unit (p_1, p_2)	(\$10,000, \$16,000)
Product cost per unit (c_1, c_2)	(\$5000, \$5000)
Contribution to profit per day (m_1, m_2)	(\$45,000, \$105,000)
Channel inventory (I_1, I_2)	(1000 units, 1000 units)
Product 1 common ratio for trailing demand (r)	95%

Applying the model with the above parameters found the optimal planned run-out date for product 1 was $t_1^* =$ February 14, 2004 and the optimal planned availability date for product 2 was $t_2^* =$ December 11, 2003. This means we are planning to have a 66-day safety period. The expected contribution to profit of $ECP =$ \$15.7 million. Both the Case 3 condition $(t_2 < t_1)$ and condition (11) are satisfied.

The forecast of the cumulative trailing demand for product 1 is $D_1 = d_1 r(1-r) = 10(.95/.05) = 190$ units. Therefore, the leadtime offset for back-scheduling product 1 is $(I_1 - D_1)/d_1 = 81$ days and the last net requirement in the MPS for product 1 is scheduled on $t_1^* - 81$, which is November 27, 2003. Considering learning curve and shop

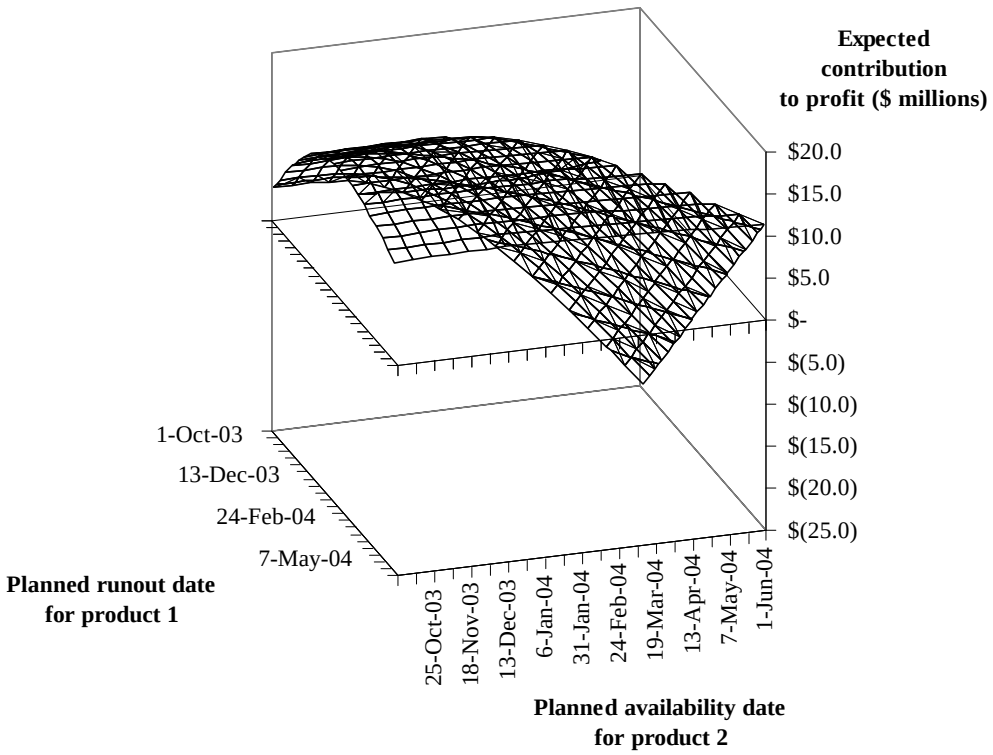
calendar issues, product 2 should be started in production on May 28, 2003. This means that both products will be in production from May 28, 2003 until November 27, 2003, which might have capacity implications for the firm.

The firm has a cumulative manufacturing and procurement leadtime for long leadtime components of 6 months. Therefore, the February 16, 2004 planned MPS stop-date for product 1 should drive the firm to stop procurement of long lead time components on August 20, 2003, long before the earliest approval date for the new product. Similarly, the planned MPS start date for product 2 on June 14, 2003 should drive the firm to begin procurement of long leadtime components on January 31, 2003.

Figure 3 displays the $ECP(t_1, t_2)$ response surface for this example. The response surface is like a paper airplane with a fold along the same-date $(t_1 = t_2)$ policy. When the solution moves into the Case 1 region, the costs take a sharp downturn due to the penalty cost of the lost goodwill. The safe policy $(T_{\max}, T_{\min})$ is the front corner of the graph. For this example, the safe policy has an expected contribution to profit of \$11.9 million, which is about \$3.7 million less than the \$15.7 million for the optimal policy -- almost a 25% difference.

Management has to make a difficult trade-off between the risk of not having the new product available on the approval date and the risk of having significant obsolescence cost. The model helps managers by recommending the optimal dates based on estimates of the cost parameters and approval date distribution -- and "takes the problem out of the world of politics and brings it into the world of economic analysis."

Figure 3. Example problem response surface



LIMITATIONS AND EXTENSIONS

The proposed model assumes that discounting cash flows is not necessary. Given that the time horizon for this planning problem is about a year, this should not be a major limitation.

The model requires several parameters. The scrap cost and lost goodwill parameters are fairly difficult to estimate. All parameters should be adjusted to reflect after-tax cash flows.

The model ignores competitive action that might impact the demand for the new product if the new product is introduced later than the competition's product. However, requests for product approvals are public information, which gives management some forewarning about competitive actions. It is likely, therefore, that the firm can anticipate the market reaction to new product offerings and estimate appropriate price and demand parameters for the model.

In some situations, the old and new products share some machine and labor capacity. We can still use the model to optimize the run-out date for product 1 and the availability date for product 2; however, capacity contention should be considered in the back-scheduling process.

The model can be implemented with any approval date distribution. However, the triangular distribution is much easier to implement than other reasonable continuous distributions because it has closed-form expressions for the distribution, inverse distribution, and partial expectation functions.

Demand is assumed to be constant for each product. Procurement leadtimes, procurement yields, manufacturing leadtimes, and manufacturing yields are also assumed to be deterministic. A stochastic simulation model could be implemented to explore these issues.

If the product development time for product 2 is highly uncertain, the firm will plan production on product 2 at the earliest date. We can define a new random variable U called the "available and approved" date that is the maximum of two random variables -- the random product 2 availability date and the random government approval date. In other words, the firm's forecasters estimate the parameters of the distribution for $U = \max(T_{available}, T_{approval})$. If we replace T with U, the optimal planned run-out time for product 1 can be found with equation (9).

CONCLUSIONS

Improved marketing-operations coordination is widely viewed as an opportunity for improving firm performance (Meredith & McTavish, 1992). One key need for marketing-operations coordination is planning product transitions when an existing product is phased out and a replacement product is phased in. This problem is particularly difficult in the context of medical device manufacturing that has an uncertain approval date for new products. This class

of problems is increasing in importance due to the growing demand for medical products requiring government approval.

This paper formulated this class of production planning problems as a stochastic optimization problem in continuous time. The expected total contribution to profit model is analogous to the newsvendor problem except that it has two continuous-time decision variables, the planned run-out date for the existing product and the planned availability date for the replacement product. The paper developed optimal closed-form expressions for both decision variables. The math modeling effort found the unexpected result that the two decision variables could be treated as independent, continuous time newsvendor problems. The two problems are related only through the approval date distribution parameters, the product 1 contribution to profit per period and the product 1 scrap loss parameters.

The paper proves that the optimal policy is always to plan to run-out of product 1 on or before the availability date for product 2. The model also shows that the safe policy of planning to run-out of product 1 at the latest approval date and planning to have product 2 available at the earliest approval date can be very costly to the firm.

Several practical suggestions for implementing the model are presented. Closed-form expressions for the inverse distribution and partial expectation functions for the triangular distribution were developed in order to make the model easy to implement in a spreadsheet. Attention was also paid to forecasting the trailing demand for product 1.

The application of the model in a large medical device firm was judged to be useful by the firm's management, both in terms of analysis and intuition. The model provided a new paradigm and vocabulary that led the management to a more intelligent analysis and discussion of the problem.

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APPENDIX A. SUMMARY OF TERMS

c_h Carrying cost per period for carrying I_2 units of product 2.

c_i Unit cost for product i.

d_i Demand rate for product i.

D_1 Cumulative trailing demand for product 1 after product 2 is introduced.

ECP Expected contribution to profit over the planning horizon.

$f(T)$ Density function for the approval date distribution.

$F(T)$ Distribution function for the approval date distribution.

$G(t)$ Partial expectation function for the approval date distribution evaluated at t, where $G(t) = \int_{T=T_{\min}}^{t} Tf(T)dT$.

g Lost goodwill per period when the firm has neither product available to sell.

h Carrying charge per dollar of inventory carried per period.

I_i Channel inventory of product *i* required to support the sales of the product.

m_T Mean of the approval date distribution, where $m_T = G(T_{\max})$.

m_i Contribution to profit per period for product i.

p_i Unit price for product i.

r Common ratio for the geometric time series used to forecast the cumulative trailing demand for product 1 with $0 < r < 1$.

r_1 Production rate for product 1.

s_1 Scrap cost per period for product 1.

t_1 Planned run-out date for inventory of the existing product (product 1).

t_2 Planned availability date for the new product (product 2).

T The random approval date for the new product (product 2). This is a random variable with density function $f(T)$, distribution function $F(T)$, and mean m_T.